INSPECTION CHECKLIST (MODEL)

Separate comments sheets may be used if space is inadequate

<table>
<tr><td>Date of Inspection</td><td colspan="2">Name of the Firm and Address</td></tr>
<tr><td>Firm's Representative</td><td colspan="2">License No. of Firm and Validity</td></tr>
<tr><td rowspan="3">Inspected by</td><td rowspan="3">Drugs Control Administration,
Telangana State.
(Names & Designation of Inspecting Officers)</td><td>Telephone No. of Firm</td></tr>
<tr><td>Fax. No. of Firm</td></tr>
<tr><td>E-mail ID of Firm</td></tr>
<tr><td>Constitution of the Firm

List of Directors/Partners/Proprietor</td><td colspan="2"></td></tr>
<tr><td>Purpose of Inspection</td><td colspan="2"></td></tr>
<tr><td>Any Certificates held by the firm (ISO,WHO etc.,)</td><td colspan="2"></td></tr>
<tr><td>Guidelines used for assessing compliance</td><td colspan="2">Indicate the Rules/ Schedule-M and Schedule L-1, or any other provisions of Drugs and Cosmetics Rules</td></tr>
<tr><td>Categories of drugs manufactured (e.g. Solid Oral Dosage Forms (Beta Lactams/Non Beta Lactams) /Liquid Orals/Semi-solids/Sex Hormones/ Cytotoxics etc. and production capacity</td><td colspan="2"></td></tr>
<tr><td>Last two years turnover of the firm
(1) Govt. Supply
(2) Trade</td><td colspan="2"></td></tr>
</table>

Schedule M Part-I –Good Manufacturing Practices for Premises and Materials GENERAL REQUIREMENTS		
1	**Location and Surroundings:**	
	Whether the factory building is so situated and have such measures to avoid risk of contamination from external environment including open sewage, drain, public laboratory or any other factory which produces disagreeable or obnoxious, odour, fumes, excessive soot, dust, smoke, chemical or biological emissions.	
2	**Building and Premises:-**	
2.1	Whether the building has been designed contructed and maintained to suit the manufacturing operations so as to production of drugs under hygienic conditions.	
2.2	Whether the building confirm to the conditions laid down in the Factories Act, 1948.	
2.3	Whether the premises used for manufacturing operations and testing purposes is:	
	a) Compatible with other drug manufacturing operations that may be carried out in the same or adjacent area	
	b) Adequately provided with working space to allow orderly and logical placement of equipment, materials and movement of personal so as to avoid risk of mix-up between different categories of drugs and to avoid possibility of the contamination by suitable mechanism.	
	c) Designed/constructed/maintained to prevent entry of insects, pests, birds, and rodents.	
	d) Whether interior surface of (walls, floors, and cellings) are smooth and free from cracks, and permit easy cleaning	
	e) Whether the production and dispensing areas are well lighted and effectively ventilated, with air control facilities.	
	f) Whether the drainage system, is so designed as to prevent back flow and to prevent insects and rodents entering the premises.	
3	**Water System:-**	
3.1	Whether the unit has validated system for treatment of water drawn from own or any other source to render it potable in accordance with standards specified by BIS and water is stored ensuring freedom from microbiological growth.	
3.2	Whether water tank are cleaned periodically and records maintained thereof.	
4	**Disposal of waste:-**	

	Whether the unit has obtained consent for air and water from pollution control board	
5	**Warehousing Area:-**	
5.1	Whether adequate areas have been allocated for warehousing of Raw Materials, Intermediates, Packaging Material, products in quarantine, finish products, rejected or returned products.	
5.2	Whether the warehousing areas have good storage conditions. Are they clean and dry and maintained with in acceptable temparature limits.	
5.3	Whether proper racks, bins and platforms have been provided for the storage	
5.4	Whether receiving and dispatch bays are maintained.	
5.5	Whether separate sampling area for active Raw Materials and Excipients is maintained.	
5.6	Whether highly hazardous, poisonous and explosive materials, narcotics and psychotropic drugs are stored in safe and secure areas.	
5.7	Whether printed packaging material is stored in safe, separate and secure areas.	
5.8	Whether separate dispensing areas with proper supply of filtered air and dust control facility are provided for B- Lactum, sex Hormones and cytotoxic substances or any special category of product.	
5.9	Whether pest control is done regularly.	
6	**Production area**	
6.1	Whether the production area has been designed to allow uni-flow and logical sequence of operations.	
6.2	Whether separate dedicated and self-contained facilities have been provided for the production of Beta lactum, Sex Hormones and Cytotoxic substances.	
6.3	Whether service lines are identified by colours for nature of supply and direction of the flow.	
7	**Ancillary areas**	
7.1	Whether rest and refreshment rooms are separate and not leading directly to the manufacturing and warehouse.	
7.2	Whether Ancillary areas are adequate in area as per rules in every section of the production	
8	**Quality Control Area:-**	
8.1	Whether separate areas have been provided each for physico chemical, biological, microbiological and instrumental analysis.	
8.2	Whether adequate space have been provided to avoid mix-up and cross contamination and also suitable storage space for test samples, returned samples, reference standards, reagents and records.	
8.3	Whether separate AHU's are provided for biological,	

