DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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

To lay down a procedure for periodic self-inspection, to ensure current Good Manufacturing Practices compliance.

2.0 SCOPE:

This SOP shall be applicable to all departments of formulation plant of ……..

3.0 RESPONSIBILITY:

3.1 Audit Team: Auditing the facility and to prepare audit report comprising of recommendations and corrective action necessary for respective departments.

3.2 Auditee Head: Head of the audited department, to ensure access is provided to internal audit team to the department and relevant documents required by audit team. He or she shall also ensure that CAPA action plan is taken within a specified time frame as mentioned in the self-inspection compliance report.

3.3 Head-Quality: Constitution of Self Inspection team & ensure compliance of report.

3.4 Head-QA: Audit schedule approval and distribution of Audit Report. Head-QA shall also ensure the compliance to the procedure.

4.0 ACCOUNTABILITY:

Head QA: Authorization of this SOP & Procedure for periodic self-inspection, to ensure current Good Manufacturing Practices compliance of SOP.

5.0 DEFINITIONS:

5.1 Self-Inspection: A systematic inspection program to detect any short comings in the implementation of cGMP and to recommend necessary corrective actions.

5.2 Auditor: A person who has the technical qualification or is trained or the experience to perform audits.

5.3 Auditee: A department to be audited.

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6.0 PROCEDURE:

6.1 Constitution of team and Conduction of Self-Inspection:

6.1.1 Periodic Self-Inspection shall be carried out by an audit team constituted by Head Quality which comprises representative from all operational departments. Minimum two auditors shall be available for conducting self inspection.

6.1.2 Team shall be a cross functional team comprising of persons from different departments such as Quality Assurance, Quality Control, Production, Warehouse, Engineering and Personnel and Administration department.

6.1.3 All the team members shall have a technical qualification/Experience so as to conduct effective Self-Inspection.

6.1.4 QA must be a part of the team. Internal auditors shall be trained on Auditor Qualification Program.

6.1.5 Internal Auditor Training shall be conducted by Head Quality.

6.1.6 Auditor candidates shall successfully complete an Auditor Qualification Program (as presented in Annexure-VIII) before auditing Quality Systems.

6.1.7 After completion of Auditor Qualification Program Certification (as presented in Annexure-IX) shall be provided to concern candidate and evidence of Auditor Qualification shall be maintained by QA Department.

6.1.8 Self-Inspection shall be conducted in an independent and detailed way by designated competent person.

6.1.9 Self-Inspection shall be carried out as per the schedule prepared by QA department (For frequencies of self-inspection refer **Annexure-III**).

6.1.10 The month and department to be audited shall be mentioned in the Self-Inspection Schedule (Annexure-III), which shall be prepared for a calendar year.

6.1.11 This internal Self-Inspection schedule shall be circulated to all concerned department by QA, preferably in the month of January of every calendar year. The actual dates of audit shall be proposed by QA before executing the audit.

6.1.12 The Self-Inspection shall have ±7 day's acceptable tolerance from the schedule and Inspection shall be done within this period.

6.1.13 The actual dates of audit shall be proposed by QA before executing the audit.

6.1.14 The representatives for conducting the self-inspection shall be nominated as auditors by the Head Quality. These nominated auditors will be informed by Head QA at least one day prior for conducting the audit.

6.1.15 Auditors should obtain the relevant checklist from In-charge Documentation Cell QA with appropriate QA stamp for conduction of audit.

6.1.16 During the audit, auditors shall use the checklists for each department as given in Annexure-1A to Annexure-1G, but the scope of audit may not be restricted to the Checklist only. In checklist under the 'Comments' column, the auditor shall mention the observation remarks.

6.1.17 In case, inspection is not completed in one day, it can be continued on next day or any other agreed day.

6.1.18 Discrepancies observed during Self-inspection are categorized as Critical, Major and Minor as described below:

6.1.18.1 Critical (C): A deficiency or an observation, which leads to or has significant risk of producing or distributing a product and making unfit for use. This type of deficiency requires thorough investigation and corrective action on immediate basis.

