DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Procedure for Self Inspection	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for self-inspection.

2.0 SCOPE:

This SOP is applicable to the self-inspection that is carried out on a periodic basis at …….

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3.0 RESPONSIBILITY:

Executive – Quality Assurance

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Head–QA shall plan the self-inspection for each department once in six months. The schedule of activities for the inspection shall be prepared and circulated to inspection team members along with the dates of the inspection and department head.

5.2 Self-Inspection plan shall be prepared as per Annexure–V.

5.3 Head–QA shall select competent persons for self–inspection cross-functional team from different department with due consideration of technical competency of the person.

5.4. Only HOD or second line managers shall be selected in inspection team.

5.5 Head QA shall also appoint the leader of the audit team.

5.6 The competent self-inspection team shall inspect following departments.

Production, Quality Control, R.M./P.M. Stores, Finished goods stores, Utility, Personnel & Administration and Quality Assurance.

5.7 List of areas to be covered during self inspections

a. Organization and personnel.
b. Building and facilities.
c. Equipment.
d. Control components and drug product containers and closures.

e. Production and process control.
f. Packaging and labeling controls.
g. Holding and distribution.
h. Laboratory controls.
i. Records and reports.
j. Returned and salvaged drug products
k. Any other area determined by Head – QA.

5.8 Self-inspection program shall be conducted in order to monitor the implementation and compliance with current good manufacturing practices and to ensure that necessary corrective actions are taken.

5.9 Self –inspection team shall first review results of previous self-inspection and corrective action taken.

5.10 Self-inspections shall be carried out with help of checklist as per Annexure –IV for each department.

5.11 Checklist is only a guidance document but the inspection may not be limited to verification of issuances listed in checklist.

5.12 A self-inspection report shall be prepared as per Annexure –I and intimated to the respective department, which are observed during self-inspection within a week of inspection.

5.13 HOD of the auditee department shall prepare a corrective action report covering the action taken and or planned with target completion date and shall forwarded to Quality Assurance department.

5.14 Planned corrective action taken by the concerned department shall be verified by the self-inspection team members/QA, in the corrective action report. Any remarks given by team members will be recorded.

5.15 Follow up audit, if required shall be conducted by self-inspection team members / Quality Assurance to verify the corrective actions taken, for the compliance, by the concerned department. QA head shall review the corrective action report and follow up report and close the self-inspection.

5.16 Quality Assurance department shall organize training programme if identified during

the self-inspection.

5.17 The Self Inspection records shall be preserved and referred for implementing changes in the systems and procedures.

5.18 The reports of the self-inspection shall remain with the QA department.

5.19 Self-inspection shall be carried out is an independent, unbiased and detailed way by self-inspection team.

5.20 Based on requirement, help of external experts shall also be taken for self-inspection. The decision in these regards shall be taken by Head – QA.

5.21 Apart from planned self-inspection, additional inspection shall also be conducted in case of major non-conformance, product failure and before major external inspector as decided by Head QA.

6.0 ABBREVIATION(S):

P M : Packing Material

Q A : Quality Assurance

R M : Raw Material

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

ANNEXURE – I : Self-inspection Report

ANNEXURE –II : Self Inspection Corrective action Report

ANNEXURE –III : Self Inspection Follow up report.

ANNEXURE –IV : Self inspection audit check list

ANNEXURE –V: Schedule for self-inspection.

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9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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Annexure I

Self-inspection Report

Self-inspection Report No. **:** **Date of Inspection**

Department inspected (with sections) **:** **Inspection team members**

S.No.	OBSERVATIONS

Self-inspection team members (Sign/Date):

Leader of the team (Sign/Date):

Quality Assurance (Sign/Date):

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Annexure II

Self Inspection Corrective action Report

Self-inspection Report No. _____ **Date of Inspection:** _____

Department (Audited): _____ **Inspection team members:** _____

S.No.	Observations	Corrective action Taken/Planned	Target Completion Date	Responsibility	Remark

Department Head

Signature/Date

Review of the Corrective action report:

Self-Inspection Team members

Signature/Date

Whether follow up inspection required: Yes / No

If Yes, Date of Follow up Audit:

Reviewed by Head –QA

Sign/Date

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Annexure III

Self Inspection Follow up report

Report No. **Date of Inspection:**

Department (Audited) **Inspection team members:**

S. No.	Observations of Self inspection report	Corrective action Taken	Remarks

(Detail report can be attached

Signature of Self-Inspection Team members : Date:

Whether follow up inspection further required : Yes/No

If Yes, Date of Follow up Audit :

Reviewed and closed by

Head -QA : Date:

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Annexure IV

Self inspection audit check list

Self Inspection Audit Check List	
PRODUCTION	
Area	
Auditor	
Auditee	
Date	

S.No.	Description	Yes	No	Remarks
1.0	**Cleaning:** Do you have written procedures that describe in sufficient details the cleaning schedule, methods, equipment and material? Check for procedure compliance			
1.1	Do you have written procedures for the safe and correct use of cleaning and sanitizing agents? What are the sanitizing agents used in this plant?			
1.2	Is each idle piece of equipment clearly marked “under cleaning” ready for use”, under maintenance?			
1.3	Is equipment cleaned promptly after use?			
1.4	Do cleaning instructions include disassembly and drainage procedure, if required to ensure that no cleaning solutions or rinse remains in the equipment?			
1.5	Has a written schedule been established and is it followed for cleaning of equipment?			
1.6	Has the cleaning procedure been properly validated?			
1.7	Is clean equipment clearly identified as “cleaned” with a cleaning date shown on the equipment			
1.8	Is clean equipment adequately protected against contamination prior to use? What sort of protection?			

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S.No.	Description	Yes	No	Remarks
1.9	Is equipment inspected immediately prior to use?			
1.10	Are written records maintained on equipment cleaning, sanitizing and maintenance on or near each piece of equipment?			
1.11	Is sewage, trash and other reuse disposed off in a safe and sanitary manner (and with sufficient frequency)			
2.0	**Operation:** Are machine surfaces that contact materials or finished goods, non- – reactive, non-absorptive and non- – additive so as not to affect the product?			
2.1	Are fibers releasing filters used in the production of injectable products?			
2.2	If air filters are used is there a written procedure specifying the frequency of inspection and replacement?			
2.3	Are drains and routine cleaning procedures sufficient to prevent stagnant water inside the facility?			
2.4	Are written procedures available for each piece of equipment used in the manufacturing, processing? Check for SOP compliance. Check the list of equipment and equipment details.			
2.5	Are all piece of equipment clearly identified with easily visible markings? Check the equipment nos. corresponds to an entry in an log book.			
2.6	Does each piece of equipment have written instructions for maintenance that includes a schedule for maintenance?			
2.7	Does the process control address all issues to ensure identity, strength, quality and purity or product?			
2.8	Is access to the facility restricted?			

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S.No.	Description	Yes	No	Remarks
2.9	Describe how entry is monitored / restricted?			
2.10	Are all weighing and measuring performed by one qualified person and checked by a second person Check the weighing balance record			
2.11	Check the calibration labels for instrument calibration status			
3.0	**Outside the processing area:** Is this plant free from infestation by rodents, birds, insects and vermin?			
3.1	Do you have written procedures for the safe use of suitable rodenticides, insecticides, fungicides and fumigating agent? Check the corresponding records.			
4.0	**Documentation:** Do records have doer & checker signatures? Check the timings, pH , yield and temperature in the batch production record.			
4.1	Is each batch assigned a distinctive code, so that material can be traced through manufacturing and distribution? Check for Inprocess analytical reports			
4.2	Check for area activity record			
4.3	Check for pH meter calibration record			
4.4	Check for equipment usage record			
4.5	Do written procedures identify steps for reprocessing batches?			
4.6	Check for product manual.			
4.7	Check for general equipment details and accessory details.			
4.8	Check for equipment layout with man & material movement			
4.9	Air handling system qualification, cleaning details and DOP test reports			
4.10	Water system in the plant. Check for purified water hose pipe status and water hold up.			

S.No.	Description	Yes	No	Remarks
4.11	Check for training records			

Self Inspection Audit Check List	
Quality System	
Area	
Auditor	
Auditee	
Date	

S.No.	Description	Yes	No	Remarks
1.0	Does the QA unit have a person specifically charged with the responsibility of designing, revising and obtaining approval for production and testing procedures, forms and records?			
1.1	Does a written SOP, which identifies how the form is to be completed and who signs and countersigns, exist for each record or form?			
1.2	Is the production batch record and release test results reviewed for accuracy and completeness before a batch of finished product is released?			
1.3	Does a formal auditing function exist in the QA department?			