	microbiological and radio iso-topes testing areas.	
9	**Personnel:-**	
9.1	Whether the manufacturing and testing of drugs is conducted under approved technical staff	
9.2	Whether personal for Quality Assurance has been designated	
9.3	Whether number of personnel employed is adequate and in direct proportion to the workload.	
9.4	Whether the personnel are provided with regular in-service training.	
9.5	Names of Technical Staff	For Manufacturing:-
		For Analysis:-
9.6	Whether head of Q.C. is independent of manufacturing unit	
10	**Health, Clothing and Sanitation of Workers:-**	
10.1	Whether personal handling Beta lactum antibiotics are tested for pencillin sensitivity before employment.	
10.2	Whether personnels in handling of sex hormones, cytotoxic and other portent drugs are periodically examined for adverse effect. They should be moved out by rotation.	
10.3	Whether all personnels have undergone medical examination including eye examination and all free from Tuberculosis, skin and other communicable or contagious diseases and records are maintained thereof.	
10.4	Whether all personnel's are trained to ensure high level of personnel hygiene.	
10.5	Whether proper uniforms and adequate facilities for personal cleanliness such as wash basin and dryers towels disinfectant are provided.	
11	**Manufacturing Operations and Controls:-**	
11.1	Whether the contents of all vessels and containers used in manufacture and storage is conspicuously labeled with the name of the products. Batch no., Batch size,	

	and stage of manufacture along with signature of technical staff.	
11.2	Whether products not prepared under aseptic conditions are free from pathogens.	
12	**Precautions against mix-up and cross-contamination:-**	
12.1	Whether proper AHU, pressure differential, segregation, status labeling have been provided to prevent mix-up and cross contamination.	
12.2	Whether processing of sensitive drugs like Beta lactum Antibiotics and Sex Hormones is done in segregated areas with independent AHU and proper pressure differentials along with demonstration of effective segregation of these areas with records.	
12.3	Whether line clearance is performed according to and appropriate checklist and records.	
12.4	Whether packing lines are independent and are adequately segregated.	
12.5	Whether segregated and secured area is provided for recalled, rejected and re-processed materials.	
13	**Sanitation in the Manufacturing areas:-**	
13.1	Whether the premises are cleaned and maintained in an orderly manner so as to free from accumulated waste, dust and any other materials along with maintenance of a validated cleaning procedure.	
13.2	Whether the manufacturing areas are used as the general thoroughfare.	
13.3	Whether a routine sanitation program has been properly recorded.	
14	**Raw Materials:-**	
14.1	Whether the records of Raw Materials are maintained as per Schedule U	
14.2	Whether they are stored in an orderly fashion to permit batch segregation and stock rotation by a FIFO principle.	
14.3	Whether they are labeled and stores as per their status - Under Test, Approved and Rejected.	
14.4	Whether integrity of the containers of the Raw Material is intact.	
14.5	Whether approved vendor list is provided.	
15	**Equipment:-**	
15.1	Whether the equipments are designed aiming to minimize risk of error and permit effective cleaning in order to avoid cross contamination, build up of dust and provided with log book where ever necessary	
15.2	Whether balances and other measuring equipments with appropriate range are available in the Raw Material stores & production areas and they are calibrated in accordance with SOP maintained.	

15.3	Whether the parts of the equipments that come into contact with the product are not reactive so as not to affect the quality of the products.	
15.4	Whether the defective equipments are removed from production areas and properly labeled.	
15.5	Check whether lubricants used in the equipment's contaminate the products	
16	**Documentation and Records:-**	
16.1	Whether the documents are prepared and reviewed as per rules and to provide an audit trail.	
16.2	Whether the records are made at the time of each operation in such a way that all significant activities concerning to the production are traceable. Records and SOPs to be retained at least one year after the expiry of finish products during which all relevant data's should be readily available.	
17	**Labels and Other Printed Materials:-**	
17.1	Whether different color codes are used to indicate the status of a product	
17.2	Whether printed packaging materials, product leaflets, etc., are stored separately to avoid chances of mix-up	
17.3	Whether packaging and labeling materials are examined by the quality control department	
17.4	Whether records of receipt of all labeling and packaging materials are maintained	
18	**Quality Assurance:-**	
18.1	Whether the system of quality assurance has ensured that: (a) the products are designed and developed in accordance with GMP	
	(b) The adequate arrangement are made for manufacture, supply and use of the correct starting and packing materials.	
	(c) Adequate controls on Raw Materials and other in process controls, calibration and validation are carried out.	
	(d) the finished product is correctly processed and checked in accordance with the established procedures.	
	(e) Pharmaceuticals products are not released for sale unless signed and certified by authorized persons as per label claim	
19	**Self Inspection and Quality Audit:-**	
	Whether the firm has constituted a self inspection team supplemented with a quality audit procedure to evaluate that GMP is being followed	
20	**Quality Control System:-**	
20.1	Whether the unit has its own quality control laboratory with qualified and experienced staff	

20.2	Whether SOPs are available for sampling, inspecting, testing of Raw Materials Finish products and Packing Materials and also for monitoring environmental conditions.	
20.3	Whether reference samples from each batch of the products are maintained	
20.4	Whether all instruments are calibrated and testing procedure validated before they are deducted for routine testing	
20.5	Whether Pharmacopoeias, reference standards, working standards and technical books as required are available	
21	**Specifications:-**	
	Whether specifications for Raw Materials, Packaging Materials, Product containers enclosures, Finish Products, In process and bulk products, for preparation of containers and closures are available and is complied with as per rules	
22	**Master Formula Records:-**	
	Whether the unit has maintained Master Formula Records relating to all manufacturing procedures and batch sizes as per rules	
23	**Packaging Records:-**	
	Whether authorized packaging instructions for each products, pack size and type are maintained and complied with as per rules.	
24	**Batch Processing Records:-**	
24.1	Whether the Batch Processing Records for each products on the basis of currently approved master formula is being maintained as per rules	
25	**Standard Operating Procedure and Records:-**	
	Whether SOPs and records are being maintained and complied with as per rules. Check whether following SOP's are available	
	(a) SOP for receipt of material	
	(b) SOP for internal labelling, quarantine, storage, packaging material and other materials	
	(c) SOP for each instrument and equipment	
	(d) SOP for sampling	
	(e) SOP for batch numbering	
	(f) SOP for testing	
	(g) SOP for equipment assembly and validation	
	(h) SOP for Analytical apparatus and calibration	
	(i) SOP for maintenance, cleaning and sanitation	
	(j) SOP for training and hygiene for the personal	
	(k) SOP for retaining reference samples	
	(l) SOP for handling, re-processing and recoveries	
	(m) SOP for distribution of the product	
26	**Validation and Process Validation:-**	
	Whether validation studies of processing, testing and	

	cleaning procedures are conducted as per rules	
27	**Product Recalls:-**	
	Whether the prompt and effective recall system of defective products is being maintained by the unit along with SOPs for Recall Operations	
28	**Complaints and Adverse Reactions:-**	
	Whether the unit has maintained review system for complaints concerning the quality of products along with SOPs	
29	**Site Master File:-**	
	Whether Site Master File as per rules have been prepared & maintained.	