6.1.18.2 Major (M): A deficiency, which indicates a major deviation from GMP and / or written procedures and indicates failure to carry out satisfactory release of batches. This type of deficiency requires time bound corrective and preventive action and its completion.

6.1.18.3 Minor (N): A deficiency, which cannot be classified as either critical or major but indicates a departure from GMP and/or written procedures or other relevant requirements. This type of deficiency must be addressed to avoid the recurrence of such deficiencies.

6.1.19 The audit team shall evaluate procedures, systems, processes, and functions of the department to ascertain current level of the cGMP.

6.1.20 The audit team shall check for the compliance for the various procedures, raw data and record the findings in "Self Inspection Report" (Annexure-II).

6.1.21 At the end of the audit, hold a meeting with the plant's senior personnel to discuss the outcome of the audit.

6.1.22 The In-charge Documentation Cell QA shall assign a eight alphanumeric character as 'SI/XX/YYY' in consultation with QA to Audit report where;

SI : Denotes self-inspection

/ : Separator

XX : Denotes last two digits of the calendar year

YYY: Denotes of Serial Number 001, 002, 003.

6.2 PREPARATION OF SELF-INSPECTION REPORT AND COMPLIANCE:

6.2.1 After completion of Self Inspection QA shall prepare observation report (as per format presented in Annexure-II, Format) as printed format (computer generated) which shall be signed by minimum two auditors involved in self inspection. It is not required to put Master Copy or Controlled Copy stamp on the self inspection report.

6.2.2 Lead auditor shall review the self inspection report in consultation with Head QA, after finalization, self-inspection report shall be shared with the respective Department.

6.2.3 The self inspection report shall be send to the concern department within 15 working days from the date of audit and a self inspection compliance report will be requested within following 30 working days from the date of sending the audit report.

6.2.4 For Self Inspection Report concerned department head shall mention CAPA action plan and tentative date for compliance based upon audit observations and shall send back the Self Inspection Compliance Report within 30 working days from receipt of Self Inspection Report to QA department on prescribed format presented in Annexure-VII.

6.2.5 Self inspection compliance report shall be prepared as printed format (computer generated).

6.2.6 If concern department unable to submit the compliance report with 30 working days then extra timeline can be granted by Head QA upon justification by department head through mail communication.

6.2.7 The record of self inspection shall be maintained as shown in **Annexure IV "Self-Inspection Log Book"** (Format No. F04).

6.3 FREQUENCY:

Self-Inspection shall be done twice in a year.

NOTE: The contents of the audit reports generated following this SOP are confidential and revelations of these observations to the external auditors shall be limited to self inspection schedule only.

7.0 ABBREVIATIONS:

QA	Quality Assurance
QC	Quality Control
SI	Self-inspection
HR	Human Recourse
Cgmp	current Good Manufacturing Practices
EN	Engineering

8.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure-I	Self-Inspection Checklist	
Annexure-II	Self-Inspection Report	
Annexure-III	Self-Inspection Schedule	
Annexure-IV	Self-Inspection Log Book	
Annexure-V	Self-Inspection Team	
Annexure-VI	List of Qualified Auditors	
Annexure-VII	Self-Inspection Compliance Report	
Annexure-VIII	Auditor Qualification Program	
Annexure-IX	Certificate of Qualified Auditor	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department

10.0 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.

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details Of Changes	Reason Of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

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ANNEXURE-I

SELF INSPECTION CHECKLIST

1A. SELF INSPECTION CHECKLIST WAREHOUSE (STORE)

Audited Department: **Auditors:**
Audit Date:

S.No.	Check Points	Comments
1.	Are incoming material and components quarantine until approved for use?	
2.	Are materials spaced to allow for cleaning and labeling?	
3.	Is the access to area restricted to authorized Personnel?	
4.	Is there any material without label?	
5.	Are all materials stored off the floor or on the pallets?	
6.	Is there a clear demarcation for the following areas: a) Quarantine b) Approved c) Rejected	
7.	Observe the staging area: a) Is the access to area restricted to authorized personnel? b) Is there proper segregation of material issued for different batches?	
8.	Is there an inventory movement record?	
9.	Whether FIFO or FEFO system is followed?	
10.	Is the area segregated for raw and packing material?	
11.	Is the area adequate for physical separation between different materials to prevent mix-ups?	