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S.No.	Description	Yes	No	Remarks
1.4	Does a written SOP specify who shall conduct audit and qualifications (education, training and experience) for those who conduct audits?			
1.5	Does a written SOP specify the scope and frequency of audits and how such audits are to be documented?			
1.6	Does a written SOP specify the distribution of the audit report?			
1.7	Are vendors periodically inspected according to a written procedure?			
1.8	Is the procedure for confirming vendor test results written and followed?			
1.9	Does a written procedure identify the steps required for product recall?			
1.10	Are complaints, whether received in oral or written form, documented in writing retained in a designated file? (Customer complaint register and its related documents)			
1.11	Are complaints reviewed on a timely basis by the quality control unit?			
1.12	Is the action taken in response to each complaint documented?			
1.13	Are decisions not to investigate a complaint also documented and the name of the responsible person documented?			
1.14	Are complaint investigations documented and do they include investigation steps, findings and follow up steps, if required? Are dates included for each entry?			
1.15	Check for Document control system			
1.16	Check for annual product review			
1.17	Check for trend on finished product quality attributes			
1.18	Check for validation documents – Cleaning and process validation			
1.19	Check for batch release system			

S.No.	Description	Yes	No	Remarks
1.20	Check for vendor samples evaluation			
1.21	Check for Change control system			
1.22	Check for Batch Production Record review system and record.			
1.23	Do you have written procedures for approval/rejections of raw materials, intermediates, finished products, packing and packaging materials?			
1.24	Is each batch assigned a distinctive code, so material can be traced through analysis?			
1.25	Does inspection start with visual examination for appropriate labeling, signs of damage or contamination?			
1.26	Is the number of representative samples taken from a container or batch based on statistical criteria and experience with each type of material?			
1.27	Is the sampling technique written and followed for each type of material?			
1.28	Is the quantity of samples collected sufficient for analysis and reserve in case re testing or verification is required?			
1.29	Is containers are cleaned before samples are removed?			
1.30	Are stratified samples composited for analysis?			

S.No.	Description	Yes	No	Remarks
1.31	Containers from which samples have been taken are so marked indicating date and approximate amount taken			
1.32	Each sample container is clearly identified by material?			
1.33	Are in- process materials tested at appropriate phases for identity, strength, quality, and purity and are they approved or rejected by Quality control?			
1.34	Are there laboratory controls including sampling and testing procedures to assure conformance of containers, closures in process materials and finished product specifications.?			
1.35	Are quality control review and approval required for any and all reprocessing of materials?			
1.36	Does quality control review such reprocessed returned goods and test such materials for conformance to specifications before releasing such material for release?			
1.37	Has the each product been tested for stability on a written protocol?			
1.38	Are written sampling and testing procedures and acceptance criteria available for each product?			
1.39	As sterility and pyrogen testing performed as required?			
1.40	Are specific tests for foreign particles done?			
1.41	Check for the compliance of standard operating procedure			

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S.No.	Description	Yes	No	Remarks
1.42	Are working standards prepared as per the protocol? Check for its storage condition			
1.43	Is reference standard kept under proper storage condition.?			
1.44	Check for department organization chart and job responsibility.			
1.45	Check for method validation			
1.46	Check for personnel validation document			
1.47	Check for compliance of stability data and its summary			
1.48	Approved label, marketing label and sampled by label re conciliation record			
1.49	Do you have written procedure for calibration of instruments? Check for its record and corresponding labels.			
1.50	Is OOS investigation carried out for failures? Check for compliance of OOS system against the system			
1.51	Check for Analytical Data Sheet			
1.52	Check for thermometer, instrument calibration procedure and record.			

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Area	
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Auditee	
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1.1	Responsibilities and Authority - Are the QA/QC organization's authority and responsibilities clearly defined in writing?			
1.2	**Does QA have authority to review and approve or reject:** Procedures and specifications? Process changes impacting on the identity, quality and purity of the material? Raw materials, packaging materials, in-process materials, and product batches? New suppliers or subcontractors?			
1.3	**Does QA assure that manufacturing and testing records are reviewed before batches are released for sale?**			
1.4	Is there an adequate system for reviewing and implementing compendial (e.g., USP) changes?			
1.5	Is there an adequate program for handling complaints, including investigation to determine the causes, corrective actions, verification of the effectiveness of corrective actions, a target time frame for responding; trend analysis, and notification of appropriate parties including management?			
1.6	Is there an adequate system, described in an SOP, for controlling changes within the production process, including review and approval of changes to processes, documents, and equipment?			
1.7	Is QA involved in the change control process?			