SPECIFIC REQUIREMENTS FOR MANUFACTURE OF STERILE PRODUCTS, PARENTERAL PREPARATIONS (SMALL VOLUME INJECTABLES AND LARGE VOLUME PARENTERALS) AND STERILE OPHTHALMIC PREPARATIONS.

1	**GENERAL** **PART-1A**	
No.	Audit Item	Observations / Remarks
1	Whether dampness, dirt and darkness is visible in the facility	
2	**Building and Civil Works:**	
No.	Audit Item	Observations / Remarks
2.1	Whether the building is devoid of cracks especially in the Aseptic solutions preparation rooms, Filling rooms, Sealing rooms	
2.2	Are the location of services like water, steam, gases etc. are such that the servicing or repairs can be carried out without any threat to the integrity of the facility	
2.2	Whether water lines pose any threat of leakage to the aseptic area	
2.3	Whether the manufacturing areas clearly separated into Support Areas (washing and component preparation areas, storage areas etc.) Preparation areas (bulk manufacturing areas, non aseptic blending areas etc) Change areas and Aseptic areas	
2.3	Whether de-cartoning areas to remove outer cardboard wrappings of primary packaging materials segregated from the washing areas	
2.3	Whether particle shedding materials like wooden pallets, fiber board drums, cardboards etc taken into the preparation areas etc	
2.4a	Whether in the aseptic areas Walls, floors and ceiling are Impervious Non-Shedding Non-Cracking	
	Coved at wall and ceiling junction	
2.4b	Whether the walls are flat, smooth and devoid of recesses	
2.4b	Whether the surface joints like electric sockets, gas points flushed with walls	
2.4c	Whether the ceiling is solid and the joints are properly sealed	
2.4c	Are the air grills and lights flushed with the walls	
2.4d	Are the grade A & B areas devoid of sinks and	

	drains	
2.4e	Are the doors made up of non-shedding materials	
2.4e	Whether doors open towards higher pressure areas and close automatically due to air pressure	
2.4f	As the windows made non-shedding material and flushed with the walls	
2.4f	In case fire escapes are provided, whether they are suitably fastened to the walls without gaps	
2.4g	Whether the quality of the furniture used is smooth & washable and made of stainless steel, or of any other suitable material other than wood	
2.5	Whether the Manufacturing and support areas have the same quality of civil structure as desired for aseptic areas except the environmental standards which may vary in the critical areas	
2.6	Is the change rooms entrance provided with air locks before entry to the sterile product manufacturing areas and then to the aseptic areas	
2.6	Whether the aseptic areas have separate exit and entrances	
2.6	Are the change rooms to the aseptic aras clearly demarcated like 'black' 'gray' and 'white' with different levels of activity and air cleanliness?	
2.6	Are the sinks and drains in the first change rooms (un-classified) kept clean all the time	
2.6	Do the specially designed drains are periodically monitored to check for pathogenic micro-organisms	
2.6	Do the change room doors open simultaneously	
2.6	Whether an appropriate inter- locking system with visual and/or audible warning system installed to prevent the opening of more than one door at a time	
2.7	Do the aseptic and non-aseptic areas provided with intercom telephones or speak phones for communication purposes	
2.8	Whether the aseptic areas and outside areas provided with suitable air-locks or pas boxes for material transfer	
2.8	Do the doors of these air-locks and pass-boxes have suitable inter-locking arrangements	
2.9	Are the rest room, canteen and toilets outside the sterile manufacturing area	

2.10	Are the animal houses outside and away from the sterile product manufacturing area with separate AHU.	
3	**HVAC System:**	
No.	Audit Item	Observations / Remarks
3.1	Whether the Air Handling Units for sterile product manufacturing area separate from those for other areas	
3.1	Give the Background Grade of air for following critical areas: Aseptic filling area Sterilized components unloading area Filling room of terminally sterilized products Batch manufacturing area Component washing and preparation area Final Change room (Aseptic Area)	
3.1	Whether Aseptic filling area, sterilized component unloading area and changes rooms conforming to Class B, C and D have separate Air Handling Units	
3.1	Are the filter configuration in the air handling system suitably designed to achieve the Grade A, B, C and D of air as per designed classified areas	
3.1	Whether the types of Operations to be carried out in the various Grades for Aseptic Preparations are as under:	
a)	**Grade Type of Operation** A Aseptic preparation & Filling	
b)	B Background room conditions for Grade A activities	
c)	C Solution preparation to be filtered	
d)	D Handling of components after Washing	
3.2	Whether for aseptically filled products the filling room meet **Grade B** conditions at rest, unmanned within a period of about **30 minutes** of the personnel leaving the room after completion of operations	
3.3	Are the filling operations undertaken in Grade A conditions and demonstrated under working of simulated conditions	
3.3	Whether these conditions achieved by Laminar Air Flow stations or by Isolator technology	
3.4	Whether the filling room meets **Grade C** conditions at rest in case of terminally sterilized products and these conditions obtainable within	