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S.No.	Check Points	Comments
12.	Are the material containers visually inspected, cleaned and weighed at the time of receipt?	
13.	Is material stored as per their status: quarantine, approved / released or rejected?	
14.	Are materials requiring special storage conditions stored as per requirement?	
15.	Are the labels with complete information and duly signed by QC and written clear and legible text?	
16.	Is sampling done as per the sampling plan by QC chemist?	
17.	Are the sampled containers labeled as 'SAMPLED'?	
18.	Are the containers re-sealed after sampling?	
19.	Is sampling being documented in log book?	
20.	Is dispensing being carried out in segregated environment?	
21.	Does the dispensing area have environmental monitoring (RH and temperature) controls? Check records?	
22.	Is Reverse LAF of Dispensing Booth working properly?	
23.	Is the dispensing area clean and clear of previous dispensing, check the log?	
24.	Does the finished goods stock adequately maintained i.e. C boxes closed, taped and status label?	
25.	Check for master weights calibration certificate.	
26.	Observer dispensing operation: a) Is it conducted by authorized person under supervision of production / IPQA b) All dispensed material properly packed in suitable container / double polybag and labeled c) All the calculations / weights checked by production / IPQA d) Are the original container re-sealed or closed after use e) Observe the area after completion of dispensing	

S.No.	Check Points	Comments
	f) Is there a documented procedure of cleaning of dispensing area after dispensing (i) between batches of same product (ii) between batches of different products	
27.	Observe the printed packaging material area : a) Is stacking / storage of material adequate b) Are the materials of different product and pack size segregated properly c) Is the labeling adequate d) Is there a SOP for dispensing printed packaging material	
28.	Is there a provision for dispensing of extra or additional material is it followed?	
29.	Are lighting and ventilation adequate to facilitate comfortable working?	
30.	Are the buildings constructed to facilitate adequate cleaning, sanitation and pest/rodent control?	
31.	Verify if schedule for cleaning and sanitation are available for: walls, floors, ceiling and fixtures.	
32.	Are written procedures (SOPs) available for cleaning and sanitation?	
33.	Does the solution of cleaning and sanitation indicate rotation of Disinfectant?	
34.	Are the workforce trained in relevant procedures. Is the training documented?	
35.	Is the list for storage condition of products available? a) Are products stored as per the storage conditions?	
36.	Are a complete index and a complete set of SOPs available?	
37.	Are the rejected goods & recalled goods completely demarcated?	
38.	Are materials requiring special storage conditions stored as per requirement?	
39.	Are monitoring devices like thermometers, hygrometers	

S.No.	Check Points	Comments
	installed, calibrated and functional?	
40.	Are the weighing balances calibrated, Check records?	
41.	Check if fire extinguishers are installed and properly labeled.	

Note: Self Inspection check points are not limited to this checklist only.

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1B. SELF INSPECTION CHECKLIST (QUALITY ASSURANCE)

Audited Department: **Auditors:**
Audit Date:

S.No.	Check Points	Comments
1.	Are the deviations recorded a) Is the Approval of deviation being done by Head QA/Designee? b) Is CAPA taken to avoid occurrence of discrepancy. Check the log?	
2.	Does the current lists of all the SOPs available? a) Verify the master copies of SOPs b) Verify the SOP distribution and retrieval record c) Are superseded/obsolete SOP's marked accordingly and preserved separately. Choose any 3 current SOPs and/verify the status of their obsolete SOPs?	
3.	Are the changes in the process, documents introduces as per Change Control procedure? a) Is the record for change control maintained? b) Is the Approval of change control done by Head QA/Designee?	
4.	Is the current list of approved vendors available? a) Is the list of vendors' segregated material wise? b) Are the vendors approved by QA verify the records?	
5.	Are market complaints processed and recorded by QA? a) Verify from the records. b) Check the action taken on any 3 complaints.	
6.	Is the Quality Policy available and displayed?	

