STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Self Inspection.

2.0 SCOPE:

This SOP is Applicable to all the Departments, to ensure that the Systems are Adequate, Implemented Effectively at all manufacturing locations.

3.0 RESPONSIBILITY:

Head CQA: Planning, Team Selection, Execution and Closing of the Self Inspection Report.

Head Auditee: Timely Compliance of Non-Conformance.

4.0 ACCOUNTABILITY:

Head-CQA

5.0 PROCEDURE:

5.1 PREPARATION OF SELF INSPECTION PLANNER:

5.1.1 At the start of every Calendar Year, Corporate Quality Assurance Department shall prepare a Self Inspection Planner which shall be approved by **Head Operations** and Authorized by **Head CQA** as per **Annexure-I,** Titled **"Self Inspection Planner"**.

5.1.2 The Frequency of Self Inspection in the Planner shall be once in a year for each Department.

5.1.3 One copy of the Self Inspection Planner shall be circulated to different Department Heads for Information and Reference.

5.1.4 In case of any external customer Audit on the self inspection planned date at any plant, Audit can be postponed with new reschedule Audit date planner with proper justification on self inspection planner.

5.2 SELECTION OF SELF INSPECTION TEAM :

5.2.1 Head CQA shall select a Self Inspection Team based on Cross Functional Departments at the Start of Every Calendar Year as shown in **Annexure-II,** Titled **"Self Inspection Team".**

5.2.2 The selection of Auditor in the Self Inspection Team shall be based on their Qualification, Experience, Expertise, Technical Skills and Power of Logical Analysis.

5.2.3 The Self Inspection Team shall comprise of Lead- Auditor and Team Members. Lead Auditors are specific based on their expertise in the different areas as identified by CQA-Head.

5.2.4 Lead Auditor and Team members in the specific Self Inspection Team shall not be of Auditee Department, where the Self Inspection is planned.

5.3 SELF INSPECTION PLANNING AND EXECUTION :

5.3.1 One week prior to the Planned Date of Self Inspection, Manager CQA or Lead Auditor shall send a Self Inspection Planning and Execution Record to Head of Auditee Department and one copy marked to Team Members identified for Self Inspection. Self Inspection Planning and Execution Record as shown in **Annexure-III,** Titled **"Self Inspection Planning and Execution Record".**

5.3.2 If Proposed Schedule is agreed, Head of the Auditee Department shall fill the Record with Sign and Date. Filled Record shall be forwarded to the **Head-CQA/Lead Auditor** along with details of Auditee (s).

5.3.3 In case of Disagreement, Head of Auditee Department shall propose the Reschedule Date within that month only, along with the reason of re-scheduling with Sign & Date.

5.3.4 Prior to start of the Self Inspection on the Planned Date, Auditors and Auditee(s) both shall sign on the Self Inspection Planning and Execution Record. After the completion of Self Inspection, Lead Auditor shall fill the Execution Part of the Self Inspection Planning and Execution Record and same shall be sign by Lead Auditor and Head-Auditee.

5.3.5 If any of the Auditor or Auditee is not present on the Date of Self Inspection Execution, as per plan, then the Lead Auditor and Head-Auditee Department put the remarks and Sign on the Self Inspection Planning and Execution Record subsequently as applicable in front of their Name.

5.3.6 During Self Inspection, the Auditors can go to the details of the documents and any online systems to check the compliance of the Processes and Procedures.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.3.7 Self Inspection of Various Departments shall be carried out as per Self Inspection Checklist No. mentioned below:

S. No.	Department Name	Checklist No.	Applicable For (Department)
1.	Building & Facility		HR
2.	Premises including Personnel Facilities		HR
3.	Water System		Engineering
4.	Computerized System Including Software used by Stores, Production and QC		Quality Assurance
5.	Calibration of Instruments & Measurement Systems		Quality Control
6.	Laundry		HR
7.	Warehouse and Dispensing		Warehouse
8.	Granulation Section		Production
9.	Compression Section		Production
10.	Coating Section		Production
11.	Hard Gelatin Capsule Section		Production
12.	Dry Syrup Section		Production
13.	Soft Gelatin Capsule Section		Production
14.	Liquid Oral Section		Production
15.	Injection Section		Production
16.	Packing		Production
17.	Personnel and Administration Department		HR
18.	Quality Control Department		Quality Control
19.	Microbiology Laboratory		Quality Control
20.	Quality Assurance Department		Quality Assurance
21.	SOP and Master Documents		Quality Assurance
22.	Engineering Department		Engineering
23.	Ointment, Cream & Gel Section		Production

5.3.8 Checklist No. consist of **Twelve Alphanumeric** characters as shown below:

CQA/SI/01-00

Where,

"CQA" : **Corporate Quality Assurance**
"/" : **Separator**
"SI" : **Self Inspection**
"/" : **Separator**
"01" : **Serial Number of Checklist**
"-" : **Separator**
"00" : **Revision Number**

5.3.9 Self Inspection Checklist of all the Departments shall be available with the CQA Department and same shall be issued to the auditors during execution of Self Inspection. CQA Department shall assign the Audit Report Number to the Issued Checklist as per the procedure mentioned below.

5.3.10 The Auditors shall refer the Self Inspection Checklist and record the observations in the checklist. The scope of the Self Inspection is not limited to the Checklist only.

5.4 The Audit Report No. is consist of an Eight Alphanumerical characters as shown below:

SI/15/01

Where,

"SI" : **Self Inspection**
"/" : **Separator**
"24" : **Year**
"/" : **Separator**
"01" : **Serial Number**

For Example, First Self Inspection Report for the year 2024 shall be numbered as **SI/24/01** and followed by **SI/24/02**.

5.5 The same Audit Report Number shall be assigned to Non-Conformance & Compliance Report (if any).
5.6 In case, Inspection is not completed in one day, it can be continued on next day or any other agreed day.

5.7 The Non-Conformance observed during the Self Inspection shall be formally detailed and discussed with the Auditee during Self Inspection closing meeting.

5.8 Discrepancies observed during Self Inspection are categorized as Critical, Major and Minor.

5.8.1 Critical (C):

Critical Observation during Self Inspection shall be based on Product Risk and can lead to any consequences of Cross Contamination or Mix-Up, if no Procedure / Systems established for controlling the activity.

5.8.2 Major (M):

Major Observation shall be based with no risk to Product Cross Contamination / Mix-Up where System is followed but not recorded occasionally.

5.8.3 Minor (N):

Minor Observation shall be of less importance, not affecting any risk to product nor to Established System. It can be a Minor Error, which can be corrected.

5.9 PREPARATION OF SELF INSPECTION REPORT AND COMPLIANCE:

5.9.1 After completion of Self Inspection, Lead Auditor shall prepare Non-Conformance Report observed during Self Inspection in "**Non-Conformance & Compliance Report"** format as shown in **Annexure-V.**

5.9.2 Printout of report shall be controlled by CQA**.**

5.9.3 Controlled Copy of Non-Conformance & Compliance Report shall be submitted to the Auditee Department for compliance within seven working days after the Date of Self Inspection Execution and same shall be recorded in the Self Inspection Log Book by the CQA Department as per **Annexure-VI, Self Inspection Log Book.** Scan Copy of the Report shall be marked to **Head Operations** for information.

5.9.4 After receiving the Non-Conformance Report, Auditee Department shall prepare the Compliance Report along with Corrective and Preventive Action (CAPA) Plan along-with the Proposed Date of Compliance on the Report and shall sign in the column of Head Auditee.

5.9.5 A copy of report with Proposed Date of Compliance shall be submitted to CQA Department for follow-up action.

5.9.6 Original Compliance Report shall be submitted to CQA Department within 15 working days from the Date of Receipt of Report. The Date of Receipt of Compliance Report shall be recorded in Self Inspection Log Book.

5.9.7 CQA Department shall verify the Compliance.

5.9.8 If compliance verification by CQA representative is found satisfactory and all the non-conformances are closed by the Auditee Department, Head-CQA shall close the Self Inspection Report (including Non-Conformance & Compliance Report).

5.9.9 All the Closed Self Inspection Reports shall be filed in the Corporate Quality Assurance Department.

5.10 Corporate Quality Assurance (CQA), other Corporate Departments, Operations, Technical, Project, PPIC, IT, Accounts & other Departments shall not come under Scope of this SOP. Function of these Departments shall be reviewed through "**Management Review"** Procedure.

6.0 REFERENCES:

- US Code of Federal Regulations, Current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR -Part 211), Food and Drug Administration.
- Drugs and Cosmetics Act, 1945.
- Quality Assurance of Pharmaceuticals, 2nd Edition, Volume-2, 2007.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Self Inspection Planner	
Annexure-II	Self Inspection Team	
Annexure-III	Self Inspection Planning and Execution Record	
Annexure-IV	Self Inspection Check List	
Annexure-V	Non-Conformance & Compliance Report	
Annexure-VI	Self Inspection Log Book	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Head Corporate Quality Assurance
- Controlled Copy No. 02 Head Quality Assurance Plant-I
- Controlled Copy No. 03 Head Quality Assurance Plant-II
- Controlled Copy No. 04 Head Quality Assurance Plant-III
- Controlled Copy No. 05 Head Quality Assurance Plant-IV
- Controlled Copy No. 06 Head Quality Assurance Plant-V
- Master Copy Corporate Quality Assurance

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

9.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
No.	Number
QA	Quality Assurance
CAPA	Corrective and Preventive Action
BPCR	Batch Production and Control Record
SI	Self Inspection
HVAC	Heating Ventilation & Air conditioning
AHU	Air Handling Unit
UPS	Uninterrupted Power Supply
DG	Diesel Generator

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I
SELF INSPECTION PLANNER

Plant: **Year:**

Planner No. :

Month / Department	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.

Note: Mark Reschedule Audit plan as **(*)** & justify the reason (if any): _____

_____

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE – II

SELF INSPECTION TEAM

Plant: **Year:**

S. No.	Name	Department	Designation	Lead Auditor*	Team Member*	Remarks

*** Mention✓, wherever applicable.**

Prepared By
Manager CQA

Approved By
Head CQA

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-III

SELF INSPECTION PLANNING AND EXECUTION RECORD

From: Manager CQA / Lead Auditor **Date:**

To: Head – (Auditee Department (Mention Department Name)

Planned Date of Self Inspection: _____ **(Schedule Agreed / To be re-scheduled)**

If to be re-scheduled then Proposed Date by Head – Auditee Department: _____

Reason for re-scheduling **:** _____

Sign of Head – Auditee **:** _____ **Date:** _____

Auditor(s) Details: (To be filled by Manager CQA / Lead Auditor)

S. No.	Name	Department	Designation	Signature (On the Date of Inspection Execution)	Remarks By Lead Auditor

Auditee Details: (To be filled by Head – Auditee Department)

S. No.	Name	Designation	Signature (On the Date of Inspection Execution)	Remarks Head- Auditee

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

INSPECTION EXECUTION DETAILS

Area / Department Inspected : _____ Inspection Time : _____

Execution Date of Inspection : _____

Sign: Date: **Sign: Date:**

Lead Auditor **Head – Auditee**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE – IV

SELF INSPECTION CHECKLIST		
Audit Report No.:	**TITLE / DEPARTMENT**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3

Body**

NOTE: (1) Acceptable, (2) Not Acceptable, (3) Not Applicable.
Put (√) or (x) in column 1, 2 and 3.

CONCLUSIONS:

Based on Self Inspection Checklist, the Building & Facility has been audited for compliance with organizational procedures and cGMP.

Corrective Action and Preventive Action (CAPA): Required ☐ Not Required ☐

If required, attach Non-Conformance Report for Compliance ☐

AUDITED BY:

Name								
Designation								
Department								
Sign								
Date								

Body*

* Common for all the Checklist
** To be changed for each checklist No. (All Checklists given on next pages of the SOP)

Footer*

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**BUILDING & FACILITY**	**Checklist No.: ……**

Point No.	Check Point	Yes / No	1	2	3
1.	**BUILDING & FACILITY**				
	Is the facility maintained in a good state of repair?				
	Are the Floors, Walls, Ceiling Smooth and Sealed?				
	Is the Building and Facility neat and orderly with sufficient space?				
	Are precautions taken to control entry of rodents and insects?				
	Are Windows sealed and closed?				
	Are there a Sanitation and Pest Control Program?				
	What is the precautionary activity done for Pest Control? (Whether Fly-O-cide available)?				
	Is the Cleaning and Usage record available for Fly-O-cide?				
	Is the Air Curtain installed at the entry of different Blocks?				
	Is the Air Curtain found in Working Condition?				
2.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are personnel clothing safety apparels Clean, Unstained & Dust Free?				
	Is Pressure Difference maintained inside cubicles and air locks at all times during work?				
3.	**EQUIPMENT AND FACILITY CLEANING**				
	Is the Area and Equipments Neat and Clean?				
	When not in use, are Equipment covered so as to prevent Accidental Contamination?				
	Are the Equipment suitably designed for its purpose?				
	Are the Equipment constructed so that product contact surfaces are not Reactive or Absorptive, so that it will not contaminate or in any way affect the product?				
	Are there specific procedures for the cleaning of major equipments?				
	Visually inspect one piece of Equipment that is not in use				
	Is it labeled with respect to its cleanliness status?				
	Is it clean?				
4.	**DOCUMENTATION**				
	Are all Daily Documents filled Correctly and Timely?				
	Are the documents properly arranged				
	Are the Formats, Logs & SOPs are Current?				
	Has all SOPs been displayed?				
	Is any obsolete copy seen in the Area?				
5.	**CANTEEN FACILITY**				

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QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the precautionary activity done for Pest Control? (Whether Fly-O-cide available)?				
	Is the Cleaning and Usage record available for Fly-O-cide?				
	Is the location of Canteen satisfactory?				
	Is the waste of canteen not contaminate the manufacturing building and Product?				
	Is the seating arrangement in the canteen satisfactory?				
	Is the quality of food is good and hygienic?				