S.No.	Description	Yes	No	Remarks
1.8	Is a log maintained for changes to processes, materials, and methods?			
1.9	Audit programs - Is there an internal quality audit program that covers all areas of the operation to verify that SOPs and other procedures and policies are being followed, and to determine effectiveness of the quality systems?			
1.10	Based on the audit findings and recommendations, are steps taken to correct any areas of noncompliance? Are corrective actions documented? Is their effectiveness verified in subsequent audits?			
1.11	If any contractors (e.g., laboratories, packagers) are used, are they periodically audited and is their performance monitored?			
1.12	Investigation of Non-conformances - Is there an SOP for investigation of manufacturing deviations and batch failures to determine the cause and institute corrective actions to prevent the situation from recurring?			

S.No.	Description	Yes	No	Remarks
1.13	Is there an SOP for determining the disposition of in-process and final material that fails to meet specifications (e.g., reprocessing, downgrading to a lesser grade, destruction)?			
1.14	Are records maintained of nonconforming materials, related investigations and corrective actions?			
1.15	For active ingredients, is there an SOP for investigation of out-of-specification (OOS) test results to assure that a uniform procedure is followed to determine why the OOS result occurred and that corrective actions are implemented?			
1.16	Raw Material control - Is a list of acceptable suppliers maintained and are incoming raw materials checked against it?			
1.18	Are statistical sampling plans used to assure that the samples are representative of the lot?			
1.19	Are sampled containers labeled with sampler's name and date of sampling?			
1.20	Are there complete written instructions for testing and approving raw materials, including methods, equipment, operating parameters, acceptance specifications?			
1.21	Are raw materials approved before being used in production? Are appropriate controls exercised to assure that they are not used in a batch prior to release by Quality Control?			

S.No.	Description	Yes	No	Remarks
1.22	If raw materials are accepted on certificates of analysis, have suppliers been appropriately certified or qualified, have results on the COA been verified by in-house testing, and is periodic monitoring performed?			
1.23	If raw materials are accepted on certificates of analysis, is at least an identification test performed (where safe) on every batch and receipt?			
1.24	Is there an effective system for monitoring and retesting or re-evaluating stored raw materials to assure that they are not used beyond their recommended use date?			
1.25	If fresh and recovered solvents are commingled, are the recovered solvents sampled and assayed and found to be satisfactory prior to commingling, and is the quality of commingled solvents monitored on an established schedule?			
1.26	Are there chemical and microbial quality standards for process water, with an established monitoring program? If water is used in the process, is it at least potable water?			
1.27	In-process testing - Are there complete written instructions for testing and approving in-process materials, including methods, equipment, operating parameters, acceptance specifications?			

S.No.	Description	Yes	No	Remarks
1.28	If operators perform in-process testing, have they been trained and was the training documented? Does QC periodically verify their results?			
1.29	Final product control - Is every batch sampled according to a plan that assures that the sample is representative of the batch?			
1.30	When and where is the finished product sampled for release?			
1.31	Is every product batch tested and approved before shipment?			
1.32	Are there complete written instructions for testing and releasing final product, including methods, equipment, operating parameters, and acceptance specifications?			
1.33	If the final product is compendial (e.g., USP / EP / JP), are the tests and specifications compendial or are additional tests performed? List additional tests.			
1.34	If additional tests are performed, are they included on the certificate of analysis (COA)?			
1.35	If skip lot testing is done, does the COA clearly indicate which tests are performed on every lot and which are critical via skip lot testing?			

S.No.	Description	Yes	No	Remarks
1.35	Have non-compendial methods been validated, including accuracy, linearity, specificity, ruggedness, and comparison with compendial methods, OR have compendial methods been verified to function properly in the company's laboratory?			
1.36	Is the stability protocol available?			
1.37	Are these stability chambers available to carryout stability of the product at 25°C / 60% RH 30°C / 60% RH 40°C / 75% RH			
1.38	Do these stability study ovens comply with respect to 21 CFR Part-11?			
1.39	Do you keep both hard copy and electronic copy of temperature/Rh monitoring?			
1.40	Are the stability results reviewed by a qualified, experienced person?			
1.41	Is stability study in primary pack done for different products?			
1.42	Laboratories - Do laboratories have adequate space and are they clean and orderly, with appropriate equipment for required tests?			
1.43	Are calibrated instruments labeled with date calibrated and date next calibration is due?			
1.44	Are daily or weekly calibration verifications performed on analytical balances using a range of weights (high, middle, low) based on the operating range of the balance?			