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S.No.	Check Points	Comments
7.	Is the current Quality manual available?	
8.	Is the current SMF available? a) Verify that all the information provided in SMF is updated.	
9.	Are the current plant layouts available	
10.	Is the Organogram of the company available? a) Does the organization chart demarcates the key responsibilities? b) Are all the functional areas headed by key persons with adequate qualification, experience and training?	
11.	Is the list of key persons available?	
12.	Is the list of current technical persons available for QC, Production, QA & Warehouse?	
13.	Are current Job descriptions available for all the key and technical persons?	
14.	Are the copies of current manufacturing licenses available?	
15.	Is the SOP for cleaning validation available for general and aseptic areas?	
16.	Is the list of all the products available? a) List of products for domestic market b) List of products for export market	
17.	Does the current lists of specification / STPs for raw materials, finished products available? a) Verify the master copies of specification / STPs. b) Verify specification / STP distribution and retrieval record. c) Are superseded / obsolete specifications / STPs marked accordingly and preserved	

S.No.	Check Points	Comments
	separately. d) Choose any 3 specification / STPs and verify the status of obsolete specifications / STPs	
18.	Are Master formulae records available for all the products? a) Choose any 2 products and verify the Master formula records. b) Are the master formula records authorized?	
19.	Are batch manufacturing records (BMRs) issued and controlled as per the SOP? a) Choose any 4 products and verify the status of BMRs b) Check the BMRs for any deviation or discrepancy	
20.	Have all the trainings been carried out as per schedule and their assessment records maintained properly?	
21.	Are the self-inspections carried out as per schedule and records maintained?	
22.	Check and verify that APR are prepared and compiled properly. Check any 03 APR's	
23.	Check all the relevant records for control sample like environment records, periodic observation records, control sample log.	
24.	Check and verify that qualification and validation protocol and reports are available and qualification & validation is done as per scheduled frequency in VMP.	
25.	Is the humidity and temperature record of stability chamber maintained regularly?	

Note: Self Inspection check points are not limited to this checklist only.

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1C. SELF INSPECTION CHECKLIST (HR DEPARTMENT)

Audited Department: **Auditors:**

Audit Date:

S.No.	Check points	Comments
1.	Verify if the list of employees is current and available.	
2.	Is there a SOP for Induction training program of new recruits, Check records?	
3.	Check induction and medical records of new joinee. Select any 2 or 3 employees.	
4.	Check the availability of a qualified medical practitioner.	
5.	Mention the schedule for medical examination.	
6.	Choose 2-3 employees from each section/dept. Verify the following: Health records, medical leave records.	
7.	Verify whether a system exists for re-examination of an employee returning after a long medical leave by the company designated medical practitioner?	
8.	Is the training imparted on Personnel Hygiene, First Aid & Entry/Exit Procedures etc. Check training records?	
9.	Is SOP on training of personnel available? Is the relevant information like attendance record, evaluation record and re-training record etc. available?	
10.	Is Job description of persons available?	
11.	Is the first aid box provided at all the key	

S.No.	Check points	Comments
	locations?	
12.	Is there SOP for pest and rodent control available?	
13.	Is there SOP for cleaning and sanitization available?	
14.	Is the facility maintained in a clean and sanitary condition?	
15.	Are the buildings constructed to facilitate adequate cleaning, sanitation and pest/rodent control?	
16.	Does the solution of cleaning and sanitation indicate rotation of Disinfectant If yes, check disinfectant log?	
17.	Check if cleaning records are maintained?	
18.	What is the level hygiene: Good (G)/Excellent (E)/Satisfactory (S)/Bad (B) (especially check nail, hair, etc.)?	
19.	Are the gowning and de gowning SOPs available and properly displayed in the change room?	
20.	Are the designated change rooms maintained properly and are provided with facilities like washrooms, cross-over benches, light, ventilation etc.?	
21.	Is there a fixed schedule for washing of uniform Check records?	
22.	Is the canteen or eating room facility neat and clean?	
23.	Check if fire extinguishers are installed, checked, properly labeled?	
24.	Is written procedure describing safety measures is available?	