	a period of about **30 minutes** of the personnel leaving the room after completion of the operations	
3.5	Whether the manufacturing and component preparation areas meet **Grade C** conditions	
3.6	Whether the washed components and vessels protected with **Grade C** background or if necessary under LAF station	
3.7	Whether the number of air changes in Grade B and Grade C areas more than 20 per hour.	
3.7	Whether the Grade A Laminar Air Flow stations meet the criteria of air flow of 0.3 meter per second in case of vertical and that of 0.45 meter per second in case of horizontal flows + / - 20%.	
3.8	Whether the differential pressure between areas of different environmental standards meets the requirements (at least 15 Pascal/ 0.06 inches/ 1.5 mm water gauge)	
3.8	Whether suitable manometers / gauges installed for measured and verification. Specify type of manometer	
3.9	Whether the final change rooms have the same class or air as specified for the aseptic area	
3.9	Whether the pressure differential in the change rooms is in the descending order, from ' white' to 'black'. Specify pressures of three change rooms	
3.10(t)	Whether temperature and humidity (NMT 27 Degrees and 55 % RH respectively) in the aseptic areas are controlled	
4	**Environmental Monitoring:**	
No.	Audit Item	
4.1	Whether the records exist to show that all the environmental parameters were verified at the time of installation and checked periodically thereafter?	
4.1	Are the recommended periodic monitoring frequencies followed	
4.1	Particulate counts - 6 Monthly	
do	HEPA filters integrity testing - Yearly	
do	Air Change rates - 6 Monthly	
do	Air pressure differentials - Daily	
do	Temperature and Humidity - Daily	
do	Microbiological monitoring by settle plates and / or swabs in: **Aseptic areas -- Daily,** **Other areas -- Decreased frequency**	

4.4.2	Does a written Environmental Monitoring Program exist? How long the settle plates are exposed in Grade A and other areas.	
4.2	Are the microbiological results recorded	
4.2	Are these results assessed with recommended limits	
4.3	Do they take action in case particulate and microbiological monitoring counts exceed the limits	
4.3	Do the SOPs contain suggestive corrective action	
4.3	In case of major engineering modifications being carried out to the HVAC system of any area, Whether all parameters reassessed and approved before starting production	
5	**Garments:**	
No.	Audit Item	Observations / Remarks
5.1	Whether Outdoor clothing is allowed in the sterile areas	
5.2	Do they use cotton garments which are not allowed?	
5.3	Are the garments made of non-shedding and tight weaving material?	
5.3	Whether the garments are of suitable design in single piece with fastening at cuffs, neck and at legs to ensure close fit Trouser legs to be tucked inside the cover Boots	
5.3	Whether the garment includes a hood or a separate hood which can be tucked inside the overall	
5.3	Whether Pockets, pleats and belts are avoided	
5.3	Whether Zips (if any used in garments) are of plastic material	
5.4	Whether the personnel wear only clean, sterilized and protective garments at each work session where aseptic filtration and filling operations are undertaken and at each work shift for products intended to be sterilized, post-filling	
5.4	Are masks and gloves are changed at every work session	
5.5	Are the gloves used made of latex or other suitable plastic material	
5.5	Are powder free gloves used in clean rooms	
5.5	Are the gloves long enough to cover the wrists completely and allow the over-all cuff to be tucked in	
5.6	Are the foot-wear used made of plastic or rubber material	
5.6	Are the foot-wear daily cleaned with a	

	bactericide	
5.7	Does the safety goggles / numbered glasses worn inside the aseptic areas have side extensions	
5.7	Are safely goggles sanitized by a suitable method	
5.8	Whether the garment changing procedure documented	
5.8	Whether the operators trained in garment changing procedure	
5.8	Whether a full size mirror been provided in the final change room to ascertain that the operator has appropriately attired in the garments	
5.8	Are periodic inspections of the garments carried out by responsible staff	
5.21	Whether the garments washed in clean area	
5.22	Specify garment sterilization procedure and its entry to the aseptic area	
6	**Sanitation:**	
No.	Audit Item	Observations / Remarks
6.1	Whether written procedures available for sanitation of sterile processing facilities	
6.1	Whether the employees carrying out the sanitation of aseptic areas specially trained for the purpose	
6.2	Whether more than one sanitizing agent is used	
6.2	Whether the concentration of the agent used has been recommended by the manufacturer	
6.2	Are the sanitizing agents used in rotation and records maintained	
6.3	Whether distilled water is used for the dilution of the disinfectant, if so is it directly collected from the distilled water plant or from re-circulation loop maintained above 70 Degees C sterilized by autoclaving and filtered through membrane filtration	
6.4	Whether alcohol or isopropyl alcohol is used as disinfectant for hand sprays?	
6.3	Whether disinfectant solutions filtered through membrane into suitable sterile containers before use?	
6.5	Whether the diluted disinfectants bear ' use before ' labels based on microbiological establishment of their germicidal properties	
6.5	Whether records maintained thereof	
6.6	Whether fumigation carried out in aseptic areas. If yes, specify fumigating agent and its conc.	

6.6	Whether an SOP exist for the purpose of fumigation	
6.7	Whether cleaning of sterile processing facility done using air suction devices non-linting sponges or clothes	
6.8	Whether air particulate quality monitored on a regular basis	
7	**Equipment:**	
No.	Audit Item	Observations / Remarks
7.1	Are the following equipment available with the sterile product manufacturing facility	
A	Component washing machines	
B	Steam Sterilizers	
C	Dry heat sterilizers	
D	Membrane Filter Assemblies	
E	Manufacturing Vessels	
F	Blenders	
G	Liquid filling Machines	
H	Powder filling Machines	
I	Sealing and labelling Machines	
J	Vacuum testing chambers	
K	Inspection Machines	
L	Lyophilisers	
M	Pressure Vessels	
N	Fully integrated washing - sterilizing filling lines (depending upon type and volume of activity)	
7.2	Whether the unit sterilizers double ended with suitable inter-locking between the doors	
7.2	Whether the initial effectiveness of sterilization process established by using microbial spores indicators	
7.2	Whether thermal Mapping of heat sterilizers is carried out on regular basis, Check records	
7.2	Whether suitable vent filters and recording thermographs provided in Autoclaves	
7.2	Whether HEPA filters for cooling air and recording thermographs provided in DHS	
7.2	Whether provisions of CIP or SIP available	
7.2	Whether firm has made provisions for pure steam generation and its use	
7.2	Whether filter integrity test carried out before and after the filtration process	
7.3	Whether the filling machines challenged initially and there after periodically by simulation trials including sterile media fills.	
7.3	Are SOPs with acceptance criteria for media fills been established, validated and documented	