SELF INSPECTION CHECKLIST

Audit Report No.:	**PREMISES INCLUDING PERSONNEL FACILITIES**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**BUILDING AND SURROUNDING**				
	Does area sufficient for manufacturing of the products?				
	Is the building paint in good condition?				
	Is any sign of fungal growth on walls of building?				
	Do the buildings fulfill the FDA & other Regulatory Bodies requirement?				
	Does their any wastage from near most factories come in contact with the Building at our end?				
	Does the ETP installed at satisfactory place to ensure that any Toxic Product does not come in contact with the Manufacturing Building?				
2.	**SECURITY SYSTEM**				
	Do all man & material movement inside the Factory Premises observed & checked through Security System				
	How it is controlled? Does any CCTV available to control the Entry & Exit from Factory Premises?				
	Does a person visiting to a factory have been identified? How? _____.				
	What is the precautionary activity taken for the movement of carriers i.e. vehicles? _____.				
	Is the satisfactory?				
3.	**PEST CONTROL**				
	Does the contract for Pest Control given to any Authorized Party?				
	Are the persons trained?				
	Does any list of Approved Pesticides available?				
	Are the Pesticides used are approved?				
	Is the activity monitored by Security & QA Personnel?				
	Does there any record for Pest Control?				
	Is it satisfactory?				
	Is the Air Curtain installed at the entry of Production Area?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is the Air Curtain found in Working Condition?				
	What is the precautionary activity done for Pest Control? (Whether Fly-O-cide available)?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**WATER SYSTEM**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available?				
	Are the index and the SOPs current?				
	Are the Obsolete documents removed from the Department?				
2.	**PERSONNEL**				
	Has the System Operator undergone training on • GMPs				
	• SOPs				
	• Departmental Operation techniques				
	Are the training records up-to-date?				
	Is the system leak free, rust free and well maintained?				
	Is access to the main water holding tank for the factory, including the software system, restricted?				
	Does any pest seen in the department?				
	What is the precautionary activity done for Pest control? (Whether Fly-O-cide available)?				
	Is the Air Curtain installed at the entry of Water System?				
	Is the Air Curtain found in Working Condition?				
3.	**WALK-THROUGH OF SYSTEM**				
	When was the Raw Water Holding Tank last sanitized? _____				
	Is this recorded and is it in accordance with the relevant SOP?				
	When the Softener Columns was last regenerated? _____.				
	Check the Hardness of the Soft Water in the record.				
	When the Purified Water Production System was last sanitized? _____				
	Was it in conformance with the relevant SOP?				
	Check the Conductivity Reading for the Purified Water at the exit from • Anion Bed. _____				
	• Mixed Bed. _____				
	Does this conform to the relevant SOP?				
	When was the Disposable Resin last replaced in • Cation Bed _____				
	• Anion Bed _____				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	• Mixed Bed _____				
	Does this conform with the relevant SOP?				
	Is the change frequency of the 3/5 micron filter after the mixed beds in accordance with the relevant SOP?				
	Is this documented?				
	Check the readings of the following parameters for the Purified Water Storage and Distribution System. • Pump pressure **1.** Conductivity on the Supply Line _____ **2.** Conductivity on the Return Line _____				
	Do they conform to the limits stated in the relevant SOP?				
	Examine the records for the replacement of the air-vent filter on the Purified Water Tank. Does the frequency conform to that stated in the relevant SOP?				
	Are User Points well maintained, with Flexible Tubing stored in such a way as to minimize contamination?				
	Are User Points flushed daily during heat sanitization of the system?				
4.	**SYSTEM DRAWINGS**				
	Is a complete set of up-to-date system drawings available to • User Department • Maintenance Personnel?				
	Compare the Drawings with those in the most recent Validation File. Are they the same Edition Number?				
	Have any changes been authorized by Quality Assurance?				
	Has a Change Control form been completed?				
	If any changes have been made, has the Validation File been updated and any necessary testing performed?				
	Did the results meet the Specifications?				
5.	**SYSTEM OPERATING RECORDS**				
	Examine the Daily Checklist for the Water System for two months preceding the audit.				
	Have they been completed on a daily basis?				
	Are they approved by Quality Assurance?				
	If any faults or breakdowns in the system were noted, was an unusual events reports form completed and distributed to concerned personnel?				
6.	**SYSTEM MAINTENANCE RECORDS**				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Examine records of performance of Preventive Maintenance. Do they include the following? • Changing of air-vent filters on Storage Tanks according to the frequency in the relevant SOP. • Cleaning and Sanitation of the Raw Water Storage Tank • Cleaning and Sanitation of the RO Water Storage Tank • Other Storage Tanks Cleaning and Sanitation • Cleaning and Sanitation of the Purified Water Storage and Distribution System. • Replacement of Resins in Cation, Anion & Mixed Bed Columns • Calibration of All Instrumentation				
7.	**SYSTEM MONITORING RECORDS**				
	Is the System sampled according to the frequency stated in the SOP?				
	Is sampling performed at all locations stated in the SOP?				
	Do results conform to the limits stated in the SOP?				
	When out-of-limit results were obtained, was Corrective Action implemented in accordance with the SOP?				
	What is the overall picture of the state of control of the Purified Water System? _____				
8.	**SYSTEM VALIDATION FILE**				
	Examine the Validation File for the Purified Water System				
	Was the Validation performed according to Schedule?				
	Does the Report indicate that the system is Operating in a Repeatable and Reliable manner?				
	Have any non conformity's with the Validation Protocol been indicated in the Report, Explained and Suitably Authorized?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**COMPUTERIZED SYSTEM INCLUDING SOFTWARE USED BY STORES, PRODUCTION & QC**	**Checklist No.: ……**

Point No.	Check Point	Yes / No	1	2	3
1.	**STORES**				
	Does the Software Validated & Qualified?				
	Check records. Are they Satisfactory?				
	Does the systems are protected with Password?				
	Does a person handling the system trained?				
	Does their Training Reports available?				
	Do they have the Back-up System?				
	Is the data recoverable?				
	Does their any SOP which includes Start & Shut Down method of the Software?				
2.	**PRODUCTION**				
	Does the Software & PLC Validated & Qualified?				
	Check records. Are they Satisfactory?				
	Does the Systems are Protected with Password?				
	Does a Person Handling the System Trained?				
	Does their Training Reports Available?				
	Do they have the Back-up System?				
	Is the data recoverable?				
	Does their any SOP which includes Start & Shut Down method of the Software?				
3.	**QUALITY CONTROL**				
	Does the Software Validated & Qualified?				
	Check Records. Are they Satisfactory?				
	Does the Systems are Protected with Password?				
	Does a person Handling the System Trained?				
	Does their Training Reports available?				
	Do they have the Back-up System?				
	Is the data Recoverable?				
	Does their any SOP which includes Start & Shut Down Method of the Software?				
4.	**QUALITY ASSURANCE**				
	Does the Software Validated & Qualified?				
	Check Records. Are they Satisfactory?				
	Does the Systems are Protected with Password?				
	Does a person Handling the System Trained?				
	Does their Training Reports available?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Do they have the Back-up System?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**CALIBRATION & QUALIFICATION OF INSTRUMENTS & MEASUREMENT SYSTEMS**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	Is the SOP available for Calibration of Instruments?				
2.	Is the Calibration SOP followed?				
3.	Is any Annual Program available for Calibration?				
4.	Is the contract given to any External Party for Calibration?				
5.	How is it traceable that the Instruments are Calibrated? _____ _____				
6.	Is the Instrument bearing a Calibration Tag?				
7.	Is the Calibration Tag bears **i.** Date of Calibration **ii.** Instrument No. / Equipment No. **iii.** Location **iv.** Calibration Due On **v.** Signature				
8.	Is the Standard Equipment / Instrument from which calibration is done has been calibrated from NPL, ERTL, IDEMI.				
9.	Do they have Calibration Certificate?				
10.	Select any balance in the Department. Is the Calibration Report available?				
11.	Is this Report bears **i.** Name of Calibrator **ii.** Name of Instrument, Location, Type, Make, Model, Least Count **iii.** Specific Accuracy, Acceptance Criteria, Range, Input Output **iv.** Test Equipment used along with Make, Range, Accuracy, Validity, Calibration done by checked by etc.				
12.	Are all results within the limit?				
13.	Are all formats used for Calibration Record Current?				
14.	Is the report bears Acceptance Criteria?				
15.	Is there any SOP available which includes Instrument to be Calibrated & Frequency of Calibration?				
16.	Is this SOP followed?				
17.	How is it Traceable? _____				
18.	**QUALIFICATION OF CONTRACT ANALYTICAL LABS**				
	Is testing performed from Outside Lab?				
	Is Contract Lab Qualified?				
	Is copy of Agreement available?				
	Is record of Outside Tested Samples available?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
19.	**ANALYSTS QUALIFICATION**				
	Is SOP available for Analysts qualification?				
	Is the SOP followed?				
20.	**INSTRUMENT QUALIFICATION**				
	Is the SOP available for Instrument Qualification?				
	Is the SOP followed?				
	Is schedule for instrument qualification available?				