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S.No.	Check points	Comments
25.	Are lighting and ventilation adequate to facilitate comfortable working?	
26.	Check if the emergency exits in the building are maintained and unobstructed?	
27.	Check if toilet cleaning and maintenance record are maintained, Availability of soap, hot and cold water, air dryers etc.?	

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1D. SELF INSPECTION CHECKLIST (ENGINEERING DEPARTMENT)

Audited Department: **Auditors:**

Audit Date:

S.No.	Check Points	Comments
1.	Are written procedure established for maintenance of equipment and utilities?	
2.	Is updated Master Index of SOP available?	
3.	Are utilities maintained and monitored as per schedule?	
4.	Is the preventive maintenance of major utilities being performed? a) Air Handling Units (AHUs) b) Compressed Air c) Chiller Plant d) Light Fittings e) DG sets	
5.	Does the filters in compressed air units are cleaned as per schedule?	
6.	Does the filters and pre-filters in AHU system are cleaned as per schedule?	
7.	Is the cleaning procedure available for a) Cooling towers b) Chiller plant c) Air handling units / duct / dampers d) Raw/PW/WFI Water storage tanks	
8.	Are the service pipes clearly marked & indicate direction of flow (steam, water, Nitrogen, Compressed Air)?	
9.	Are Preventive Maintenance Records for critical manufacturing equipments available?	
10.	Does preventive maintenance planner is available and check for the compliance?	
11.	Is the validation/calibration of equipment's/gauges performed as per schedule? Check any three.	
12.	Is there adequate space in the building for the orderly placement of equipment, materials and products?	

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S.No.	Check Points	Comments
13.	Is the plant layout conducive to smooth product flow? (e.g. unidirectional flow, avoiding back and forth movements).	
14.	Are operations performed within separate or defined areas of adequate size?	
15.	Are there adequate sanitary facilities and designated eating and drinking areas separate from manufacturing areas?	
16.	Do the eating areas have drinking water?	
17.	Are change rooms designed and used so as to minimize contamination of protective garments?	
18.	Is there an SOP for cleaning and sanitizing of the water purification system? Do records show that the SOP is followed?	

Note: Self Inspection check points are not limited to this checklist only.

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1E. SELF INSPECTION CHECKLIST (PRODUCTION DEPARTMENT)

Audited Department: **Auditors:**
Audit Date:

S.No.	Check Points	Comments
1.	What is the specified minimum number of air changes in the rooms, per hour? (Should be 20 or more)	
2.	The specified minimum unidirectional airflow speed under the vertical flow work station is 0.3% m/s (check records)	
3.	The specified minimum unidirectional airflow speed in front of the horizontal flow observation is 0.45 m/s	
4.	Within the workstation the specified maximum permitted number of particles of 5 µm is in limit.	
5.	The specified maximum permitted number of viable organisms within the workstation, is less than one per cubic meter whilst normal operations are in progress?	
6.	Are there specified methods to test for compliance to the environmental parameters specified? (Particle size, air changes, viable micro-organisms, air velocity?	
7.	Are records of environmental tests for particle size, air change, viable micro-organisms and air flow speed available?	
8.	Is there a standard operating procedure and record to define the action to be taken if any of the results of the tests indicate that the environmental standards of the area are out of specified limits?	
9.	Is there SOP for monitoring Personnel Hygiene?	
10.	Are the garments comfortable, loose fitting and free of external pockets? Verify with operator	
11.	These garments are restricted to use in this area only?	
12.	Headgear specified for this area is of the helmet type, totally enclosing hair and beard and tucked	