7.4	Whether the material of construction of the parts of equipment which are in direct contact with the product and the manufacturing vessels of stainless steel 316 and of glass containers Borosilicate glass	
7.4	Whether the tubing used capable of washing and autoclaving	
7.5	Whether the installation qualification been done of all the equipments by the engineers (with the support of production and quality assurance personnel)	
7.5	Whether the critical processes such as aseptic filling and sterilizers suitably validated before these were put to use	
7.6	Whether SOPs available for each equipment for its calibration, operation and cleaning	
7.6	Whether the measuring devices attached to equipment calibrated at suitable intervals	
7.6	Whether a written calibration program is available	
7.6	Whether calibration status documented and displayed on the of the equipment and the gauges	
8	**Water and Water Systems:**	
No.	Audit Item	Observations / Remarks
8.1	Whether potable water used for the preparation of purified water meets the requirement of not more than 500 cfu/ml	
8.1	Whether potable water tested (100 ml sample) for freedom from pathogenic microorganisms; Escherichia coli, Salmonella, Staphylococcus aureus and Pseudomonas	
8.2	Whether the Purified Water prepared by de-mineralization / distillation and meet the microbiological specification of not more than 100 cfu/ml	
8.2	Whether Purified Water tested for freedom from pathogenic microorganisms (Sample size 100 ml)	
8.2	Whether Purified Water meet IP Specifications for chemical testing	
8.2	Whether purified water is stored in stainless steel tanks	
8.6	Are the distribution lines made of stainless steel 316 grades?	
8.3	What is the water source for preparation **Water for Injection (WFI)**:	
8.3	Potable Water or	
8.3	Purified Water	

8.3	Whether WFI meet microbiological specification of not more than 10 cfu/100ml	
8.3	Whether WFI meet IP Specifications for Water for Injection	
8.3	Whether WFI meet the endotoxin level of not more than 0.25 EU/ml	
	Whether WFI used for	
8.3	Bulk preparations of liquid parenterals	
8.3	Final rinse of product containers	
8.3	Final rinse of machine parts	
8.3	Preparation of disinfectant solutions for use in aseptic areas	
8.4	Whether WFI used for liquid injectables collected freshly from the distillation plant or from a storage / circulation loop kept at above 70 Degrees C.	
8.5	Whether the steam condensate meets the microbiological specification of not more than 10 cfu/100 ml and IP specifications of WFI	
8.3	Whether steam used in production meet the endotoxin level of not more than 0.25EU/ml	
8.9	What is the schedule for the monitoring of steam quality exist	
9	**Manufacturing Process:**	
9.2	whether the bulk raw materials and bulk solutions monitored for bio-burden periodically (solutions not to contain more than 100 cfu/ml	
9.2	Whether the principle of minimum possible time between the preparation of the solution and its sterilization or filtration through microorganism retaining filters followed and also specified in Master formula.	
9.4	Whether the filter the gases coming into contact with the sterile product through two 0.22 micron hydrophobic filters connected in seriers.	
9.4	Whether gas cylinders are kept out side of the aseptic areas	
9.5	Whether the washed containers sterilized immediately before use.	
9.5	Whether the sterilized containers not used within an established time, rinsed with distilled or filtered purified water and re-sterilized.	
9.6	Is each lot of the finished product filled in one continuation operation	
10.5iii	Whether integrity of the sterilizing filter verified and confirmed immediately after use. If so, by which method. Bubble point, Diffusive flow or	

	pressure Hold Test	
	Sterilization(Autoclaving)	
10.6.2	Whether the sterilizing processes have been validated (Dry heat, Moist heat, filtration, ETO, ionizations whichever applicable.	
10.6.2	Whether the validity of the process verified at regular intervals (at least annually)	
10.6.2	Whether significant changes made to the equipment and / or the prodcut. Whether the records of such changes maintained.	
10.6.3	Whether sterilizer double ended.	
	Whether the terminal sterilizer's capacity is sufficient to sterilize one batch completely at one time. If not specify controls and measures taken in lot sterilization	
10.6.4	Whether the monitoring of products bio-burden carried out before terminal sterilization.	
10.6.4	Whether bio-burden controlled to the specified limits in the Master Formula.	
10.6.5	Whether biological indicators used in monitoring of sterilization.	
10.6.5	Whether the biological indicators stored and used as per manufacturer’s instructions. Whether quality of BI's checked by positive controls.	
10.6.6	Whether a clear means ofdifferenting 'sterilized' from 'unsterilized' products in place. Specify.	
10.6.6	Whether the label on the basket/tray or other carrier of product/component clearly states: Name of the material Its batch number Its Sterilization status Indicator (in case it has passed through sterilization process)	
10.6.7	Whether sterilization records inlcuding thermographs and sterilization monitoring slips attached with the Batch Production Record	
	Sterilization (By Dry Heat)	
10.7.1	Whether the sterilization cycle recording device of stuitable size and precision provided in DHS	
10.7.1	Whether the position of temperature probes used for controlling and / or recording determined during validation and (where applicable) been checked against a second independent temperature probe located in the same position	
10.7.1	Whether the chart forms a part of the batch record.	