S.No.	Description	Yes	No	Remarks
1.45	Are appropriate reference standards used and are they stored in a proper manner to ensure stability? Are their expiration dates adequately monitored so they are not used beyond the expiration dates?			
1.46	Are reagents and microbiological media adequately controlled and monitored to assure that they are periodically replaced and that old reagents are not used?			
1.47	Are all containers of materials or solutions adequately labeled to determine identity and dates of preparation and expiration (if applicable)?			
1.48	Are data recorded in notebooks or on pre-numbered sheets, including appropriate cross-reference to the location of relevant spectra and chromatograms? Are equipment ID numbers recorded for each analysis?			
1.49	Are data and calculations checked by a second person and countersigned?			

S.No.	Description	Yes	No	Remarks
1.50	**Microbiological Laboratories** Are positive and negative controls used for testing? Are their results recorded? Is growth support testing with low levels of organisms performed on all incoming media lots and is it documented? Is an expiration date assigned to prepared media and are prepared media stored at manufacturers' recommended storage temperatures? Are isolates from microbiological testing identified if appropriate? Is each lot of microbial ID systems checked with positive and negative controls?			

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Engineering	
Area	
Auditor	
Auditee	
Date	

S.No.	Description	Yes	No	Remarks
1.0	Equipment-Construction, Installation, **Qualification**			
1.1	Is there an SOP for qualifying new or significantly changed equipment?			
1.2	Is equipment dedicated to the process?			
1.3	If equipment is not dedicated, what other materials are manufactured in the same equipment?			

S.No.	Description	Yes	No	Remarks
1.4	Is equipment of suitable type and size for intended use? Is it constructed so that product-contact surfaces are not reactive, additive, or absorptive and will not adversely affect the product?			
1.5	Is equipment designed to preclude adulteration of product with lubricants, coolants, fuel, metal fragments, or other extraneous materials?			
1.6	Are holding, conveying and manufacturing systems designed and constructed so as to allow them to be maintained in a sanitary condition?			
1.7	Is equipment installed with sufficient clearance to allow access to both the equipment and the surrounding area for cleaning and maintenance operations?			
1.8	Are freezers and cold rooms equipped with thermometers or other temperature sensing devices / recorders, and with automatic temperature controls and automatic alarms?			
1.9	Is equipment operated in a manner that will prevent contamination and cross-contamination and will ensure product integrity?			

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1.10	**Are written procedures available for:** Set-up of equipment Maintenance of equipment Cleaning of equipment Calibration of manufacturing equipment Calibration of control instruments			
1.11	**Are records kept for:** The sequence of products manufactured on particular equipment Maintenance and cleaning logs Calibration of manufacturing equipment Calibration of control instruments			
1.12	**Maintenance and Calibration**			
	Is there a master list of all equipment that specifies those requiring maintenance and/or calibration?			
1.13	Are there SOPs for inspection (monitoring the condition) and maintenance of equipment and of measuring and testing instruments? Do SOPs assign responsibilities; include schedules; describe methods, equipment, and materials to be used; and require maintenance of records?			
1.14	If equipment and instruments malfunction or are determined to be defective, are they immediately taken out of use?			
1.15	If water is purified for use in the process, is the purification system periodically sanitized and appropriately maintained?			

S.No.	Description	Yes	No	Remarks
1.16	Are there SOPs for calibration of critical equipment, and measuring and testing instruments? b) Do SOPs assign responsibilities; include schedules; describe methods; equipment, and materials to be used, including calibration over actual range of use and standards traceable to national standards; and include specifications and tolerances?			
1.17	If calibration operations are performed in-house, do SOPs specify proper handling and storage conditions for the traceable standards?			
1.18	Does a SOP specify that equipment cannot be used if it is beyond the calibration due date, and describe actions to be taken if equipment is used that is found to have been beyond the due date or is found to be out of calibration time?			
1.19	Is calibrated equipment labeled with date of calibration and date next calibration is due?			
1.20	Is equipment in use observed to be within calibration dating?			
1.21	Are periodic verifications performed on critical production scales (e.g., for raw material dispensing or portable scales) to assure that they remain within calibration in the time between full calibrations?			
1.22	Are records maintained for maintenance and calibration operations?			
2.0	**Equipment cleaning**			

