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 personnels 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 aspectic conditions are free from pathogens.	
12	**Precautions against mix-up and cross-contamination:-**	
12.1	Whether proper AHU, pressure differential, segregation, status labelling 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 alongwith 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 alongwith 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 effect 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 siignificant activities concerning to the production are traceable. Records and SOPs to be retained atleast one year after the expiry of finish products during which all relevant datas should be readily available.	
17	**Labels and Other Printed Materials:-**	
17.1	Whether different colour codes are used to indicate the status of a product	
17.2	Whether printed packaging materials, product leaflets, etc., are stored separetly 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 labelling 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 inprocess 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 authorised 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, Inprocess 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 authorised 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 alongwith SOPs for Recall Operations	
28	**Compliants and Adverse Reactions:-**	
	Whether the unit has maintained review system for compliants concerning the quality of products alongwith SOPs	
29	**Site Master File:-**	
	Whether Site Master File as per rules have been prepared & 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 extration 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 temporature 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 pharmacopial parameters like apperance 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 (temparature 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	Number 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 Steal Vessels			
20	Stainless Steal 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	**Equiments 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 Casule Loading Machine			
6	Counter Pan			
7	Physical Balance			
8	Semi Atutomatic 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 sanitised 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 personnels 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 homogenious			
3.3	Whether the primary packaging area has an air supply filtered through 5 micron filters and the temparature 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

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 Steal Vessels			
	Stainless Steal Scoops			
	Conveyor Belt			
	Air Handling Unit (Specification of Filter and Blower Capacity)			

CASE STUDIES

SUMMARISED OBSERVATIONS

RECOMMENDATIONS