10.7.2	Whether sterilization cycle validated only by biological indicator and chemical indicators	
10.7.3	Whether the time allowed reaching the required temperature before commencing the measurement of sterilizing time, separately determined for each type of load	
10.7.3	Are adequate precautions taken to protect the load during cooling after it has gone through the high temperature phase of a heat sterilization cycle	
10.7.4	In case the cooling is affected with any fluid or gas in contact with the product, is it sterilized	
10.7.4	Whether the equipment air inlet and outlets been provided with bacteria retaining filters	
10.7.5	In the process of sterilization by dry heat, does the equipment has: Air circulation facility within the chambers Positive pessure to prevent entry of non-sterile air	
10.7.5	Whether the process of dry heat sterilization is also intended to remove the pyrogens	
10.7.5	If so, has the validation been done with challenge tests using endotoxins	
	Sterilization (By Moist Heat)	
10.8.1	Whether recording of both temperature and pressure carried out to monitor the process	
10.8.1	Whether the control instrumentation independent of the monitoring instrumentation and recording charts	
10.8.1	Whether the equipment has automated control and monitoring system, if so, have these been validated to ensure that critical process requirements are met.	
10.8.1	Whether the system record the system and cycle faults	
10.8.1	Whether records observed / retained by the operator	
10.8.1	Whether the reading of the independent temperature indicator routinely checked against the chart recorder during the sterilizing period	
10.8.1	Whether the sterilizer fitted with a drain at the bottom of the chamber	
10.8.1	If so, does the record of temperature at this position is recorded throughout the sterilizing period	
10.8.1	Are frequent leak tests conducted on the chamber during the vacuum phase of the cycle	
10.8.2	Whether all items to be sterilized (other than sealed containers) are wrapped for sterilization	
10.45	Whether the wrapping material allows removal	

	of air and penetration of steam ensuring contact with the sterilizing agent at the required temperature for required time	
10.8.2	Whether the wrapping prevent contamination after sterilization	
10.8.4	Whether the steam used for sterilization is of suitable quality	
10.8.4	Whether steam contain any additives, if, so, what is the level	
10.8.4	Whether the additives can cause contamination of the product or equipment	
10.9.1	Whether the minimum time for all unit operations and processes are specified in the manufacture of a batch.	
10.9.1	Whether the shortest validated time being adhered from the start of a batch to its ultimate release for distribution	
10.9.2	Whether the containers closing methods been validated	
10.9.2	Whether the containers closed by fusion e.g. glass or plastic ampoules, subjected to 100 % testing	
10.9.2	Whether the samples of other containers checked for integrity as per appropriate procedures	
10.9.3	Whether the containers sealed under vacuum checked for required vacuum conditions	
10.9.4	Whether the filled containers of parenterals inspected individually for extraneous contamination / other defects	
10.9.4	Whether the inspection process done visually, if so, are the illumination and background conditions controlled	
10.9.4	Whether the workers engaged in inspection activity pass the regular eye-sight test (with spectacles if worn)	
10.9.4	Whether the visual inspectors allowed frequent rest from inspection	
10.9.4	If other method of inspection of containers is used, What is the method Has it been validated Are the equipment used for the purpose checked at suitable intervals Are the results / recorded maintained	
11	**Product Containers and Closures:**	
No.	Audit Item	Observations / Remarks

11.1	Whether the containers and closures used comply to pharmacopoeia or other specific requirements	
11.1	To assure suitability of the containers / closures and other component parts of drug packages, whether they have: Suitable sample sizes Specifications Test methods Cleaning procedures Sterilizing procedures	
11.1	What are the measures to ensure that containers are not reactive, additive, adsorptive, leach-able or toxic to an extent that significantly affects the quality or purity of the drug	
11.1	Whether second hand containers and closures used	
11.2	Whether the plastic granules used checked for fulfillment of Pharmacopoeia requirements including physico- chemical and biological tests	
11.3	Whether containers and the closures rinsed with WFI before sterilization	
11.3	Whether a written procedure exist for washing process. Do they follow the written schedule for cleaning of the glass bottles	
11.4	Whether the design of closures and containers suitable to make cleaning easy, and to make an air tight seal when fitted to the bottles	
11.5	Whether the material quality of the stoppers and closures ensures that it does not affect the quality of the product and avoids the risk of toxicity	
11.6	In case the bottles are not dried after washing are these rinsed with distilled water for pyrogen free water as the case may be as per written procedure	
11.7	Do they examine the individual containers of parenteral preparations / opthalmic preparations afater filling for foreign matters	
11.7	Is this examination carried out against a black/white background fitted with diffused light	
11.10t	Do the rubber stoppers used for Large Volume Parenterals comply requirements of the current edition of Indian Pharmacopoeia	
12	**Documentation:**	
No.	Audit Item	Observations / Remarks
12.1	Do the manufacturing records pertaining to manufacture of sterile products indicate the following details:	

12.1.1	Serial number of Batch Record	
12.1.2	Name of the product	
12.1.3	Reference to Master Formula Record	
12.1.4	Batch/Lot number	
12.1.5	Batch/Lot size	
12.1.6	Date of commencement and completion of manufacture	
12.1.7	Date of manufacture and assigned date of expiry	
12.1.8	Date of each step in manufacturing	
12.1.9	Names of all ingredients with grade given by the quality control department	
12.1.10	Quality of all ingredients	
12.1.11	Control reference numbers for all ingredients	
12.1.12	Time and duration of blending, mixing etc. where even applicable	
12.1.13	PH of solutions whenever applicable	
12.1.14	Filter integrity testing records	
12.1.15	Temperature and humidity records whenever applicable	
12.1.16	Records of plate-counts whenever applicable	
12.1.17	Results of pyrogen and / or bacterial endotoxin and toxicity	
12.1.18	Records of weight or volume of drug filled in containers	
12.1.19	Bulk sterility in case of aseptically filled products	
12.1.20	Leak test records	
12.1.21	Inspection records	
12.1.22	Sterlization records including leakage test records, load details, date, duration, temperature, pressure etc.	
12.1.23	Container washing records	
12.1.24	Total number of containers filled	
12.1.25	Total number of containers rejected at each stage	
12.1.26	Theoretical yield, permissible yield, actual yield and variation there of	
12.1.27	Clarification for variation in yield beyond permissible yield	
12.1.28	Reference number of relevant analytical reports	
12.1.29	Details of re-processing, if any	
12.1.30	Names of all operators carrying out different activities	
12.1.31	Environmental Monitoring records	
12.1.32	Specimens of different packaging material	
12.1.33	Records of destruction of rejected containers and packaging material	
12.1.34	Signature of the competent technical staff	