S.No.	Check Points	Comments
	into the neck of the suit?	
13.	Prescribed footwear totally covers the feet?	
14.	Trouser bottoms are worn tucked into the footwear?	
15.	All garments are sterilized prior to being used in the area?	
16.	Fresh, clean and sterilized garments are supplied each time a person enters the area?	
17.	Powder free sterile rubber or plastic gloves are worn with the garment sleeves tucked inside the gloves?	
18.	Are non-fibre releasing face masks worn?	
19.	Face masks are discarded each time the operator leaves the aseptic area?	
20.	Operators are prohibited by procedure from bringing outdoor clothes into the change rooms leading into this area?	
21.	Operators change dresses in accordance with clearly defined procedures, prior to entering this area.	
22.	SOP calls for all jewellery, wristwatches and cosmetics to be removed before the prescribed garments are donned?	
23.	The aseptic garments are laundered and handled according to a defined procedure so as to avoid possible contamination?	
24.	Surfaces of walls, floors and ceiling are smooth, impervious and unbroken?	
25.	Bare wood has been avoided?	
26.	Have pipes and ducts been sealed into the walls through which they pass so as not to create recesses which are difficult to clean?	
27.	Have drains been avoided wherever possible and where present, have they been fitted with an air break or other mechanical device to prevent back siphon age?	

S.No.	Check Points	Comments
28.	Do the drain traps (if any) contain a means of disinfection?	
29.	Are floor channels (if any) open, shallow and easily cleanable and connected to drains outside the area in a manner, which prevents ingress of microbial contamination?	
30.	Is the room temperature and humidity controlled and maintained at a level, which will not cause excessive sweating of operators clad in protective garments? (Relative humidity NMT 55% & temperature NMT 25ºC)	
31.	Do operators enter through a changing room where normal factory clothing is exchanged for special protective garments?	
32.	Are the change rooms effectively air-locked and flushed with filtered air?	
33.	Are change rooms designed and used so as to minimize microbial and particulate contamination of protective garments?	
34.	Are the pass boxes and airlocks for the passage of materials, containers and equipment into and from the area designed so that only one door can open at any one time? (e.g. interlocking system or visual and/or audible warning system)	
35.	Has the use of sliding doors been avoided?	
36.	Are there no conveyer belts, which pass through the walls enclosing the aseptic areas?	
37.	Is the use of this area for sterility or other microbiological test procedures prohibited?	
38.	Does the program specify rotation of different types of disinfectants and detergents to prevent development of resistance to the disinfectants?	
39.	Are dilutions of disinfectants and detergents made up in previously cleaned containers?	
40.	Are the leftover of diluted detergents and disinfectants discarded after use?	
41.	Is equipment in the area designed and installed so as to enable easy cleaning and sanitization?	

S.No.	Check Points	Comments
42.	Is there a planned maintenance program for all equipments?	
43.	Are all details of maintenance operations and performance checks recorded? (Check records).	
44.	Are articles required in the aseptic area, sterilized and passed into the area through double-ended sterilizers sealed into the walls?	
45.	Is the efficacy of new processes validated on introduction and at regular intervals thereafter?	
46.	Are Master and/or Batch production records properly assembled and sufficient in the following content: a) Is each prepared, dated and signed in full signature by one person and independently checked, dated and signed by a second person? b) Is the name, strength and description of the dosage form included? c) Is the name, weight, measure of each active ingredient and total weight indicated? d) Is there a statement of percentage yield that includes percentages limit beyond which an investigation is made? e) Is there a description of the drug product containers, closures and packaging materials including a specimen or copy of labels? f) Are there complete manufacturing and control instructions that include any special notations or precautions that are needed	
47.	Are line clearance procedures employed to prevent packaging or labeling mix-ups?	
48.	Are the batch records kept at the workstations during the entire operation? Are the directions strictly followed?	

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S.No.	Check Points	Comments
49.	Are critical steps performed by a competent individual, checked by a second individual and recorded in the batch record?	
50.	Does the batch production records show that each significant step in the manufacture, packaging, or holding was accomplished, including: a) Dates? b) Time started and time completed? c) Identification of major equipment used? d) Identification of each component used? e) Weights and measures of components used? f) In-process laboratory control results? g) Inspection of the packaging and labeling area before and after use? h) Any investigations made of all discrepancies found during the final review of the production records.	

Note: Self Inspection check points are not limited to this checklist only.