SELF INSPECTION CHECKLIST

Audit Report No.:	**LAUNDRY**	**Checklist No.: ……**

Point No.	Check Point	Yes / No	1	2	3
1.	Is there written agreement with out-side laundry				
2.	Is the Laundry Qualified?				
3.	Does the Laundry have a written procedure of the Laundering Process?				
4.	Whether all the personnel of the Laundry are properly trained for our procedure requirements?				
5.	Is there a closed system for transport uncleaned & cleaned garments?				
6.	Is it Satisfactory?				
7.	Does Quality of water used for the washing is of Quality Level? **Specify Source of Water:**				
8.	What he does in case the Water from the Regular Source is not available? _____				
9.	Check the area of Washing and Drying for **a.** Drainage System **b.** Cleanliness **c.** Arrangement of Detergent Solution / Accessories for Washing. **d.** Separate Washing Area for Special Type of Garments Is it Satisfactory?				
10.	Name of cleaning Agent/ Detergent used to clean the Garments				
11.	Is there facility for decontamination of Potent Drugs (Cephalosporin/ Penicillin) Garments				
12.	Is there dedicated personnel for cleaning of General , Potent Drugs (Cephalosporin / Penicillin) Garments				
13.	Is Cephalosporin Sensitivity Test Report available of personnel for cleaning of Cephalosporin Garments				
14.	Is there separate Area / Washing Machine/Dryer for cleaning of General , Potent Drugs (Cephalosporin/ Penicillin) Garments				
15.	Is there Automatic Dryer or Sun Drying.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
16.	What is the frequency of cleaning the Laundry? Quality of Utensils & Equipment.				
17.	Do they have Procedure for Disposal of Waste/ used Water?				
18.	Is there separate area for drying of uniform?				
19.	What is the quality of ropes he uses for dangling the linen?				
20.	Is the Collar, Sleeve & Pockets of uniforms cleaned properly?				
21.	Is there separate area for storage of cleaned uniforms?				
22.	Is cleaned garments ironed and folded properly after drying				
23.	Is there is separate arrangement to keep the Linen Block Wise / Department Wise? Is it satisfactory? If not? What is Alternative Arrangement?				
24.	Packing & labeling of cleaned uniforms.				
25.	Is there training program for workers? (If yes attached the training record.)				
	Who performs the inspection of clean uniform before supplying				
	Qualification of the people				
	No. of supervisors				
	Qualification				
	Experience of Supervisor				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**WAREHOUSE AND DISPENSING**	**Checklist No.: ……**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of Applicable SOPs available in the Area?				
	Are the Index and the SOPs current?				
	Is the Set of SOPs correctly organized according to the index?				
	Are the Obsolete Documents removed from the Department?				
2.	**PERSONNEL**				
	Select three Employees Working in the Area. Are their Training Records up-to-date? **1._____2._____3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Warehouse / Weighing Techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all employees attired according to the appropriate Gowning SOP, including, where necessary, Masks, Gloves and Beard covers?				
3.	**FACILITIES**				
	Is access to the Department restricted to Authorized Personnel only?				
	Are the materials stored in separate areas according to status?				
	Is the Department maintained in a good state of repair?				
	Is there any sign of Pest Activity?				
	Is the Department neat and orderly with sufficient space for dispensing of material?				
	Is there adequate physical separation between different operations to prevent Mix-Ups and / or Cross –Contamination?				
	Is there an SOP describing precautions to be taken when weighing high-potency drugs, including cleaning procedures after weighing?				
	Is there an SOP for monitoring the Temperature and the Relative Humidity in the Department				
	Is there documented evidence that it is followed?				
4.	**CLEANING PROCEDURE**				
	Are there written procedures for cleaning the Stores and Racks?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there documented evidence that the Cleaning Procedures are being followed?				
5.	**WAREHOUSE PROCEDURE**				
	Is there an SOP describing the receipt of components and the examination to be done? Is the examination documented?				
	Where a shipment contains more than one batch, is each batch tested and released separately?				
	In the event that containers are damaged, does the SOP specify the Corrective Action to be taken? Is there documented evidence that the SOP is followed?				
	Are containers of Raw Materials cleaned externally on receipt? Is cleaning in accordance with a written SOP?				
	Is there an SOP defining the maximum amount of time materials with special storage requirements may be stored at room temperature (i.e. prior to Storage in a Refrigerator /Freezer)?				
	Is the Temperature of the Refrigerator monitored according to an SOP? What Corrective Action is required in the event that the Temperature is Out-of –Limits? _____ _____				
	Can materials be located easily within the stores according to the assigned location?				
	Is there an SOP for recording stock movement during Computer Unavailability? Is it followed?				
	Are all items in the stores labeled as to their status?				
	Have all items designated released been tested and if necessary, retested according to an Approved SOP?				
	Is there a Separate Area for the Storage of Rejected Materials?				
	Is there a Separate Area for the Storage of Materials whose disposition has not yet been decided?				
	Is stock rotated according to the FEFO Rule? Is this required by an SOP?				
	Where the FEFO Rule is deviated from is there written justification of the Deviation? _____				
6.	**PRINTED PACKAGING MATERIALS**				
	Are all Printed Packaging Materials stored in a Restricted Access Area?				
	Are Printed Packaging Materials of different Product, Strengths, Dosage Form, or Quantity of Contents stored separately?				
	Is there an SOP for checking the accuracy of the balance used for dispensing of packing materials?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Examine records of these checks. • Are they performed according to the frequency shown in the SOP? • Where necessary, has appropriate corrective action been implemented?				
	Is there an SOP describing the dispensing and control of printed packaging materials?				
7.	**FINISHED GOODS STORE**				
	Are the Finished Goods awaiting release stored in a Separate Area from Raw Materials?				
	Is there an SOP describing the process for dealing with Returned Goods?				
	Is there an area in the stores assigned for the Storage of Returned Goods until their disposition is known?				
8.	**SAMPLING PROCEDURE**				
	Examine the Status Board of the Sampling Booth. Is the material currently being sampled recorded on it?				
	Select one of the Raw Materials currently under Quarantine. Is the material recorded as having been sampled?				
	Is there an SOP describing Sampling Operations, including a Sampling Plan?				
	Is the Sampling Booth clean?				
	Is the Dust Collection System Operational?				
	Are the containers that are to be sampled clean of External Dust and Powder?				
	Is sampling equipment stored in a manner to prevent its contamination?				
9.	**WEIGHING PROCEDURE**				
	Are all Instruments in the Department labeled with a Valid Calibration Tags?				
	Is there an SOP requiring the inspection of the area for cleanliness prior to and at the end of dispensing operations :				
	Is the operation documented on the Status Board?				
	Examine the record of the daily check of Balances in the Department.				
	• Is it complete and accurately filled out?				
	• Are all results within the specifications?				
	• If not, is there a record of the implementation of corrective action?				
	Perform a visual examination of the Weights used for the check. • Are they in a good state of repair? • Do they bear a Valid Calibration Tag?				
	Is there an SOP describing Weighing Operations? Does it require verification of vendor Tare Weights?				
	Watch a Weighing Operation being performed.				
	Is all documentation filled in up to the ingredient being weighed?				
	Is the weigher appropriately attired?				
	Is all equipment used clean at the start of the operation?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**GRANULATION SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the Section?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Are Obsolete documents removed from the Granulation Section?				
2.	**PERSONNEL**				
	Select three employees working in the Granulation Section. Are their Training Records Available? Is the Training Index updated? **1. _____2. _____3. _____**				
	Have the employees undergone training in the following areas during the last year? • cGMP • SOPs • Granulation Techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Granulation Section maintained in a good state of repair?				
	Is the Granulation Section neat and clean with sufficient space for Equipment and Operations?				
	Is all the Dispensed Raw Material for one batch kept on a pallet?				
	Where more than one pallet is designated for one batch, is each pallet clearly labeled as one of the total number of pallets?				
	Are all work areas clearly labeled with the name and the Batch Number of the product being Processed and Signature of the Production Officer?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp. _____, Relative Humidity: _____**)				
	Does any pest seen in the Granulation Section?				
	What is the precautionary activity done for Pest control? (Whether Fly-O-cide available)?				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is a personnel clothing Clean, Unstained and Dust Free, including Shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Granulation Section (filter designation)? _____, _____				
	Is there a cleaning SOP for slippers or shoes that is being used in the manufacturing area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are pallets and drums brought into the area clean and free from Powder/Dust/Dirt?				
	Is the equipment Neat, Clean and Rust Free?				
	When not in use, is equipment covered so as to Prevent Accidental Contamination?				
	Is the equipment suitably designed for its purpose?				
	Is the equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Are there specific procedures for the cleaning of major equipment items?				
	Select any major equipment used for manufacturing. Equipment Name: ID No.: Examine the following records: * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Visually inspect one piece of equipment that is been cleaned. Is it cleans?				
	Is it labelled with respect to its cleanliness status?				
	Do cleaning procedures include a requirement for the cleaning of small items?				
	Do cleaning procedures specify the detergent type and concentration to be used?				
	Is the cleaning agent detergents available in the Granulation Section identical to those listed in the cleaning procedures?				
	Are there records of Cleaning Agent Preparation?				
	Is there an Approved Protocol for Cleaning Validation?				
	Is there a written procedure for washing the Finger Bags of Fluidized Bed Dryers?				
	Are the finger bags dedicated for each product?				
	How are they stored? Is it satisfactory?				
6.	**WORKING PROCEDURES**				
	Examine the record of the daily and weekly calibration. Check of balances in the Granulation Section. Are they satisfactory?				
	Is it complete and accurately filled out?				
	Are all in process results within the specifications?				
	If not, is there a record of the implementation of corrective action?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Perform a visual examination of the weights with which the check is performed.				
	Is the in process Quality Control Instruments calibrated to today's date for use?				
	Are they in a good state of repair?				
	Do they bear a Valid Calibration Label?				
	Examine the Batch Record for a batch that is being processed. **Product:_____ Batch No.: _____**				
	Is the Master Batch Manufacturing Record signed and BMR used for this batch is an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Are all in-process results within the defined limits?				
	Is there a written procedure for the cleaning of containers after use?				
	Are the blend containers properly labeled?				
	Is there an SOP defining the maximum storage period of blend stand prior to compression?				
	Is it adhered to?				
	Do yield calculations after Granulation conform to the relevant SOP?				
	Is yield calculation performed after each distinct phase of Production? • Sizing • Blending				
	Is there written procedure for Handling of Breakdown of Equipment and System? Is Breakdown details properly recorded?				
	Is there a record of checking the sieves and screens before and after use for signs of damage?				
7.	**LUBRICANTS**				
	Is the equipment designed in such a way that lubricants not come into contact with components or drug product?				
	Is there an approved list of Food-Grade Lubricants for use where they may contact product?				
	Is there a written procedure for the receipt and approval of such Lubricants?				
	Examine the lubricants available in the Granulation Section. Are they clearly labeled and stored in a sanitary manner?				
8.	**EQUIPMENT CALIBRATION**				
	Is there an approved schedule for the calibration of all production equipment?				
	Select three equipment items and examine the calibration records. **1. _____ 2. _____3. _____**				
	Are the equipment items identified with a Distinguishing Code Number?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is all critical instrumentation on the equipment items identified with a valid calibration tag?				
	Physically verify that all instruments found associated with the equipment are included in the Calibration File?				
	Do all appropriate personnel approve the Calibration Reports?				
	Are the reports completely and accurately filled out?				
	Where compressed air is supplied to machinery, is it Oil Free and Filtered?				
	Is there an SOP for cleaning and replacement of these filters?				
	What measures are taken to prevent cross-contamination of product from these filters when inlet air is not functioning? _____				
9.	**FILTERS**				
	Do they maintain the record of Filters?				
	Is there written procedure for Cleaning of Filters at the time of Product Changeover?				
	Do they check the Filter Integrity on routine basis?				
10.	**LABELS**				
	Are the status labels affixed to all Equipments?				
	Is the status labels duly signed by Production Officer?				
	Is the status board bears necessary information?				
11.	**DOCUMENTATION**				
	Are all daily documents filled correctly and timely?				
	Are the formats, logs are current?				
	Has all SOPs related with the Equipment or the Process been Displayed?				
	Is any Obsolete Copy seen in the Granulation Section?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**COMPRESSION SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of Applicable SOPs available in the Compression Section?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are the Obsolete documents removed from the Compression Section?				
2.	**PERSONNEL**				
	Select three employees working in the Compression Section. Are their training records available? Is the training index updated? **1. _____ 2. _____3. _____**				
	Have the employees undergone training in the following areas during the last year? • GMP • SOPs • Compression Techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Compression Section maintained in a good state of repair?				
	Is the Compression Section neat and orderly with sufficient space for equipment and operations?				
	Is all work areas cleared labeled with Name & Batch Number of the Product being processed & sign of the Production Officer?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed. Temp: _____, Relative Humidity: _____**)				
	Is any pest seen in the Compression Section?				
	What is the precautionary activity done for the Pest Control? (Whether Fly-O-cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is a Personnel Clothing Clean, Unstained and Dust Free, including Shoes?				
	Are the Return Risers cleaned during Product Change Over?				
	What is the quality of the air in the Compression Section (Filter Designation)? _____, _____.				
	Are their approved SOPs for the maintenance of ceiling filters?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
5.	**EQUIPMENT AND FACILITY CLEANING AND SANITATION**				
	Are IPC or bin brought into the area clean and free from Powder/Dust/Dirt?				
	Is the Equipment Neat, Clean and Rust Free?				
	When not in use, is Equipment covered so as to prevent accidental contamination?				
	Is the Equipment suitably designed for its purpose?				
	Is the Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Are there procedures for the cleaning of Compression Machine?				
	Select a Compression Machine. **ID No.:** Examine the following Records:				
	* Machine Log Book				
	* Qualification Documents				
	* Cleaning Log Book				
	* Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Visually inspect one machine that is not in use, Is it labeled respect to its cleanliness status? Is it clean?				
	Do cleaning procedures include a requirement for the cleaning of small items (e.g. Scoop)?				
	Do cleaning procedures specify the Cleaning Agent and concentration to be used?				
	Is the cleaning agent available in the Compression Section identical to those listed in the cleaning procedures?				
	Are there cleaning agent labeled with a catalog number indicating that they were received through the warehouse?				
	Are there records for cleaning agent preparation?				
	Is there an approval protocol for Cleaning Validation of Compression Machine?				
6.	**WORKING PROCEDURES**				
	Examine the record of the daily & weekly calibration of balances in the Compression Section. Is it complete and accurately filled out?				
	Are all results within the Specification?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed. Are they kept in the Weight Box Trolley?				
	Are they clean?				
	Do they bear a Valid Calibration Seal?				
	Examine the Batch Record for a batch that is being processed. **Product:** _____ **Batch No.:** _____				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Have any changes to the process or equipment been authorized by QA?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the Speed of Compression Machine return on the batch record?				
	Do the working pressure and machine speed conform to the required standards?				
	Examine the containers used for collecting tablets.				
	Are they correctly labeled?				
	Is the weight recorded on real time (i.e. after the bin is completely filled)?				
	Is there a SOP for inspection the punches and dies after each use for signs of deterioration (gouging, chipping, corrosion, etc.) that could impact the tablets?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for in process checked?				
	Does the SOP state at what frequency tests must be performed by?				
	Examine a batch record. Is the test frequency adhered to? **Product Name:_____ B. No.: _____**				
	Do all test results conform to Specifications?				
	Is all testing Instruments labeled with a Valid Calibration Label? **1. _____2. _____3._____**				
	Is the SOP specific with regard to corrective action in the event that results do not conform to Specifications?				
	Examine a Batch Record. **Product Name: _____, Batch No.: _____**				
	Do the recorded Specifications conform to the Approved Product Specifications?				
	Is the SOP specific with regard to Corrective Action in the event that results do not conform to Specifications?				
	Are results recorded in the correct units as stated on the form?				
	Are Tablets stored in Bulk Containers before Coating and/or Packaging?				
	If yes, has a time limitation been set regarding the maximum storage time of bulk?				
	Is the time limitation adhered to?				
	Examine the lubricants available in the Compression Section. Are they clearly labeled and stored in a sanitary manner?				
8.	**EQUIPMENT QUALIFICATION & CALIBRATION**				
	Is there an Approved Annual Program for the Calibration of all Compression Machines?				
	Select one Compression Machine and Examine the Qualification Record?				
	Is the machine identified with a Distinguishing Code Number?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is all-critical instrumentation identified with a Valid Calibration Label?				
	Physically verify that all instruments found on the machine are included in the Calibration File.				
	Are the reports approved by all Appropriate Personnel?				
	Are the reports completely and accurately filled out?				
9.	**LABELS**				
	Are the status labels affixed to the equipments?				
	Are the status labels duly signed by Production Officer?				
	Is the status board bears necessary information?				
10.	**DOCUMENTATION**				
	Are all daily documents filled correctly and timely?				
	As the formats, logs are current?				
	Has all SOPs related with the Equipment or the Process been Displayed?				
	Is any obsolete copy seen in the Compression Section?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**COATING SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of Applicable SOPs available in the Coating Section?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are Obsolete documents removed from the Coating Section?				
2.	**PERSONNEL**				
	Select three Employees working in the Coating Section. Are their Training Records available? Is the Training Index updated? **1._____ 2._____3. _____.**				
	Have the Employees undergone training in the following areas during the last year? • GMP • SOPs • Coating techniques				
	Question several Employees about the Operations they are Performing. Are they Knowledgeable about their Job Functions?				
	Are all employees attired according to the appropriate Gowning SOP?				
3.	**FACILITIES**				
	Is the Coating Section maintained in a good state of repair?				
	Is the Coating Section neat and orderly with sufficient space for Equipment and Operations?				
	Is all the Dispensed Raw Material for one batch kept on a Pallet Wrapped in Polythene?				
	Is the Liquid Raw Material used for Coating kept in clean and closed Containers?				
	Are all work areas clearly labeled with the name and the Batch Number of the Product being processed and sign of Production Officer?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp._____, Relative Humidity:_____**)				
	Does any pest seen in the Coating Section?				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are Doors closed at all times?				
	Is Personnel Clothing Clean, Unstained and Dust Free, including Shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Coating Section (Filter designation)? _____ , _____				
	Is there cleaning SOP for Slippers or Shoes that is being used in the Manufacturing Area?				
	Are there approved SOPs for the Maintenance of Ceiling Filters?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are IPCs brought into the area clean and free from Powder/Dust/Dirt?				
	Is the Equipment neat, clean and rust free?				
	Is the Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Are there specific procedures for the cleaning of Tablet Coating Machine?				
	Select a Coating Machine. **ID No.:** Examine the following records:				
	* Machine Log Book				
	* Qualification Status				
	* Cleaning Log Book				
	* Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Visually inspect one piece of Equipment that is been cleaned. Is it clean?				
	Is it labeled with respect to its cleanliness status?				
	Do cleaning procedures include a requirement for the cleaning of Small Items?				
	Does cleaning procedure specify the Detergent Type and Concentration to be used?				
	Are there records of Cleaning Agent Preparation?				
	Is there an approved protocol for the Cleaning Validation Tablet Coating Machine?				
6.	**WORKING PROCEDURES**				
	Examine the record of the Daily and Weekly Calibration? Check of balances in the Coating Section. Are they satisfactory?				
	If not, is there a record of the implementation of corrective action?				
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the Implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they clean?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Do they bear a Valid Calibration Seal?				
	Examine the batch record for a batch that is being processed. **Product :** _____ **Batch No.:** _____				
	Is the Master Batch Manufacturing Record signed and BMR used for this batch is an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Are all in-process results within the defined limits?				
	Is there an SOP that specifies the maximum amount of time for holding of coated tablet?				
	Is there an SOP that specifies the maximum amount of time for coating solution may be kept after preparation prior to the completion of coating?				
	Examine the bin used for collecting Tablets?				
	Are they correctly labeled?				
	Is the weight recorded on real time (i.e. after the bin is completely filled)?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for in-process control?				
	Does the SOP state at what frequency tests must be performed by Production and QA personnel?				
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				
8.	**EQUIPMENT CALIBRATION**				
	Is there an approved schedule for the Calibration of all Coating Equipment?				
	Select one Coating Machine and examine the Calibration Record.				
	Is the Machine identified with a Distinguishing Code Number?				
	Is all Critical Instrumentation identified with a Valid Calibration Label?				
	Physically verify that all instruments found on the machine are included in the Calibration File.				
	Are the reports approved by all appropriate Personnel?				
	Are the reports completely and accurately filled out?				
9.	**LABELS**				
	Are the Status Labels affixed to all Equipments?				
	Is the Status Labels duly signed by Production Officer?				
	Is the Status Board bears necessary information?				
10.	**DOCUMENTATION**				
	Are all daily documents filled correctly and timely?				
	As the formats, logs are current?				
	Has all SOPs related with the equipment or the process been displayed?				
	Is any obsolete copy seen in the Coating Section?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**HARD GELATIN CAPSULE SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of applicable SOPs available in the Section?				
	Are the Index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are Obsolete documents removed from the Hard Gelatin Capsule Section?				
2.	**PERSONNEL**				
	Select three employees working in the Hard Gelatin Capsule Section. Are their Training Records available? Is the Training Index updated? **1. _____ 2. _____3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Capsule Filling Techniques				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all Employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Hard Gelatin Capsule Section maintained in a good state of repair?				
	Is the Hard Gelatin Capsule Section neat and orderly with sufficient space for Equipment and Operations?				
	Is all Dispensed Raw Material for one batch kept on a pallet wrapped in a polythene ?				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp.**_____, **Relative Humidity :**_____)				
	Does any Pest seen in the Hard Gelatin Capsule Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly –O – cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is Personnel Clothing Clean, Unstained and Dust Free, including Shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Hard Gelatin Capsule Section (filter designation)? _____ , _____				
	Is there cleaning SOP for Slippers or Shoes that is being used in the Manufacturing Area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are Pallets and Drums brought into the Area Clean and Free from Powder/Dust?				
	Is the Equipment Neat, Clean and Rust Free?				
	When not in use, is equipment covered so as to Prevent Accidental Contamination?				
	Is Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Select a Equipment: Equipment Name: ID No.: Examine the following records : * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Select one batch recorded on the Machine Log Book and thoroughly check that Batch Record. **B. No. _____**				
	Is the Cleaning Checklist for the Equipment completed? Does the checklist describe machine disassembly and assembly for cleaning procedure?				
	Is the cleaning correctly recorded on the Area Cleaning Record?				
	Visually inspect one machine that is not in use				
	Is it labeled with respect to its cleanliness status?				
	Is it clean?				
	Do Cleaning Procedures include a requirement for the cleaning of Small Items (e.g., Portable Computers, Balances, etc.)?				
	Do Cleaning Procedures specify the cleaning agent and concentration to be used?				
	Is the Cleaning Agent available in the Hard Gelatin Capsule Section identical to those listed in the Cleaning Procedures?				
	Is the Cleaning Agent labeled with a catalogue number indicating that they were received through the Warehouse?				
	Are the records of Cleaning Agent Preparation?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there an Approved Protocol for the Cleaning Validation of Capsule Filling Machine?				
	Is there documented evidence that it is being followed?				
6.	**WORKING PROCEDURES**				
	Examine the record of the Daily & Fortnightly Calibrations & check of balances in the Hard Gelatin Capsule Section.				
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they in a good state of repair?				
	Are they clean?				
	Do they bear a Valid Calibration Seal?				
	Examine the Batch Record for a batch that is being processed. **Product :** _____ **Batch No.:** _____				
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the speed of filling recorded in the batch documents?				
	Does the filling speed conform to the required parameters?				
	Is the suction system filling during work?				
	Question the employees. Does he or she know what the correct procedure is if the suction system stops functioning?				
	Do yield calculations after Capsule Filling Conform with the relevant Batch Records?				
	Has BMR been completed and an investigation conducted. If any?				
	Is the yield checked by a Production Officer?				
	Examine the bins used for collecting Capsules?				
	Are they correctly labeled?				
	Is the weight recorded on real time (i.e. after the bin is completely filled)?				
	Are they correctly labeled?				
	Is there an SOP for monitoring capsule weight during production?				
	Is it followed?				
	If necessary, is there an SOP for Inspection Capsules after Filling?				
	Is it followed?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for In-Process Control?				
	Does the SOP state at what frequency tests must be performed by Production Officer/Executive and QA Officer/Executive?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				
	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?				
	Are there printouts available for in-process test results labeled with • Product Name • Batch Number • Date and Time of Testing?				
	Examine the Recorded Results? • Do the recorded results conform to the approved product Specification? • Do the recorded data match the attached printouts? • Are the results recorded in the correct units stated on the form?				
	Is there an SOP for collecting a composite sample for final testing by Quality Control?				
	Is the SOP followed?				
	Is all testing instruments labeled with a valid Calibration Label?				
8.	**EQUIPMENT QUALIFICATION**				
	Is there an Approved Schedule Program for the Qualification of all Equipments?				
	Select one machine and examine the DQ/IQ/OQ/PQ protocol. **Machine :** _____				
	Is the Machine Identified with a Distinguishing Code Number?				
	Are all Critical Instrumentation / Equipment identified with a valid Calibration Label?				
	Physically verify that all Instruments found on the machine are included in the Protocol.				
	Cross-check with the Calibration Records that the Instruments have the same Classification in the Qualification Protocol as in the Calibration Report.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**DRY SYRUP SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of applicable SOP's available in the Section?				
	Are the Index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are Obsolete documents removed from the Section?				
2.	**PERSONNEL**				
	Select three employees working in the Dry Syrup Section. Are their Training Records available? Is the Training Index updated? **1. _____ 2. _____ 3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Dry Syrup Manufacturing / Filling Techniques				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all Employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Section maintained in a good state of repair?				
	Is the Section neat and orderly with sufficient space for Equipment and Operations?				
	Is all Dispensed Raw Material for one batch kept on a pallet wrapped in a polythene				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp.**_____, **Relative Humidity :**_____)				
	Does any Pest seen in the Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly –O – cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is personnel clothing Clean, Unstained and Dust Free, including Shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Area / Section (filter designation)? _____ , _____				
	Is there cleaning SOP for slippers or shoes that is being used in the Manufacturing Area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are Pallets and Drums brought into the Area Clean and Free from Powder/Dust?				
	Is the Equipment Neat, Clean and Rust Free?				
	When not in use, is equipment covered so as to Prevent Accidental Contamination?				
	Is Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Select a Equipment: Equipment Name: ID No.: Examine the following records: * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Select one batch recorded on the Machine Log Book and thoroughly check that Batch Record. **B. No.:**_____				
	Is the Cleaning Checklist for the Equipment completed? Does the checklist describe machine disassembly and assembly for cleaning procedure?				
	Is the cleaning correctly recorded on the Area Cleaning Record?				
	Visually inspect one machine that is not in use				
	Is it labeled with respect to its cleanliness status?				
	Is it clean?				
	Do Cleaning Procedures include a requirement for the cleaning of small items (e.g., portable computers, balances, etc.)?				
	Do Cleaning Procedures specify the Cleaning Agent and Concentration to be used?				
	Is the Cleaning Agent available in the Section identical to those listed in the Cleaning Procedures?				
	Is the Cleaning Agent labeled with a catalogue number indicating that they were received through the Warehouse?				
	Are the records of Cleaning Agent Preparation?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there an Approved Protocol for the Cleaning Validation of Dry Syrup Filling Machine and other Machines which is used in Manufacturing?				
	Is there documented evidence that it is being followed?				
6.	**WORKING PROCEDURES**				
	Check the Calibration record of balances in the Dry Syrup Section.				
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the Weights with which the check is performed.				
	Are they in a good state of repair?				
	Are they clean?				
	Do they bear a valid Calibration Seal?				
	Examine the Batch Record for a batch that is being processed. **Product :** _____ **Batch No.:** _____				
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the speed of filling recorded in the batch documents?				
	Does the filling speed conform to the required parameters?				
	Question the employees. Does he or she know what the correct procedure is if the suction system stops functioning?				
	Do yield calculations after Dry Syrup Filling Conform with the relevant Batch Records?				
	Has BMR been completed and an Investigation conducted .If any?				
	Is the yield checked by a Production Officer?				
	Is there an SOP for monitoring Dry Syrup Fill Weight during Production?				
	Is it followed?				
	If necessary, is there an SOP for Inspection of Dry Syrup after Filling and Sealing?				
	Is it followed?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for In-Process Control?				
	Does the SOP state at what frequency tests must be performed by Production officer/Executive and QA Officer/Executive?				
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				
	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are there printouts available for in-process test results labeled with the • Product Name • Batch Number • Date and Time of Testing?				
	Examine the Recorded Results? • Do the recorded results conform to the approved product Specification? • Do the recorded data match the attached printouts? • Are the results recorded in the correct units stated on the form?				
	Is there an SOP for collecting a composite sample for final testing by Quality Control?				
	Is the SOP followed?				
	Is all testing instruments labeled with a valid Calibration Label?				
8.	**EQUIPMENT QUALIFICATION**				
	Is there an Approved Schedule Program for the Qualification of all Equipments?				
	Select one Machine and Examine the DQ/IQ/OQ/PQ Protocol. **Machine :** _____				
	Is the Machine Identified with a Distinguishing Code Number?				
	Are all Critical Instrumentation / Equipment identified with a Valid Calibration Label?				
	Physically verify that all Instruments found on the machine are included in the protocol.				
	Cross-check with the Calibration Records that the Instruments have the same Classification in the Qualification Protocol as in the Calibration Report.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**SOFT GELATIN CAPSULE SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of Applicable SOPs available in the Section?				
	Are the Index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are Obsolete documents removed from the Section?				
2.	**PERSONNEL**				
	Select three employees working in the Section. Are their training records available? Is the training index updated? **1. _____ 2. _____ 3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Encapsulation Techniques				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all Employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Section maintained in a good state of repair?				
	Is the Section neat and orderly with sufficient space for equipment and operations?				
	Is all Dispensed Raw Material for one batch kept on a pallet wrapped in a polythene				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp.**_____, **Relative Humidity :**_____)				
	Does any Pest seen in the Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly –O – cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is personnel clothing clean, unstained and dust free, including shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Section (filter designation)? _____ , _____				
	Is there cleaning SOP for slippers or shoes that is being used in the manufacturing area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are Pallets and Drums brought into the area clean and free from Powder/Dust?				
	Is the Equipment neat, clean and rust free?				
	When not in use, is equipment covered so as to prevent accidental contamination?				
	Is Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Select one batch recorded on the Machine Log Book and thoroughly check that Batch Record. **B. No.:**_____				
	Select a Equipment: **Equipment Name:** **ID No.:** Examine the following records: * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Is the Cleaning Checklist for the Equipment completed? Does the Checklist describe Machine Disassembly and Assembly for Cleaning Procedure?				
	Is the cleaning correctly recorded on the Area Cleaning Record?				
	Visually inspect one machine that is not in use				
	Is it labeled with respect to its Cleanliness Status?				
	Is it clean?				
	Do Cleaning Procedures include a requirement for the cleaning of small items (e.g., Portable Computers, Balances, etc.)?				
	Do Cleaning Procedures specify the Cleaning Agent and Concentration to be used?				
	Is the Cleaning Agent available in the Section identical to those listed in the cleaning procedures?				
	Is the Cleaning Agent labeled with a Catalogue Number indicating that they were received through the Warehouse?				
	Are the records of Cleaning Agent Preparation?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there an Approved Protocol for the Cleaning Validation of Encapsulation Machine?				
	Is there documented evidence that it is being followed?				
6.	**WORKING PROCEDURES**				
	Examine the record of the Daily & Fortnightly Calibrations & Check of Balances in the Section.				
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they in a good state of repair?				
	Are they clean?				
	Do they bear a Valid Calibration Label?				
	Examine the Batch Record for a batch that is being processed. **Product :** _____ **Batch No.:** _____				
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the speed of filling recorded in the batch documents?				
	Does the filling speed conform to the required parameters?				
	Do yield calculations after Encapsulation, Conform with the relevant Batch Records?				
	Has BMR been completed and an investigation conducted. If any?				
	Is the yield verified by a second person?				
	Examine the bins used for collecting Capsules?				
	Are they correctly labeled?				
	Is the weight recorded on real time (i.e. after the bin is completely filled)?				
	Are they correctly labeled?				
	Is there an SOP for monitoring Capsule Weight during Production?				
	Is it followed?				
	If necessary, is there an SOP for Inspection Capsules after Filling?				
	Is it followed?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for In-Process Control?				
	Does the SOP state at what frequency tests must be performed by Production Officer/Executive and QA Officer/Executive?				
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?				
	Are there printouts available for in-process test results labeled with the • Product Name • Batch Number • Date and Time of Testing?				
	Examine the Recorded Results? • Do the recorded results conform to the approved product Specification? • Do the recorded data match the attached printouts? • Are the results recorded in the correct units stated on the form?				
	Is there an SOP for collecting a composite sample for final testing by Quality Control?				
	Is the SOP followed?				
	Is all testing instruments labeled with a valid Calibration Tag?				
8.	**EQUIPMENT QUALIFICATION**				
	Is there an Approved Schedule Program for the Qualification of all Equipments?				
	Select one Machine and Examine the DQ/IQ/OQ/PQ protocol. **Machine :** _____				
	Is the Machine Identified with a Distinguishing Code Number?				
	Are all critical Instrumentation / Equipment identified with a valid Calibration tag?				
	Physically verify that all instruments found on the machine are included in the protocol.				
	Cross-check with the Calibration Records that the Instruments have the same Classification in the Qualification Protocol as in the Calibration Report.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**LIQUID ORAL SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Are a Complete Index and a Complete Set of applicable SOPs available in the Liquid Oral Section?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Are Obsolete documents removed from the Liquid Oral Section?				
2.	**PERSONNEL**				
	Select three employees working in the Liquid Oral Section. Are their Training Records available? Is the Training Index updated? **1. _____ 2. _____ 3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Liquid Manufacturing & Filling Techniques				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all Employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Liquid Oral Section maintained in a good state of repair?				
	Is the Liquid Oral Section neat and orderly with sufficient space for equipment and operations?				
	Is all Dispensed Raw Material for one batch kept on a pallet wrapped in a polythene				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is the Temperature and Relative Humidity maintained in the Area? (**Observed: Temp.**_____, **Relative Humidity :**_____)				
	Does any Pest seen in the Liquid Oral Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly –O – cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is personnel clothing clean, unstained and dust free, including shoes?				
	Are the Return Risers cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Liquid Oral Section (filter designation)? _____, _____				
	Is there cleaning SOP for slippers or shoes that is being used in the manufacturing area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are Pallets and Drums brought into the area clean and free from Powder/Dust?				
	Is the Equipment neat, clean and rust free?				
	When not in use, is equipment covered so as to prevent accidental contamination?				
	Is Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Select a Equipment: **Equipment Name:** **ID No.:** Examine the following records: * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Select one batch recorded on the Machine Log Book and thoroughly check that Batch Record. **B. No.:**_____				
	Is the Cleaning Checklist for the Equipment completed? Does the checklist describe machine disassembly and assembly for cleaning procedure?				
	Is the cleaning correctly recorded on the Area Cleaning Record?				
	Visually inspect one machine that is not in use				
	Is it labeled with respect to its cleanliness status? Is it clean?				
	Do Cleaning Procedures include a requirement for the cleaning of small items (e.g., portable computers, balances, etc.)?				
	Do Cleaning Procedures specify the cleaning agent and concentration to be used?				
	Is the Cleaning Agent available in the Liquid Oral Section identical to those listed in the cleaning procedures?				
	Is the Cleaning Agent labeled with a catalogue number indicating that they were received through the Warehouse?				
	Are the records of Cleaning Agent Preparation?				
	Is there an Approved Protocol for the Cleaning Validation of Equipment used in Liquid Manufacturing and Liquid Filling Machine?				
	Is there documented evidence that it is being followed?				
6.	**WORKING PROCEDURES**				
	Examine the record of the daily & fortnightly calibrations & check of balances in the Liquid Oral Section.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they in a good state of repair?				
	Are they clean?				
	Do they bear a valid Calibration Seal?				
	Examine the Batch Record for a batch that is being processed. **Product : _____ Batch No.: _____**				
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the speed of filling recorded in the batch documents?				
	Does the filling speed conform to the required parameters?				
	Do yield calculations after Liquid Manufacturing and Liquid Filling and Sealing, Conform with the relevant Batch Records?				
	Has BMR been completed and an investigation conducted .If any?				
	Is the yield verified by a production officer?				
	Are they correctly labeled?				
	Is there an SOP for monitoring of Fill Volume during production?				
	Is it followed?				
	Is there an SOP for Inspection of filled and sealed bottles?				
	Is it followed?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for In-Process Control?				
	Does the SOP state at what frequency tests must be performed by Production officer/Executive and QA Officer/Executive?				
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				
	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?				
	Are there printouts available for in-process test results labeled with the • Product Name • Batch Number • Date and Time of Testing?				
	Examine the Recorded Results? • Do the recorded results conform to the approved product Specification? • Do the recorded data match the attached printouts? • Are the results recorded in the correct units stated on the form?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there an SOP for collecting a composite sample for final testing by Quality Control?				
	Is the SOP followed?				
	Is all testing instruments labeled with a valid Calibration Tag?				
8.	**EQUIPMENT QUALIFICATION**				
	Is there an approved schedule program for the qualification of all equipments?				
	Select one machine and examine the DQ/IQ/OQ/PQ protocol. **Machine :** _____				
	Is the Machine Identified with a Distinguishing Code Number?				
	Are all critical Instrumentation / Equipment identified with a valid Calibration tag?				
	Physically verify that all instruments found on the machine are included in the protocol.				
	Cross-check with the Calibration Records that the Instruments have the same Classification in the Qualification Protocol as in the Calibration Report.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**INJECTION SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the Section?				
	Are the index and the SOPs Current?				
	Is the set of SOPs correctly Organized according to the Index?				
2.	**PERSONNEL**				
	Select three Employees working in the Section. Are their training records up-to-date? **1._____2._____3._____**				
	Have the employees undergone training in the following areas during the last year? • GMP • SOPs • Sterile Manufacturing Techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP? When necessary, do Operators wear Masks and Gloves?				
	Observe employees performing the Gowning procedure. Are they accurately following the SOP?				
	Is a fresh set of garments used on each entry into the Clean Room?				
	Examine a set of garments ready for use. • Is the package sealed? • Is the package labelled with an Expiration Date? • How was the Package Sterilized? • Is sterilization in accordance with the relevant SOP?				
3.	**FACILITIES**				
	Is the Section maintained in a good state to repair, neat and with sufficient space for Equipment and Operations?				
	Are there written records to indicate that the cleaning schedule is being followed as stated in the relevant SOP?				
	Are Cleaning and Sanitizing agents labeled with a catalogue number indicating that they were received through the Warehouse?				
	Are the Cleaning and Sanitizing Solutions being used identical to those listed in the relevant SOP?				
	Are Cleaning and Sanitizing solutions labeled with a Expiration Date according to the relevant SOP?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are the records of the preparations of * Cleaning and Sanitizing Solutions * Are the solution sterilized by Antibacterial Filtration?				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Is any pest seen in the Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly-O-cide available)?				
	Is the Equipment suitably designed for its purpose?				
	Is the Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will contaminate or in any way affect the product being manufactured?				
	Are there specific procedures for the cleaning of Major Equipment Items?				
	Do they include Instructions as to which parts of the machine require assembly and Disassembly for cleaning?				
	Are they followed?				
	Select a major piece of Equipment.				
	Examine the following records : • Machine Log Book • Cleaning Checklist				
	Is Equipment suitably identified as to its cleanliness status?				
	Is there an SOP for the transfer of materials to the clean area via pass-through windows?				
	Is the Sanitizing Agent left in contact with the materials for the amount of time specified in the SOP?				
	Is there a functioning alarm device to prevent simultaneous opening of doors on the clean and non-clean side of • Pass-through Windows? • Autoclaves? • Sterilizing Ovens?				
	Test the door Interlocking Indicator Lamps by attempting to open the doors.				
	How is Critical Equipment Controls protected from accidental interference during Operation?				
	Are there Approved, Validated Loading Patterns and are they followed for • Autoclaves • Sterilizing Ovens?				
	Examine one of the ovens after loading and compare it to the Approved Loading Pattern?				
	Examine the Recorder chart for the most recent cycle performed in one of the autoclaves. Does it meet the required parameters of time and temperature as defined in the relevant SOP?				
	Are Recorder charts verified and approved prior to the utilization of the load?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are there maintenance records for the air-vent filter on the Autoclave for • Change Frequency? • Integrity Test Results?				
	Do the records conform to the requirements of the relevant SOP?				
	Are the drains on the Autoclave Air-Breaked? Physically verify that the break is adequate				
	Are sterilization cycles defined and authorized in an SOP?				
	Are operating parameters / cycle selection verified by Qualified Personnel prior to the Initiation of the Cycle?				
	Examine the documentation of any changes made to the sterilization cycle for one product. Is a change control procedure followed?				
	Are there approved loading patterns for the sterilization?				
	Are the maintenance records of • Filter Replacement on the Nitrogen Line? • Filter Replacement on the Compressed Air Line? • Integrity Testing of the Filters?				
	Do the records conform to the requirements of the relevant SOP?				
	Are there records of cleaning the sterilizer • Between batches of the same product? • Between different product? • According to the relevant SOP?				
	Are there records of the Sterilization between each production batch?				
	Are sterilization charts verified and approved prior to manufacturing the next production batch?				
	Are the drains of the sterilization air-breaked? Physically verify that the break is adequate.				
4.	**MANUFACTURING PROCEDURES**				
	Examine the record of the daily check of balances in the Section. • Is it complete and accurately filled out? • Are all results within the Specifications? • If not, is there a record of the Implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they in a good state of repair?				
	Do they bear a Valid Calibration Tag?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is all location where product or product components are exposed protected by a LAF Stream providing air quality of class 100 or better?				
	Are Components handled in such a manner as to prevent their Accidental Contamination?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are sterilized components removed from the clean area if the time is exceeded?				
	Are they Re-Sterilized?				
	Has the procedure been Validated?				
	Is Validation / Verification according to the relevant SOP?				
	Are aseptic processing Filters • Pre-use Integrity Tested? • Post-use Integrity Tested?				
	Is there documented evidence that each batch of aseptic processing filters has passed a bacterial retention challenge test?				
	Have the aseptic processing filters been validated on a product specific basis? Examine the validation report.				
	How many post-use integrity test filter failures have there been in the past year? _____				
	What action was taken with respect to the product solution? _____				
	Is the corrective action documented?				
	Are all vessels and utensils labeled as to their cleanliness status?				
	Observe a work station during the production of a batch.				
	Are manufacturing instructions at hand?				
	Are the instructions complete, including special instructions is relevant?				
	Are the instructions accurately followed?				
	Are records and signatures made on real time?				
	Is bulk solution held according to the relevant SOP?				
	Are there written records for preparation of solutions used for pH adjustment?				
	Are time limitations adhered to for the holding of bulk solutions prior to • Filtration? • Filling? • Sterilization?				
	Are the records signed by two individual?				
	Do the records follow a written procedure?				
5.	**BATCH RECORDS**				
	Examine the Batch Record for a batch that is being processed. **Product :** **Batch No.:**				
	Is the Master Formula signed as being an accurate copy of the original?				
	Have any changes to the master formula been Authorized by QA prior to start of work?				
	Has the batch been recorded on the Machine Log Book?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the Aseptic Filtration start and finish time recorded?				
	Is there any In-Process results not within the defined limits?				
	Have all relevant sterilization charts been fully labeled, verified, approved and attached to the batch record?				
	Select three recently released batches.				
	Are the batch documents readily available and easy to retrieve?				
	Is all relevant information included, complete and accurately filled in as follows? • Raw-materials Weighing • Manufacturing Method • Sterilization Charts • Yield Reconciliation • In-process Tests • Packaging Control • Laboratory Results • Deviation Report , is applicable				
	Do in-process control results meet Specifications (e.g. fill weights)?				
	If not, is there Documented Corrective Action?				
	Do yield Calculations after each production step conform to the relevant SOP?				
	Has the BMR been completed and investigation conducted?				
	Is Yield Calculation performed after each distinct phase of Production? • Compounding • Filtration • Filling • Visual Inspection • Labelling • Packaging				
	Is the Yield Calculation verified by a second Individual?				
	Where required, is there documented evidence of Line Clearance?				
	Are corrections to writing errors made by crossing out and initialing?				
	Do environmental monitoring results meet Specifications?				
	If not, was Appropriate Corrective Action Taken?				
	Do laboratory results for the batches meet Specifications?				
	If not, was Appropriate Corrective Action Taken?				
	Have all the batches been reviewed, signed and dated and their disposition (release or reject) indicated by Quality Assurance Personnel?				
6.	**CRITICAL SYSTEMS**				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are there valid calibration labels affixed to the following systems indicating that all instruments are within calibration? • Pure Steam System • Water for Injection System • HVAC System • Compressed Air System • Nitrogen System				
	Examine maintenance records for all of the above systems. Is there a complete history of maintenance, including where appropriate • Filter Changes? • Filter Integrity Test Data? • System Sterilization? • System Cleaning and Passivation?				
	Examine records of Temperature and Conductivity for the Water for Injection System.				
	Do they meet the Specifications in the relevant SOP?				
	If not, is there Documented Evidence of Corrective Action?				
7.	**MONITORING**				
	Is there a Valid Calibration Label affixed to monitoring Sensors for Pressure, Temperature and Relative Humidity?				
	Examine records of air pressure, temperature and relative humidity for the last month. Do they meet the specifications stated in the relevant SOP?				
	Are any deviations recorded together with corrective action taken?				
	Examine a copy of the air sampling plan for controlled manufacturing areas.				
	Is sampling of viable particles performed at the locations indicated on the plan?				
	Is sampling of nonviable particles performed at the locations indicated on the plan?				
	Question the person responsible for performing sampling. Is he or she knowledge about exposure time and sampling methods?				
	Examine microbiological results for three months preceding the audit.				
	Is the frequency of testing in conformance with the relevant SOP?				
	Were all tests performed as required by the SOP?				
	If not, is there a documented Justification for the Deviations.				
	Where results exceed the limits, was corrective action implemented according to the relevant SOP?				
	Were Micro-Organisms Identified?				
	What is the overall picture obtained of the state of Control of the facility?				
	Is a tracking system employed whereby high counts on a particular day initiate an investigation of batches filled on that day?				
	Examine the results for monitoring air changes from the last year.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Do they meet the specifications in the relevant SOP?				
	If not, is there Documented Evidence of Corrective Action?				
	Examine the year's results for testing Compressed Air and Nitrogen.				
	Do they meet the Specifications in the relevant SOP?				
	If not, is there documented evidence of corrective action?				
	Examine the results for monitoring air Velocities from the Last Year.				
	Do they meet the Specifications in the relevant SOP?				
	If not, is there documented evidence of corrective action?				
	Examine the results for Monitoring Air Flow Patterns from the last year.				
	Do they meet the specifications in the relevant SOP?				
	If not, is there documented evidence of Corrective Action?				
	Is Bioburden monitoring of Aseptic Solutions performed according to the frequency stated in the relevant SOP?				
	Are the results Satisfactory?				
	Examine the monitoring results for WFI from last year.				
	Do they meet the Specifications in the Relevant SOP?				
	If not, is there documented evidence of Corrective Action?				
	What is the overall picture of the microbial control of the System? _____ _____				
	Examine the monitoring results for pure steam from the last year.				
	Do they meet the Specifications in the relevant SOP?				
	If not, is there documented evidence of Corrective Action?				
8.	**EQUIPMENT VALIDATION**				
	Is there an approved annual program for the Validation of all Production Equipment and Critical System?				
	Is the Program adhered to and are the Validations performed on schedule?				
	Select three items (include at least one critical system) and examine the DQ/IQ/OQ/PQ.				
	Are the equipment items identified with distinguishing code number?				
	Is all critical instrumentation on the equipment/system identified with a calibration tag?				
	Physically verify that all instruments found on the equipment / system is included in the validation report.				
	Cross check with the calibration records that the instruments have same classification in the validation protocol as in the calibration report.				
	Are the validation reports complete and do they indicate the equipment or system is operating in a repeatable and reliable manner?				
	Are the validation reports approved by all appropriate personnel?				
	Are the reports completely and accurately filled out?				
	Are aseptic media fills performed according to the relevant SOP?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there documented evidence that all operators from all shifts have participated in successful media fills in the past year?				
	Examine media fill results for all fills performed in the past year. Review per product group, per filling room, and overall for the facility. Do the results indicate that the process is under control?				
	Where a media fill failure has occurred, is there documented evidence of corrective action according to the relevant SOP?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**PACKING**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Are a complete index and a complete set of applicable SOPs available in the Area?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Is the Obsolete documents removed from the Area?				
2.	**PERSONNEL**				
	Select three employees working in the Area. Are their training records up-to-date? **1. _____2. _____3. _____**				
	Have the employees undergone training in the following areas during the last year? • GMP • SOPs • Packaging techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP?				
	When necessary, do operators wear masks and gloves?				
3.	**FACILITIES**				
	Is the department maintained in a good state to repair?				
	Is the department neat and orderly with sufficient space for equipment and operations?				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is there adequate physical separation between different packaging lines to prevent mix-ups and/ or cross- contamination?				
	Are all parts of the line where product or primary packaging components are exposed covered to prevent accidental contamination of the product?				
	Is relative humidity control employed in areas where moisture sensitive drugs are packaged?				
	Examine the records for moisture –sensitive drug that was processed recently. Is the relative humidity recorded in the batch record?				
	Does the relative humidity conform to specifications?				
	Is there an area dedicated to the packaging of high-potency drugs?				
	Does any pest seen in the Department?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is precautionary activity done for Pest control? (Whether Fly-O-cide available)?				
4.	**CLEANING PROCEDURE**				
	Is there a written procedure for the cleaning of the packaging facility?				
	Is there documented evidence that the cleaning of packaging equipment?				
	Is there a written procedure for the cleaning of packaging equipment • Between batches of the same product? • Between batches of different products?				
	Is the procedure specific to a particular machine?				
	Does the procedure specify which parts of the machine must be disassembled for cleaning?				
	Examine the machine duty card for the product currently being filled. It is filled out with all the required information?				
5.	**LINE CLEARANCE PROCEDURES**				
	Watch personnel performing line clearance. Is each stage of the process performed by one individual and then independently verified by a second individual?				
	Examine the area prior to the introduction of packaging materials. Is it clean and free from any material from the previous batch?				
	Do the packaging materials arrive on a covered trolley?				
	Are all cartons of printed packaging materials on the trolley sealed?				
	Are packaging materials verified against a master set to ensure that they are the most recent edition and the correct materials for the batch?				
	Are the quantities of packaging materials verified against the amounts stated as dispensed from the warehouse?				
	Is the monitoring code (bar code, pinhole, etc.) for each of the packaging materials (label, insert and box) entered into the machine from the master set of materials?				
	Is this covered by a written procedure?				
	Is the monitoring code (bar code, pinhole etc.) challenged for each of the packaging materials by altering the code and running the material through the machine?				
	Is this covered by a written procedure?				
	Is the device for the detection of label presence challenged prior to the initiation of work?				
	Is the check required by as SOP?				
	Is the check documented in the batch record?				
	Is the device for the detection of the presence of over-printing challenged prior to the initiation of work?				
	Is the check required by as SOP?				
	Is the check documented in the batch record?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
6.	**MASTER PACKAGING MATERIALS FILE**				
	Is complete set of files available in the department with samples of packaging materials for each product packaged there?				
	Is there a procedure for maintaining and updating of these files?				
	Are all samples of printed packaging materials in the files signed and dated by a QA representative to indicate that they are the correct master materials?				
7.	**WORKING PROCEDURE**				
	Is there a procedure for the daily checking of balances used in the department?				
	Are there records to indicate that the procedure is being followed?				
	Is all instrumentation in the department labeled with a valid Calibration Label?				
	Are all product covered for product protection closed at all times during the packaging operation?				
	Are samples of all printed packaging materials used in the batch attached to the batch record?				
	Is there written procedure for the reconciliation of printed packaging materials?				
	Watch the reconciliation being made. Are remaining packaging materials accurately counted?				
	Are rejected packaging materials collected throughout the batch in a manner that permits accurate counting for reconciliation?				
	Is there a written procedure for cleaning and inspection the packaging area at the end of the batch?				
	Is the inspection documented in the batch record?				
	Is there written procedure for the issuance of additional packaging materials if the amount dispensed is not sufficient?				
	Does the procedure require • QA approval prior to the dispensing of the additional quantity? • QA verification of the materials against the master prior to use? • Is the procedure followed?				
	Is the batch yield calculated immediately upon completion of the packaging operation and prior to the introduction of a new batch into the area?				
	Is the yield calculation independently verified by second individual?				
	Are any excess overprinted packaging materials destroyed on completion of the batch?				
	Is there a written procedure for the destruction of printed packaging materials on completion of the batch or for their return to the warehouse?				
	Is it followed?				
	Is there a provision in the department for the separation of printed packaging materials for destruction and rejected product?				
8.	**PROCESS CONTROL**				
	Examine the records for the batch being processed. Are there written				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is the frequency of checks in accordance with the relevant SOP?				
	If the packaging operation continues over more than one shift, is there a written requirement for re-verification of all electronic controls?				
	Is this performed?				
	Is there a written procedure for the examination of packaged product during finishing operations to ensure correct labeling?				
	Is a representative sample of units collected at the end of the operation and visually examined for correct labeling?				
9.	**EQUIPMENT QUALIFICATION**				
	Is there an approved annual program for the qualification of all tableting equipment?				
	Select three equipment items and examine the DQ/IQ/OQ/PQ protocols				
	Are the equipment items identified with a distinguishing code number?				
	Is all critical instrumentation identified with a valid calibration tag?				
	Physically verify that all instruments found on the machine are included in the protocols?				
	Cross-check with the calibration records that the instruments have the same classification in the qualification protocol as in the calibration report.				
	Is all qualification reports completely and accurately filled in?				
10.	**LABELS**				
	Are the status labels affixed to all equipments?				
	Is the status labels duly signed by Production Officer?				
	Is the status board bears necessary information?				
11.	**DOCUMENTATION**				
	Are all daily documents filled correctly and timely?				
	Are the formats, logs are current?				
	Has all SOPs related with the Equipment or the process been displayed?				
	Is any obsolete copy seen in the department?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**HUMAN RESOURCE DEPARTMENT**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a Complete Index and a Complete Set of applicable SOPs available in the Section?				
	Are the Index and the SOPs current?				
	Is the set of SOPs correctly organized according to the Index?				
	Are the Obsolete documents removed from the Section?				
2.	**PERSONNEL**				
	Select three employees working in the Department. Are their Training Records available? Is the Training Index updated? **1. _____ 2. _____ 3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • HR Policies				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Is there SOP for Induction Training of New Entrants?				
3.	**EMPLOYMENT PROCEDURE**				
	What is the designation of the person conducting interviews? _____				
	Does list of persons working in the factory available?				
	Does all records of persons working in the factory segregated person wise?				
	Is their filing system satisfactory?				
	Is the person called for interview properly judged?				
	Do medical examination of new entrant perform?				
	Is the physician approved & qualified?				
	Does the medical examination test includes eye examination (Colour Blindness), Pathological Test (Blood & Urine Test), Chest 'X' Ray, VDRL, ECG				
	Does any Annual Medical Examination carried out?				
4.	**SECURITY**				
	Is the enough Staff available for Security?				
	Is each person monitored entering inside the company & while going outside?				
	Does any Camera System available to monitor Entry & Exit procedure?				
	Does any Match Box, Chewing, Cigarettes & Tobacco allowed inside factory premises?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Other than temporary & permanent employees, if any new person visits, how he is identified? _____				
	Is the procedure satisfactory?				
	Is the name of person visited been documented?				
	If the vehicle inside the factory premises has been checked while entry & exit?				
5.	**OTHERS**				
	Is there SOP for Cleaning of Company Shoes/Sleepers ?				
	Is it followed?				
	Is the shoe racks and Garment Cabinets available in the Change Rooms?				
	Is there SOP for Cleaning of Shoe Racks and Garment Cabinets?				
	Is it followed?				
	Is there SOP for Cleaning of Toilets and Wash Rooms?				
	Is it following?				
	Is there any written procedure for attendance?				
	Is there SOP for Scrap Management and its disposal procedure?				
	Is there an appropriate facility for emergency and medical treatment in case of any accident? Is the Ambulance available around the clock?				
6.	Is there written Leave Policy available?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**QUALITY CONTROL DEPARTMENT**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the department?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Obsolete documents removed from the Department.				
2.	**PERSONNEL**				
	Select three Employees working in the department. Are their training records up-to-date? **1._____2._____3._____**				
	Have the Employees undergone training in the following areas during the last year? • GLP • SOPs • Analytical techniques				
	Question Several Employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Have the Employees undergone Qualification according to the relevant SOP?				
	Are detailed, written job descriptions available for all Employees?				
3.	**FACILITIES**				
	Is the laboratory maintained in a good state of repair?				
	Is the laboratory neat and orderly with sufficient space for Equipment and Operations?				
	Is there evidence of good housekeeping?				
	Is the laboratory facilitated with safety equipments (i.e. Eye Shower, Body Shower, Safety Goggles etc) and gowns?				
4.	**INSTRUMENTATION AND CALIBRATION**				
	Is there an approved Preventative Maintenance Program for all Instruments used in the Laboratory?				
	Is there evidence that it is followed?				
	Is the program based on Manufacturer's Recommendations?				
	If not, is there a Documented Rationale for the Alteration of the Schedule?				
	Is there Documented Evidence that the person who performs the Preventative Maintenance is Qualified to do so?				
	Select three major Instruments used in the Laboratory.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point		Yes / No	1	2	3
	1) _____	**ID No.:** _____				
	2) _____	**ID No.:** _____				
	3) _____	**ID No.:** _____				
	Are there written Procedures for Operating the Instruments?					
	Is there SOP for Corrective Action in the event that an Instrument is found to be out of Calibration?					
	Are standards used to Calibrate an instrument, is there a written procedure for their Preparation?					
	Is there SOP for cleaning of Quality Control Glassware and Instruments?					
	Is the cleaning procedure validated?					
5.	**SAMPLE RECEIPT, STORAGE AND DOCUMENTATION**					
	Is a specific person responsible for the receipt of samples for testing?					
	Is there a written SOP describing sample receipt and recording (logging in)?					
	Where are samples stored before and after testing?					
	Are samples retained after testing is complete?					
	What happens to samples retained after testing and reporting are complete?					
	Is there a time limit on how long a sample may remain in the laboratory prior to testing?					
6.	**SAMPLING PROCEDURE**					
	Is there an SOP describing Sampling Operations, including a Sampling Plan?					
	Is the Sampler appropriately attired?					
	Is sampling performed as per SOP					
	Watch a Sampling Operation?					
	Is sampling activity recorded?					
	Is sampling equipment stored in a manner to prevent its contamination?					
7.	**TEST PROCEDURE**					
	Are there approved specifications available for all products, raw materials and packing materials?					
	Are there approved test procedures available for all tests performed in the Laboratory?					
	Is there a written procedure for ensuring that all Pharmacopoeial procedures are updated when a supplemental monograph is issued?					
8.	**REPEAT TESTING**					
	Is there an SOP for repeat testing • On the same sample? • On a new sample?					
	Does the SOP require supervisory intervention prior to repeating any test?					
	Does the SOP describe a procedure for Invalidating Results?					
	Does the procedure require a written explanation of the reason for the retest?					

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
9.	**EVALUATION / SUPERVISION OF RESULTS**				
	Is there an SOP for review of test data and Calculations?				
	Are raw data reviewed prior to release from the Laboratory by a person other than the analyst who performed the test?				
	Are notebooks routinely reviewed by a supervisor?				
	Do reviewers sign the Note Book to Indicate that it has been reviewed?				
10.	**REFERENCE AND WORKING STANDARDS**				
	Are they following the procedure of SOP for the Preparation and Handling of Reference and Working Standards?				
	Are the Reference and Working Standards are stored according to the Recommended Storage Conditions?				
	Do they maintain the record of Preparation, Storage and Destruction of Reference and Working Standards?				
11.	**OTHER**				
	Do they maintain the record of Stability Studies?				
	Do they maintain the record of Receipt, Issuance, Usage and Destruction of Columns?				
	Is the list of Authorized Person displayed on restricted entry?				
	Are the Status Labels affixed on Instruments?				
	Do they maintain the record of Preparation of Reagent Solutions?				
	Is there approved procedure for destruction of reagent solutions?				
	Is there written procedure or any agreement for perform tests from outside laboratory?				
	Is there any SOP for handling of Hazardous and Poisonous Chemicals?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST		
Audit Report No.:	**MICROBIOLOGY LABORATORY**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the Section?				
	Are the index and the SOPs Current?				
	Is the set of SOPs correctly organized according to the Index?				
	Is the Obsolete documents removed from the Department?				
2.	**PERSONNEL**				
	Select three Employees working in the Department. Are their training records up-to-date? **1._____2._____3._____**				
	Have the employees undergone training in the following areas during the last year? • GLP • SOPs • Microbiological Techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their Job Functions?				
	Are detailed, written job descriptions available for all Employees?				
3.	**FACILITIES**				
	Is the laboratory maintained in a good state of repair?				
	Is the laboratory neat and orderly with sufficient space for Equipment and Operations?				
	Is there evidence of Good Housekeeping?				
	Is the clean room maintained in a good state of repair?				
	Is there an SOP for the cleaning and disinfection of the Clean Room?				
	Is the Microbiological Section provided with an Air Locks and Laminar Flow				
	Are all Reagents and Solutions • Clearly labeled with their proper name. • Labeled with date of receipt and/or Expiration Date?				
	Are prepared solutions labeled with the ⇒ Name of Person who prepared them? ⇒ Date of Preparation ⇒ Expiration Date				
	Are there records of the Preparation of Disinfectants?				
	Are disinfectants labeled with Expiration Dates?				
	Are cleaning records available and correctly Filled Out?				
4.	**EQUIPMENT AND INSTRUMENTATION**				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there an Approved Preventative Maintenance Program for all Equipment used in the Laboratory?				
	Is there evidence that it is followed?				
	Select three pieces of Equipment used in the Laboratory.				
	Are there written procedures for operating the Equipment?				
	Is there a valid Calibration Sticker on each Instrument?				
	Are Temperature Recorders attached to all Incubators and Refrigerators?				
	Is there an approved SOP that requires the Routine checking and signing of Temperature Charts?				
	Is there an SOP defining cleaning and sanitization procedures for the incubators and Refrigerators?				
	Is there documented evidence that it is being followed?				
	Examine the most Recent Validation for the Autoclave.				
	Was the Validation performed on Schedule?				
	Do the results meet the Relevant Acceptance Criteria?				
5.	**SAMPLING RECEIPT, STORAGE AND DOCUMENTATION**				
	Is a specific person responsible for the receipt of samples for testing?				
	Is there a written SOP describing sample Receipt and Recording (logging in)?				
	Where are samples stored before and after Testing? _____				
	Are samples retained after testing is Complete?				
	What happens to samples retained after testing and Reporting are complete? _____				
	Is there a time limit on how long a sample may remain in the Laboratory prior to Testing?				
	Examine the contents of a Refrigerator and an Incubator.				
	Is the Equipment Clean?				
	Are all test samples recorded in the Laboratory Log Book?				
	Are all items clearly labeled?				
6.	**TEST PROCEDURE**				
	Are there approved test procedures available for all tests performed in the Laboratory?				
	Is there a written procedure for ensuring that all Pharmacopoeial Procedures are updated when a Supplemental Monograph is issued?				
	Are records available for the preparation of media used for performing the test?				
	Is the medium labeled with an Expiration date?				
	Is labeling in accordance with an approved SOP?				
7.	**RECORDING RESULTS**				
	Examine any analyst's Test Report.				
	Are any cross-outs initialed and dated?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are all calculations recorded?				
	Is there a statement in the Test Report as to whether or not the sample passes the test?				
	Is the analyst's signature recorded in the Test Report?				
8.	**STOCK CULTURES**				
	Is there an SOP for the receipt and Handling of Cultures?				
	Are cultures received with a certificate of analysis?				
	How often cultures are transferred? _____				
	Is there a maximum number of times cultures may be transferred?				
	Is it adhered to?				
9.	**REPEAT TESTING**				
	Is there an SOP for Repeat Testing • On the Same Sample? • On a New Sample?				
	Does The SOP Require Supervisory Intervention Prior To Repeating any Test?				
	Does the SOP describe a procedure for invalidating results?				
	Is periodic follow-up performed to assess how many retest are being performed?				
	Examine results of LAL Endotoxin Testing for the past six months.				
	Have any Retest been performed?				
	If yes, is an investigation report/invalidation of the first test available?				
	Examine investigation reports for any repeat sterility tests performed within the past year.				
10.	**EVALUATION / SUPERVISION OF RESULTS**				
	Is there an SOP for review of test data and calculations?				
	Are raw data reviewed prior to release from the laboratory by a person other than the analyst who performed the test?				
	Do reviewers sign the Test Report to indicate that it has been reviewed?				
11.	**ENVIRONMENTAL AND PERIODIC MONITORING (CLEAN ROOM)**				
	Is there an SOP for monitoring Differential Air Pressures?				
	Are there written records of air pressure checked and signed?				
	Is there an SOP for Environmental Monitoring in the Clean room?				
	Do results conform to the limit stated in the SOP?				
	When Out-of-Limit results were obtained, was Corrective Action implemented in accordance with SOP?				
	Examine records of monitoring for the Past Three Months.				
	Are there records of checking Laminar Airflow Velocities?				
	Are there records of checking Air Changes in the Area?				
12.	**CULTURE MEDIA**				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there SOP for Preparation, Issuance, Storage, Handling, Usage and Destruction of Culture Media?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**QUALITY ASSURANCE DEPARTMENT**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the department?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
2.	**PERSONNEL**				
	Select three employees working in the department. Are their training records up-to-date? **1. _____ 2. _____ 3. _____**				
	Have the employees undergone training in the following areas during the last year? • GMP / GLP • SOPs • Quality Assurance responsibilities				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP?				
	Is detailed, written job description available for all employees?				
	Is an up-to-date organizational chart of the Quality Assurance Department available?				
3.	**BATCH RECORD REVIEW**				
	Is there a SOP for batch record review prior to release?				
	Is there a comprehensive checklist for batch record review prior to release?				
	Is there a tracking procedure in place to ensure that a batch record with a deviation report attached to it cannot be released prior to the completion of any required investigation?				
	Examine recently released any one batch record from each section				
	Product : **Batch No.:**				
	Product : **Batch No.:**				
	Product : **Batch No.:**				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
4.	Are the records complete with respect to the following? • The master Batch records are signed as true copy. • Any changes to the Batch document are QA authorized prior to manufacturing. • All relevant signatures are present. • All relevant data are present • All relevant data are accurate. • Yield calculation at each stage of production conforms to the SOP. **1.** All calculations are verified by a second individual. **2.** Any deviations are justified, fully explained and authorized.				
5.	**DEVIATION REPORTS**				
	Select three deviation reports prepared within the last six months				
	Deviation No.:				
	Deviation No.:				
	Deviation No.:				
	Were the Deviations completed prior to release of the batch?				
	Does the relevant SOP require a written investigation and follow-up on implementation of recommendations?				
	If necessary, is there a fully documented investigation?				
	Have recommendations been made to prevent the deviation from recurring?				
	Have recommendations for corrective action been implemented?				
	Examine the daily deviation reports from the three months preceding the audit. Is there follow-up to ensure that each department sends in a report every day?				
	Select three reports at random. Are they filled out in accordance with the relevant SOP?				
	Review the monthly summaries of all deviations (not product specific) for the six months preceding the audit. Are there deviations that recur more than once?				
6.	**CHANGE CONTROL RECORDS**				
	Are all changes that may impact product quality authorized by Quality Assurance prior to implementation?				
	Examine three recent change control forms.				
	Have the forms been completed and the results evaluated prior to closing the forms?				
	Has all relevant documentation been updated? Verify that validation protocols have been revised where appropriate.				
7.	**ANNUAL PRODUCT REVIEW**				
	Examine any one product Annual Product Review completed.				
	Product : **Compilation Date :**				
	Does the review comment on any out-of-limit unusual results?				
	Does the review include No. of release batches?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Does the relevant SOP require that management be informed of problems identified during the review?				
	Is there a record of examination of reserve samples for the products reviewed? Were the samples found to be satisfactory?				
	Have recommended corrective actions been implemented?				
8.	**SELF-INSPECTION**				
	Is there a SOP that requires that self-inspection be performed in all departments?				
	Is self-inspection performed according to the frequency stated in the schedule?				
	Is there tracking system that all points raised during self inspection been compiled.				
	Do all personnel required by the SOP to participate in inspections actually do so ?				
	Are written reports available for all inspections performed during the past year?				
	Is there written evidence of corrective action implemented as a result of the inspections?				
9.	**COMPLAINTS**				
	Is there an SOP for dealing with complaints?				
	Examine three recent complaints files.				
	Product : **Batch No.:** **Product :** **Batch No.:** **Product :** **Batch No.:**				
	Does the summary of complaints available?				
	Have the files been investigated for the relevant personnel?				
	Could any of the above complaints for the year preceding the audit. Are there products that have several complaints and if so has appropriate action taken?				
	Examine the list of complaints for the year preceding the audit. Are there products that have several complaints and if so has appropriate corrective action been implemented?				
10.	**GOODS DESTRUCTION RECORDS**				
	Is there an SOP for destruction of • Product components and packaging materials? • Raw-material? • In-process material? • Finished product?				
	Examine the goods destruction records.				
	Is it identical to that in the warehouse?				
	Are all goods destruction forms QA approved prior to destruction or as per SOP?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there written evidence that the destruction order has been carried out?				
11.	**RELEASE OF BATCHES**				
	Is their an SOP for release of bathes?				
	What is the designation of the person doing batch release? _____				
	Is he qualified?				
	Is their an system to ensure that how many batches are to be released on one day?				
	Is there a written investigation, including conclusion and, if appropriate, follow-up action for each of the batches?				
12.	**REJECTED BATCHES**				
	Examine the list of rejected batches for the current year. Select three batches.				
	Product : **Batch No.:** **Product :** **Batch No.:** **Product :** **Batch No.:**				
	List the reason (s) for the rejection. **Product :** **Batch No.:** _____ _____ **Product :** **Batch No.:** _____ _____ **Product :** **Batch No.:** _____ _____				
	Specify at which stage of production the batches were rejected. **Product :** **Batch No.:** **Stage :** **Product :** **Batch No.:** **Stage:** **Product :** **Batch No.:** **Stage:**				
	Is there a written investigation, including conclusion as to the cause of the failure and, if appropriate, follow-up action for each of the batches?				
	Are there any products that have more than one rejected batch and, if so, has corrective action been recommended and implemented?				
13.	**RETURNED GOODS**				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there a written procedure for holding, testing and reprocessing returned drug products?				
	Examine the list of returned goods for the current year. Select three batches?				
	Product : **Batch No.:** **Product :** **Batch No.:** **Product :** **Batch No.:**				
	Is there a record for each batch, including the following details? • Name of Customer • Name and Strength of the Product • Batch Number • Reason for Return • Quantity Return • Date of Disposition • Ultimate Disposition				
	List the reason (s) for the return **Product :** **Batch No.:** **Reason:**_____ **Product :** **Batch No.:** **Reason:**_____ **Product :** **Batch No.:** **Reason:**_____				
	List the disposition of the returned goods. _____				
	Is the disposition adequately justified with a documented investigation and conclusions authorized by Quality Assurance?				
	Could the reason for any of the returns implicate other batches of the product and, if so, has an investigation been initiated and appropriate action taken?				
14.	**RECALLS**				
	Is there a written procedure for the recall of drug products that ensures that responsible officials of the firm are notified in writing of the recall?				
	Have there been any recalls during the current year?				
	Specify :				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	List the disposition of the recalled goods. _____ _____				
	Is the disposition adequately justified with a documented investigation and conclusions authorized by Quality Assurance?				
	Could the reason for the recall implicate other batches of the product and, if so, has an investigation been initiated and appropriate action taken?				
15.	**VALIDATION, REVALIDATION & CALIBRATION SYSTEMS**				
	Is there Validation Schedule available?				
	Is it followed?				
	Check the validations actually done against the Validation Schedule.				
	After a completion of three batches, does summary available for product?				
	Check the filing system of the filled validations? Is system satisfactory?				
	Select any one product & check the all validation related with it. Does any deficiency found?				
	Does all the results within specification?				
	Check the batch manufacturing record & validation reports of the same batches & check the in process observation. Do they comparable?				
	Do the list of Master validation protocol available?				
	Does all master validation protocol available? Duly authorized?				
16.	**CALIBRATION SYSTEMS**				
	Is SOP for Calibration Policy available?				
	Is there Calibration Schedule available? Duly authorized?				
	Is it followed?				
	Check the Calibration actually done against the Calibration Schedule.				
	Check the recording system of the filled Calibration record? Is system satisfactory?				
	Select any one Calibration Record. Does any deficiency or deviation found? Is it recorded?				
	Does all the results within specification?				
	Is current Calibration Status label with complete details affixed on respective Equipment / instruments?				
17.	**BATCH DOCUMENTS GENERATION SOFTWARE**				
	Does it only authorized to run for authorized personnel?				
	Does it accessed through password only?				
	Is the list of passwords available with QA Manager?				
	Are the BMR / BPR are of current version?				
	Is the backup of system taken daily?				
	Is the backup system found useful & recoverable?				
	Does the person properly trained, allowed to run the programme?				
	Does his training report available?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Does their any SOP stating that action to be taken in case of future of computer system?				
	Is the qualification & validation of computer system available?				
18.	**DOCUMENTATION**				
	Does following approved document available with the department?				
	Site Master File				
	Safety Manual				
	Quality Manual				
	Training Manual				
	Master Validation Plan				
	Organization Charts of all Departments				
	Layout of buildings & facilities				
	List of Qualified persons in all department				
	List of products				
	Job responsibilities of all individual working in QA				
	Job responsibilities of each Section Head / Department Head				
	Schedules (self inspection, Audit, Training, Observation rounds etc.)				
	Does the Retrieval system of the batch documents satisfactory? How it traceable is that document has been withdrawn & kept back?				
	Select any three batch No. from batch No. Register and check in the storage area. How much time is required for retrieval? (Time:)				
19.	**STABILITY STUDY**				
	Is SOP for Stability Study Policy available?				
	Is there Stability Study Schedule available? Duly authorized?				
	Select any one Stability Study Record. Does any deficiency or deviation found? Is it recorded?				
	Stability Study actually done against the Stability Study Schedule.				
	Check the recording system of the filled Stability Study record? Is system satisfactory?				
	Does all the results within specification?				
	If No, than proper investigation carried out.				
	Is SOP for Stability Chamber Management available?				
	Is it followed?				
	Check the samples in Chamber, is they are properly stored?				
	Is Temperature & RH record available?				
	Select one record; is it complete with respect to the frequency?				
	Is Status Label with complete details affixed on each sample?				
	Is SOP for Preventive Maintenance of Stability Chamber available?				
	Is there Preventive Maintenance Schedule available? Duly authorized?				
	Check the Preventive Maintenance actually done against the Schedule.				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Is there Calibration Schedule for instrument of stability chambers available? Duly authorized?				
	Check the Calibration actually done against the Calibration Schedule.				
	Select One Stability Chamber & Check Performance Qualification report. **ID No.:** **Stability Study Condition:**				
	Is it complete with respect to Approved Performance Qualification Protocol?				
	Is frequency of PQ followed?				
	Any deviation from predefined Acceptance Criteria? **Deviation No.:**				
	If yes, is it recorded & investigated?				
	Is SOP for transfer of stability sample available?				
	Is it followed?				
	Are all Persons trained according to their work?				
	Are Training records available?				
20.	**RISK MANAGEMENT**				
	Is SOP for Risk Management available?				
	Is the Risk Assessment conducted as per defined frequency?				
	Are Risk Assessment records available?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**SOP AND MASTER DOCUMENTS**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	Is there a SOP of role of Production, QC, QA, Engineering & Warehouse available?				
2.	Is there a system of Quality Assurance Department functions available?				
3.	Obsolete documents removed from the Department.				
4.	Is up-to-date organization chart of QA and Manufacturing Department available?				
5.	Is up-to-date document of list of product, list of Master Document available?				
6.	Is there a system of QA Document available?				
7.	Are the SOPs available for specific operation in stores, production, QC, engineering, safety and ETP ?				
8.	Is there an SOP available for preparation of SOP?				
9.	Is there SOP available for Documentation & Data Control?				
10.	Is there an SOP for Preparation, Approval and Authorization of Document available?				
11.	Is their any list of Quality Assurance Procedure available?				
12.	Is there an SOP for Sanitization and up keeping of premises?				
13.	Is there SOP for Training Programme for new entrant existing staff, workmen?				
14.	Are there any separate Batch No. Register for established Product, Product Development and Trial / F&D Batches available?				
15.	Is there an SOP for Numbering of Batch available?				
16.	Is there any system of Issuing Batch Document?				
17.	Is SOP for Management Review available?				
18.	Is SOP for Incident Reporting System available?				
19.	Is there an SOP for Vendor Selection Approval Programme Available?				
20.	Is the Vendor Audit conducted as per the Frequency?				
21.	Is detailed, Written Job Description available for all employees?				
22.	Is there a tracking procedure in place to ensure that a batch record with a Deviation Report attached to it cannot be released prior to the completion of any required investigation?				
23.	Is SOP for Pharmacopoeial Amendment & Guidelines Updates available?				
	Is it followed?				
	Check One Record, Is it satisfactory?				
24.	Is SOP for Qualification of Contract Analytical Laboratory available?				
	Is it followed?				
25.	Is SOP for Qualification of External Calibrating Agency available?				
	Is it followed?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**ENGINEERING DEPARTMENT**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Is a complete index and a complete set of applicable SOPs available in the department?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Obsolete documents removed the Department.				
2.	**PERSONNEL**				
	Select three employees working in the department. Are their training records up-to-date? **1.**_____ **2.**_____ **3.**_____				
	Have the employees undergone training in the following areas during the last year? • GMP • SOPs • Engineering techniques				
	Question several employees about the operations they are performing. Are they knowledgeable about their job functions?				
	Are all employees attired according to the appropriate gowning SOP?				
3.	**CALIBRATION RECORDS**				
	Is there an approved list of instrumentation included in the calibration program?				
	Is the instrument classification (critical, process control, reference) indicated on the list?				
	Is there an approved annual calibration planner?				
	Is there a tracking procedure in place to ensure that every instrument included in the program actually undergoes calibration on time?				
	Are there written SOPs describing in detail how to perform calibrations?				
	Is there a written procedure in place for informing the relevant QA and production personnel of instruments that have not undergone calibration according to schedule?				
	Are traceable calibration standards employed?				
	Traceable to which agency? _____				
	Are there certificates of calibration available for the standards?				
	Is there a written procedure for corrective action in the event that the calibration standard is found to be out-of-limits during re-calibration?				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Are the standard instruments stored in a manner that ensures their integrity and accuracy? Physically verify the storage and condition of three reference standard.				
	Examine the calibration history of three critical instruments.				
	Is there written evidence that the calibration standard used were within calibration?				
	Were the instruments calibrated according to the frequency indicated in the relevant SOP?				
	In the event that the frequency was not adhered to, is there written authorization from Quality Assurance?				
	Were the calibrations performed exactly as defined in the relevant procedure?				
	Are the formats completely and accurately filled in?				
	Were all the calibrations within the defined limits of accuracy?				
	If the calibrations were outside the limits, were QA and production personnel informed immediately in writing?				
4.	**PREVENTATIVE MAINTENANCE RECORDS**				
	Is there an approved annual preventative maintenance program?				
	Are there written procedure for preventative maintenance for all production equipment?				
	Select three equipment items and examine the preventative maintenance history?				
	Is there written evidence for each machine that the preventive maintenance was performed in accordance with the relevant SOP?				
5.	**BREAKDOWN MAINTENANCE RECORDS**				
	Is there a record of breakdown maintenance for each piece of production equipment?				
	Is there a procedure whereby breakdowns are analyzed so that, if appropriate, the preventative maintenance program is revised to prevent recurrence?				
6.	**LUBRICANTS**				
	Is there an approved list of food – Grade Lubricants for use where they may contact product?				
	Is there a written procedure for the receipt and approval of such lubricants?				
	Is a record made of the catalogue number of the lubricant used when maintenance is performed?				
7.	**EQUIPMENT QUALIFICATION**				
	Is there an approved annual program for the qualification of all production equipment?				
	Select three equipment items and examine the DQ/IQ/OQ/PQ protocols.				
	Physically verify that all instruments found on the equipment are included in the protocols.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Cross-check with the calibration records that the equipment items have the same classification the qualification protocol as in the calibration report.				
	Are the qualification reports approved by all appropriate personnel?				
	Are the reports completely and accurately filled out?				
8.	**DRAWINGS**				
	Is there a complete set of approved drawings for systems and equipment available in the department?				
	Select three equipment items/systems and examine the available drawings.				
	Are the drawings the latest edition?				
	Are the drawings QA approved?				
9.	**ALARMS PROCEDURES**				
	Is there an SOP for responding to alarms for critical systems?				
	Is there procedure followed?				
	Does the procedure require recording of the alarm and of the corrective action taken in response?				
10.	**RECEIPT OF NEW EQUIPMENT**				
	Is there an SOP describing the receipt and checking of new equipment prior to installation?				
	Is there documented evidence that the procedure is adhered to?				
	Does the SOP require checking of the equipment according to approved purchasing specifications?				
11.	**FILTER INTEGRITY TEST**				
	Is there an SOP for performing Filter Integrity Tests?				
	Is the procedure adhered to?				
	Examine records of the most recent tests performed.				
	Is there written evidence of corrective action in the event that a filter fails the test?				
	Was the Quality Assurance Department informed of the failure?				
	Is the report approved by the Quality Assurance Department?				
12.	**HVAC QUALIFICATION**				
	Is current version of AHU drawings display in service floor?				
	Are all AHUs Qualified?				
	Qualification Records are available?				
13.	**UTILITY**				
	SOPs of related Utility are display in the respective area?				
	Is the following utility System qualified?				
	Compressed Air				
	Steam (Raw / Pure) & Boiler				
	Nitrogen				
	DG / UPS				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Any other (Specify) _____ _____				
	Safety Measures & Safety Tools available & followed for:				
	Service Floor				
	DG Set Area				
	Boiler				
	Electrical Panel Area & Transformer				
	Diesel Storage area				
	Working at Height				
	Production & other areas				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

SELF INSPECTION CHECKLIST

Audit Report No.:	**OINTMENT, CREAM & GEL SECTION**	**Checklist No.:**

Point No.	Check Point	Yes / No	1	2	3
1.	**SOPs**				
	Are a Complete Index and a Complete Set of applicable SOPs available in the Section?				
	Are the index and the SOPs current?				
	Is the set of SOPs correctly organized according to the index?				
	Are Obsolete documents removed from Ointment Section?				
2.	**PERSONNEL**				
	Select three employees working in the Section. Are their Training Records available? Is the Training Index updated? **1. _____ 2. _____ 3._____**				
	Have the Employees undergone Training in the following areas during the last year? • GMP • SOPs • Manufacturing & Filling Techniques				
	Question several Employees about the Operations they are performing. Are they knowledgeable about their Job Functions?				
	Are all Employees attired according to the appropriate gowning SOP?				
3.	**FACILITIES**				
	Is the Section maintained in a good state of repair?				
	Is the Section neat and orderly with sufficient space for equipment and operations?				
	Is all Dispensed Raw Material for one batch kept on a pallet wrapped in a polythene				
	Examine the area at the end of a day's work. Is it left neat and tidy?				
	Are all work areas clearly labeled with the name and the batch number of the product being processed?				
	Is the Temperature and Relative Humidity maintained in the Area? **(Observed: Temp._____, Relative Humidity :_____)**				
	Does any Pest seen in the Section?				
	What is the Precautionary Activity done for Pest Control? (Whether Fly –O – cide available)				
4.	**PREVENTION OF CROSS-CONTAMINATION**				
	Are doors closed at all times?				
	Is personnel clothing clean, unstained and dust free, including shoes?				
	Are the Return Risers are cleaned during Product Change Over?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	What is the quality of the air in the Section (filter designation)? _____, _____				
	Is there cleaning SOP for slippers or shoes that is being used in the manufacturing area?				
5.	**EQUIPMENT AND FACILITY CLEANING**				
	Are Pallets and Drums brought into the area clean and free from Powder/Dust?				
	Is the Equipment neat, clean and rust free?				
	When not in use, is equipment covered so as to prevent accidental contamination?				
	Is Equipment suitably designed for its purpose?				
	Is Equipment constructed so that product contact surfaces are not reactive or absorptive, so that it will not contaminate or in any way affect the product being manufactured?				
	Select a Equipment: **Equipment Name:** **ID No.:** Examine the following records: * Machine Log Book * Qualification Documents * Cleaning Log Book * Relevant SOPs (Cleaning, Operation & Preventative Maintenance SOPs)				
	Select one batch recorded on the Machine Log Book and thoroughly check that Batch Record. **B. No.:**_____				
	Is the Cleaning Checklist for the Equipment completed? Does the checklist describe machine disassembly and assembly for cleaning procedure?				
	Is the cleaning correctly recorded on the Area Cleaning Record?				
	Visually inspect one machine that is not in use				
	Is it labeled with respect to its cleanliness status?				
	Is it clean?				
	Do Cleaning Procedures include a requirement for the cleaning of small items (e.g., portable computers, balances, etc.)?				
	Do Cleaning Procedures specify the cleaning agent and concentration to be used?				
	Is the Cleaning Agent available in the Section identical to those listed in the cleaning procedures?				
	Is the Cleaning Agent labeled with a catalogue number indicating that they were received through the Warehouse?				
	Are the records of Cleaning Agent Preparation?				
	Is there an Approved Protocol for the Cleaning Validation of Equipment used in Manufacturing and Filling Machine?				
	Is there documented evidence that it is being followed?				
6.	**WORKING PROCEDURES**				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Examine the record of the daily & fortnightly calibrations & check of balances in the Section.				
	Is it complete and accurately filled out?				
	Are all results within the Specifications?				
	If not, is there a record of the implementation of Corrective Action?				
	Perform a visual examination of the weights with which the check is performed.				
	Are they in a good state of repair?				
	Are they clean?				
	Do they bear a valid Calibration Seal?				
	Examine the Batch Record for a batch that is being processed. **Product :** _____ **Batch No.:** _____				
	Is the Master Batch Manufacturing Record signed as being an accurate copy of the original?				
	Is the record completely and accurately filled out up to the appropriate stage of processing?				
	Is the speed of filling recorded in the batch documents?				
	Does the filling speed conform to the required parameters?				
	Do yield calculations after Bulk Manufacturing and Filling and Sealing, Conform with the relevant Batch Records?				
	Has BMR been completed and an investigation conducted. If any?				
	Is the yield verified by a Second Person?				
	Are they correctly labeled?				
	Is there an SOP for monitoring of Fill Volume / Weight during production?				
	Is it followed?				
	Is there an SOP for Inspection of filled Tubes / Jar / Bottle?				
	Is it followed?				
7.	**INPROCESS CONTROL**				
	Is there an approved SOP for In-Process Control?				
	Does the SOP state at what frequency tests must be performed by Production officer/Executive and QA Officer/Executive?				
	Examine a batch record. Is the test frequency adhered to?				
	Do all test results conform to Specifications?				
	Is the SOP specific with regard to corrective action in the event that results do not conform to specifications?				
	Are there printouts available for in-process test results labeled with the • Product Name • Batch Number • Date and Time of Testing?				

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Point No.	Check Point	Yes / No	1	2	3
	Examine the Recorded Results? • Do the recorded results conform to the approved product Specification? • Do the recorded data match the attached printouts? • Are the results recorded in the correct units stated on the form?				
	Is there an SOP for collecting a composite sample for final testing by Quality Control?				
	Is the SOP followed?				
	Is all testing instruments labeled with a valid Calibration Tag?				
8.	**EQUIPMENT QUALIFICATION**				
	Is there an approved schedule program for the qualification of all equipments?				
	Select one machine and examine the DQ/IQ/OQ/PQ protocol. **Machine :** _____				
	Is the Machine Identified with a Distinguishing Code Number?				
	Are all critical Instrumentation / Equipment identified with a valid Calibration tag?				
	Physically verify that all instruments found on the machine are included in the protocol.				
	Cross-check with the Calibration Records that the Instruments have the same Classification in the Qualification Protocol as in the Calibration Report.				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-V

SELF AUDIT NON-CONFORMANCE & COMPLIANCE REPORT

Audit Report No.:	**Department Audited:**	**Date of Audit:**	**Plant:**

S. No.	**Details of Non – Conformance** (To be filled by Lead Auditor)	**Category (C/M/N)***	**Corrective and Preventive Action Plan** (To be filled by Auditee Department)	**Proposed Date of Compliance**	**Actual Date of Compliance**	**Compliance Verified By CQA (Sign & Date)**

* **C** = Critical, **M** = Major, **N** = Minor

Closing Comments (By Head CQA): _____

Lead Auditor	**Head – Auditee**	**Audit Compliance Closed By (Head – CQA)**
Sign : **Date:**	**Sign :** **Date :**	**Sign:** **Date:**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Self Inspection	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-VI

SELF INSPECTION LOG BOOK

Plant: **Year:**

S. No.	Audit Report No.	Department Inspected	Self Inspection Date	Inspection Report send to Auditee Department on	Sent By	Received By Auditee	Inspection Report received by CQA after Corrective and Preventive Action on	Received By Sign & Date	Compliance Verified By CQA (Sign & Date)	Closed By Head CQA (Sign & Date)	Remarks