	responsible for manufacture and testing	
12.1N1	Whether products released only after complete filling and testing	
12.1N2	Whether result of the tests relating to sterility, pyrogens and bacterial endotoxins are maintained in the analytical records	
12.1N3	Whether validation details and simulation trial records maintained are separately	
12.1N4	Whether records of environmental monitoring like temperature, humidity, microbiological data etc., are maintained	
12.1N4	Whether records of periodic servicing of HEPA filters, sterilizers and other periodic maintenance of facilities and equipment carried out are maintained.	

PART - I B

Specific Requirements for manufacture of Oral Solid Dosage Forms (Tablets and Capsules)

1	**General:-**	
1.1	Whether the unit has provided effective air extraction systems with discharge points to avoid contamination of other products and process. Filters to be installed to retain dust.	
1.2	Whether the unit has taken precaution to avoid contamination of fiber shedding materials like wood	
1.3	Whether the unit is monitoring environmental conditions of pressure differentials between rooms	
1.4	Whether temperature and humidity is controlled while processing of Aspirin, Ferrous Sulphate, Effervescent tablets etc.	
1.5	Whether metal detector provided	
2	**Sifting, Mixing and Granulation:-**	
2.1	Whether mixing, sifting and blending equipment's are fitted with dust extractors unless operated as a closed system	
2.2	Whether critical operating parameter like time and temperature for each mixing and drying operation are recorded in BPR	
2.3	Whether filter bags fitted to fluid bed drier are used for different products without being washed in between used	
2.4	Whether air entering in to the drier is filtered	
3	**Compression (Tablets):-**	
3.1	Whether Tablet compressing machine are provided with effective dust control facilities and installed in separate cubicles	
3.2	Whether tablets are being inspected and checked for	

	suitable pharmacopeial parameters like appearance weigh variation, disintegration, hardness, friability and thickness and records maintained thereof.			
3.3	Whether tablets are being de-dusted and monitored for the presents of foreign materials and collected in clean labeled containers.			
3.4	Whether compressed tablets are stored properly			
4	**Coating (Tablets) :-**			
4.1	Whether air supplied to coating pan is filtered and of suitable quality. The area should be provided with suitable exhaust system and environmental control (temperature and humidity)			
4.2	Whether coating solutions be made afresh and used in a manner to minimize the risk of microbial growth			
5	**Packaging (Strip & Blister)**			
5.1	Whether rogue tablets and capsules are removed before packaging			
5.2	Whether the strips/Blister coming out of the machines is inspected for directs such as mis-print, outs on the foil, missing tablets and improper sealing			
5.3	Whether integrity of individual packaging strips is vaccum tested periodically to ensure leak proofness			
6	**Equipments and Area in the Tablet Section**			
	TABLET SECTION (GENERAL)			
Sl.No.	Name	Make/Model	no. of machine	Total Area
1	Mass Mixer			
2	Drum Mixer			
3	Rotary Tablet Machine			
4	Rotary Tablet Machine			
5	Single Stroke Multi punch Machine			
6	Hot Air Oven Tray Drier			
7	Fluid Bed Dryer with thermal heat			
8	Multi-mill			
9	Coating Pan			
10	Polishing Pan			
11	Sifter			
12	Counter Pan			
13	Tablets Disintegration Machine			
14	Dehumidifier			
15	Physical Balance			
16	Single Pan Balance			
17	Hardness Tester			
18	Deduster Machine			
19	Stainless Steel Vessels			
20	Stainless Steel Scoops			
21	Table Inspection Belt			
22	Air Handling Unit (Specification of filter and blower capacity)			

	TABLET SECTION (BETALACTUM) SEPARATE DESPENSING BOOTH IN THE TABLET SECTION			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Mass Mixer			
2	Drum Mixer			
3	Rotary Tablet Machine			
4	Fluid Bed Dryer			
5	Multi-mill			
6	Sifter			
7	Tablets Disintegration Machine			
8	Dehumidifier			
9	Physical Balance			
10	Tablet Inspection Belt			
11	Deduster Machine			
12	Air Handling Unit (Specification of filter and blower capacity)			
13	Blister Packing Machine			
	TABLET SECTION (SEX HORMONES) SEPARATE SAMPLING AND DISPENSING BOOTH			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Roller Compactor			
2	Drum Mixer			
3	Rotary Tablet Machine			
4	Multi-mill			
5	Sifter			
6	Tablets Disintegration Machine			
7	Dehumidifier			
8	Physical Balance			
9	Single Pan Balance			
10	Hardness Tester			
11	Deduster Machine			
12	Tablet Inspection Belt			
13	Air Handling Unit (Specification of filter and blower capacity)			
14	Blister Packing Machine			
7	**Equipments' and Area in Capsule Section :-**			
	CAPSULE SECTION (BETALACTUM ANTIBIOTICS)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Rota Cube			
2	Capsule Filling Machine			
3	Sifter			
4	Dehumidifier			
5	Capsule Loading Machine			
6	Counter Pan			
7	Physical Balance			
8	Capsule Polishing Machine			
9	Blister Packing Machine			