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1F. SELF INSPECTION CHECKLIST (QUALITY CONTROL)

Audited Department: **Auditors:**
Audit Date:

S.No.	Check Points	Comments
1.	Is the lab neat and orderly with enough space for working?	
2.	Is a complete index and a complete set of applicable SOPs available in the department?	
3.	Are persons trained on the relevant procedures as per their work distribution? Check Job description of 3 persons and their training records?	
4.	Is Data Integrity maintained? Check any three records as per SOP.	
5.	Is the GLP is followed during operation of instrument	
6.	Lab Reagents: a) Reagents bottles properly labeled (Name, date of preparation, use before date, prepared by) b) Reagents bottle properly closed c) Placed as per temperature requirements	
7.	Is there a ledger maintained for stock of chemicals and media?	
8.	Is there proper storage area with different chemicals differentiation?	
9.	Are there written procedures for operating the instruments?	
10.	Are there written procedures for calibrating the instruments?	
11.	Check the calibration status of any three instrument	
12.	Are the solutions, reagents, indicators etc. stored in orderly manner?	
13.	Are the glass wares cleaned properly?	

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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S.No.	Check Points	Comments
14.	Is a specific person responsible for the receipt of samples for testing?	
15.	Is there a written SOP describing sample receipt and recording.	
16.	Is chemical analysis of purified water done daily and record maintained?	
17.	Are all the instruments kept on shelves in orderly manner?	
18.	Are there Specification and standard testing procedure of Raw material and finished product?	
19.	Is there Standardization of volumetric solution and documentation?	
20.	Is there Working standards & Reference standards Maintenance, Documentation?	
21.	What expiration date is given to working standards?	
22.	Is there a written procedure for ensuring that all Pharmacopoeial procedures are updated when a supplemental monograph is issued?	
23.	Is there a SOP on out of specification results?	
24.	Is there Retesting period procedure available?	
25.	Is there Preservation of Analytical Reports and reserve sample?	
26.	Is there Procedure for handling hazardous chemical or potential hazards in the lab?	
27.	Is analytical balance calibration record maintained? Check if it is calibrated as per scheduled frequency given in SOP?	
28.	Is stability study schedule available?	
29.	Are protocols for all stability study samples available?	

Note: Self Inspection check points are not limited to this checklist only.

Checked By
Sign/Date

Approved By
Sign/Date

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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1G. SELF INSPECTION CHECKLIST (MICROBIOLOGY)

Audited Department: **Auditors:**
Audit Date:

S.No.	Check Points	Comments
1.	Is entry/exit procedure & pictorial is displayed in change room?	
2.	Are there standardized and validated autoclave loads for media used for environmental monitoring?	
3.	Is there an SOP describing preparation, usage and discarding of used cultured media in Micro lab? Check physical stock of any two media and records of the same.	
4.	Is growth promotion test (GPT) carried out before use of media? Check report of GPT.	
5.	Does procedure for Analyst Validation available?	
6.	Are analyst performing analysis are validated?	
7.	Check analyst validation reports of any three analysts.	
8.	Is each sterilization cycle recorded on a time-temperature chart?	
9.	Is the Incubator in proper working order & required temperature maintained?	
10.	Is there Sterility Testing Procedure?	
11.	Are log books of all Instruments in Micro lab maintained regularly?	
12.	Is there an environmental monitoring program for the aseptic area, sterile filling room, sterile filling line and ancillary areas?	
13.	Are all the Instruments in Micro Lab neat & clean?	
14.	Are the standard bacterial cultures available?	
15.	Is gowning and de gowning SOP available for Sterility area?	
16.	Is there a SOP for fogging in sterility area?	

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S.No.	Check Points	Comments
17.	Is there a procedure for cleaning & sanitation of micro lab?	

Note: Self Inspection check points are not limited to this checklist only.

Checked By
Sign/Date

Approved By
Sign/Date

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QUALITY ASSURANCE DEPARTMENT

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1H. SELF INSPECTION CHECKLIST (IT DEPARTMENT)

Audited Department: **Auditors:**

Audit Date:

S.No.	Check Points	Comments
1.	Is there one IT personnel available who is familiar with Production, operations, QC lab personnel?	
2.	Is Procedure available for access control of ERP system & review of audit trails?	
3.	Is password policy available?	
4.	Is system Admin rights deletion of user ID, Creation of Passwords available with IT person only?	
5.	Is ERP system controlled with audit trail?	
6.	Are users well aware of their privileges?	
7.	Is each change in the ERP system controlled through change control after approval of Head-Quality? Check in SOP.	
8.	Is printout facility of audit trail available?	
9.	Is data backup available with IT person?	

Note: Self Inspection check points are not limited to this checklist only.

Checked By
Sign/Date

Approved By
Sign/Date

DECODING PHARMA

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ANNEXURE-I

SELF INSPECTION REPORT

Audit Report No.:		**Date of Audit:**			**Dept. Audited:**
Name of Auditee:					
Auditor					
Designation					
Department					
Signature					
Date					

S. No.	Observation	Observation category

Prepared By:
Sign/Date

Approved By:
Sign/Date

STANDARD OPERATING PROCEDURE	
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ANNEXURE-II

SELF INSPECTION SCHEDULE for Year _____

Months	Department	Tentative Date	Actual Date of Audit	Auditors
January				
February				
March				
July				
August				
September				

The actual dates of audit shall be recorded at the time of start of audit.

Prepared by QA

(Sign/Date): ……..

Approved by Head QA

(Sign/Date):……

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE-III

SELF INSPECTION LOG

S.No.	Report No.	Audit Date	Department Audited	Audit report sent for CAPA action plan to concerned Department Head		Audit report received after CAPA action plan	Closure of Self Inspection Report By (Sign & Date)
				Sent by (Sign)	Date	Received by (Sign & Date)	

STANDARD OPERATING PROCEDURE	
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ANNEXURE-IV

SELF INSPECTION TEAM

S.No.	Name	Department	Designation	Sign

Approved By:
Head Quality
Sign & Date

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ANNEXURE-V

LIST OF QUALIFIED AUDITORS

Effective date: **Revision No.:**

S. No.	Name of Auditor	Qualification	Experience	Expertise

Approved By:
Head Quality
Sign & Date

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE-VI

SELF INSPECTION COMPLIANCE REPORT

Audit Report No.:	**Date of Audit:**	**Dept. Audited:**
Name of Auditee:		

S. No.	Audit Findings	CAPA Action Plan	Tentative date for compliance	Review Status (By Audit team/ member)/ Sign with date

Prepared By Concerned Dept.:
Sign & Date

ANNEXURE-VII

AUDITOR QUALIFICATION PROGRAM

Name of Trainer: **Department:**

Qualification: **Experience:**

S.No.	Assessment Parameters	Marks	Obtained Marks
01	Auditor shall be qualified by education, training and well experienced in auditing techniques.	**20**	
02	Level of cGMP Awareness and knowledge of Pharmaceuticals Quality System.	**20**	
03	Auditor shall have good communication skills.	**10**	
04	Subject matter expert.	**20**	
05	Technical Competences/Level of Confidence.	**10**	
06	Exposure to external audits faced.	**10**	
07	Level of understanding the observations & handling the audit.	**10**	
Total		**100 Marks**	

Acceptance Criteria:

Above 90: Excellent	Between 80-90: Good	Below 80: Poor

Note: Person is deemed to be qualified Auditor if he/she scores 80 % and above in overall rating.

Comments of Head Quality:

_____

_____

_____

Approved By:
(Sign/Date)

ANNEXURE-VIII

CERTIFCATE OF QUALIFIED AUDITOR

This is to certify that Mr./Ms. _____ of_____ Department /Section is qualified as "Internal Auditor" based on his/her experience, qualification, competency/ expertise and skills. He/she is authorized to conduct Internal Audit in the plant functions/Operation/Activity and Standard Operating Procedures, cGMP and Pharmaceutical Quality System.

Approved By:
Head Quality (Sign /Date)