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S.No.	Description	Yes	No	Remarks
2.1	Are there written procedures for cleaning, specifying cleaning agents and methods?			
2.2	Are there data to show that cleaning procedures for non-dedicated equipment are adequate to remove the previous materials? For active ingredients, have these procedures been validated?			
2.3	Are there data to show that the residues left by the cleaning and/or sanitizing agent are within acceptable limits when cleaning is performed in accordance with the approved method?			
2.4	Are seams on product-contact surfaces smooth and properly maintained to minimize accumulation of product, dirt, and organic matter and to avoid growth of microorganisms?			
2.5	Is there adequate system to assure that unclean equipment and utensils are not used (e.g., labeling with clean status)?			
2.6	Is there proper storage of cleaned equipment so as to prevent contamination?			
2.7	Are utensils and sampling devices cleaned and stored in a proper manner to prevent contamination?			
3.0	**Building Facility**			
3.1	Check the all piping properly painted with colour code.			
3.2	Check all piping to check for air / water / steam leakages if any.			
3.3	Check the hot and cold lines / surfaces properly insulated.			
3.4	Check any cracks in wall and updating wall painting.			

S.No.	Description	Yes	No	Remarks
3.5	All doors and its door closer to function properly.			
3.6	Check all the toilets, bathrooms valves and flush.			

Self Inspection Audit Check List	
Engineering	
Area	
Auditor	
Auditee	
Date	

S.No.	Description	Yes	No	Remarks
1.0	Is there a potential for contamination or cross-contamination from any sources? If so, how it is controlled / prevented?			
1.2	Are critical process parameters monitored and recorded?			
1.3	Is the identity of major equipment and lines recorded in the batch manufacturing record?			
1.4	Are there complete written master manufacturing instructions that specify formula, names and codes of raw materials, equipment, manufacturing flow, operating parameters, in-process sampling, packaging materials, labeling, and documentation of each significant step?			
1.5	Are any unplanned process changes (process excursions) documented in the batch record?			

S.No.	Description	Yes	No	Remarks
1.6	Are there written instructions describing how to use in-process data to control the process?			
1.7	If the product is blended, are there blending parameters and/or homogeneity specifications?			
1.8	Are materials and equipment clearly labeled as to identity and, if appropriate, stage of manufacture?			
1.9	Is a list of acceptable suppliers maintained and are incoming raw materials checked against it?			
1.10	Are statistical sampling plans used to assure that the samples are representative of the lot?			
1.11	**Are sampled containers labeled with sampler's name and date of sampling?**			
1.12	**If raw materials are accepted on certificates of analysis, is at least an identification test performed (where safe) on every batch and receipt?**			
1.13	**Are there complete written instructions for testing and approving raw materials, including methods, equipment, operating parameters, acceptance specifications?**			

S.No.	Description	Yes	No	Remarks
1.14	**Packaging and Labeling** Is there documentation to support to the use of the container/closure system, demonstrating that it is adequate to protect product from deterioration and contamination? Is there an SOP for receiving, handling, storing, and accountability of pre-printed labels? Is there a written procedure for clearing the packaging area after one packaging operation, and cleaning before the next operation, especially if the area is used for packaging different materials?			
	If filled unlabeled containers are set aside for future labeling, is there sufficient identification to determine name, strength, quantity, lot number, and other information needed for tractability?			
1.15	**Are raw materials approved before being used in production?** **Are appropriate controls exercised to assure that they are not used in a batch prior to release by Quality Control?**			
1.16	If raw materials are accepted on certificates of analysis, have suppliers been appropriately certified or qualified, have results on the COA been verified by in-house testing, and is periodic monitoring performed?			

S.No.	Description	Yes	No	Remarks
1.17	**Is there an effective system for monitoring and retesting or re-evaluating stored raw materials to assure that they are not used beyond their recommended use date?**			
1.18	If fresh and recovered solvents are commingled, are the recovered solvents sampled and assayed and found to be satisfactory prior to commingling, and is the quality of commingled solvents monitored on an established schedule?			
1.19	Are there chemical and microbial quality standards for process water, with an established monitoring program? If water is used in the process, is it at least potable water?			

Annexure V

Schedule for self-inspection

Quality Assurance Department
SCHEDULE FOR SELF INSPECTION

(Period:)

S.No.	Department	Audit Team	Audit Team leader	Audit Date		Status
				Scheduled	Audited on	
1	Production Small tablet block					
2	Production Soft Gelatin Capsules					
3	Quality Control					
4	RM Stores					
5	PM Stores					
6	Finished Goods Stores					
7	Utility					
8	Personnel & Administration					
9	Quality Assurance					

Prepared By:
(Sign/Date)

Approved By (Head-QA):
(Sign/Date)