10	Air Handling Unit (Specification of filter and blower capacity)			
	CAPSULE SECTION (NON BETALACTUM)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Sifter			
2	Rota Cube			
3	Capsule Filling Machine			
4	Dehumidifier			
5	Automatic Capsule Loading Machine			
6	Counter Pan			
7	Physical Balance			
8	Semi Automatic Capsule Filling Machine			
9	Capsule Polishing Machine			
10	Air Handling Unit (Specification of filter and blower capacity)			

PART - I C

Specific Requirements for manufacture of Oral Liquid

1	**Building and Equipments :-**	
1.1	Whether the manufacturing area have entrance through double air lock facility and has been made fly proof	
1.2	Whether the drainage is of adequate size and without open channels	
1.3	Whether the production area is cleaned and sanitized at the end of every production process	
1.4	Whether all the equipments and furniture's are of stainless steel and are capable of cleaned effectively	
1.5	Whether suitable machine equipped with high pressure air, water and steam jets available for cleaning of containers	
2	**Purified Water:-**	
2.1	Whether the Microbial quality of purified water is monitored routinely. It should not exceed 100 cfu per ml for absence of pathogens.	
2.2	Whether the unit has return procedure for operation and maintenance of purified water system. Specify the	

	method.			
3	**Manufacturing : -**			
3.1	Whether the manufacturing personnel's wear non fiber shedding cloths also fiber shedding materials like gunny bags, or wooden pallets should not be carried in this area.			
3.2	Whether mixing and cleaning processes are specified and monitored to ensure that the product is uniformity homogeneous			
3.3	Whether the primary packaging area has an air supply filtered through 5 micron filters and the temperature does not exceed 30 degrees C.			
3.4	Whether the maximum period of storage before packing is specified in the mater formula			
4	**Area and Equipment's**			
	LIQUID ORAL SECTION			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Double Head Liquid Filling Machine			
2	Stainless Steel Storage Tank			
3	Stainless Steel Storage Tank			
4	Stainless Steel Storage Tank			
5	Stainless Steel Storage Tank			
6	Stainless Steel Storage Tank			
7	Stainless Steel Storage Tank			
8	Stainless Steel Storage Tank			
9	Bottle Washing Machine			
10	Rotary type Bottle Washing Machine			
11	Oven Bottle Drying			
12	Horizontal Plate Filter Press			
13	Colloidal Mill			
14	Automatic P.P. Cap Sealing Machine			
15	P.P. Cap Sealing Machine			
16	Stirrer			
17	Filled bottle checking apparatus			
18	Deioniser			
19	Air Handling Unit (Specification of filter and blower capacity)			

PART - I D

Specific Requirements for manufacture of topical products (Ointments, Creams, Lotion & Dusting Powders)

1.1	Whether the undersigned manufacturing area is through a suitable air lock and insectocutors			
1.2	Whether the air to the manufacturing area is filtered through 20 micron air filters and is air conditioned			
1.3	Whether the water used in the compounding is purified water I.P			
1.4	Whether the powders whenever used are suitably sleved before use			
1.5	Whether heating of base like petroleum jelly is done in a separate mixing area in suitable SS vessels			
1.6	Whether a separate packing section is provided for primary packaging of products			
1.7	Whether area is fitted with an exhaust system to remove vapours, fumes etc.			
2	**Area and Equipments**			
	OINTMENT & CREAM SECTION (STEROIDS)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
1	Planetary Mixer			
2	Automatic Tube Filling Machine			
3	Stainless Steel Vessels			
4	Stainless Steel Scoops			
5	Air Handling Unit (Specification of Filter and Blower Capacity)			
	OINTMENT & CREAM SECTION (GENERAL)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
	Colloid Mill			
	Automatic Tube Filling Machine			
	Semi Automatic Tube Filling Machine			
	Planetary Mixer			
	Stainless Steel Vessels			
	Stainless Steel Scoops			
	Conveyor Belt			
	Air Handling Unit (Specification of Filter and Blower Capacity)			

PART 1-F
BULK DRUGS/ ACTIVE PHARMACEUTICAL INGREDIENTS
Specific requirements for the manufacture of Bulk Drugs

1	BUILDING AND CIVIL WORKS	
1.1	Whether confined areas are provided for the manufacture of hazardous reactions, B-lactum antibiotics, steroids and steroidal hormones, cytotoxic substances.	
1.2	Whether air filtration system (terminally with 5µ) system is provided from isolation of finally stage of product to packaging stage.	
1.3	Whether suitable exhaust system is provided to control floating dust particles.	
2	STERILE PRODUCTS	
	Whether sterile API are manufactured.	
3	Whether utilities are serviced at frequent intervals.	
4	EQUIPMENT, DESIGN, SIZE AND LOCATION	
4.1	Whether equipment in the mfg. sections are of adequate size and suitably located.	
4.2	Whether cleaning procedures are prescribed for switching over to another product.	
4.3	Whether cleaning procedures are prepared and followed.	
4.4	Whether written procedures are established and followed.	
4.5	Whether cleaning validation of equipment done and followed.	
5	INPROCESS CONTROL	
5.1	Whether inprocess control for chemical reactions are checked and recorded.	
5.2	Whether inprocess control for physical operations are followed and recorded.	
6	PRODUCT CONTAINERS AND CLOSURES	
6.1	Whether containers and closures comply with the pharmacopoeial or requirements not to affect the quality or purity of the drug	
6.2	Whether approved or rejected containers are identified and quarantined if rejected.	
6.3	Whether adequate protection system is provided to container closure system.	
6.4	Whether bulk drug containers and closures are cleaned.	
6.5	Whether container is conspicuously labeled with required information.	

6.6	Whether different operations are suitably partitioned.	

Signatures of the Inspecting Officers:

Date: