DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF ANDHRA PRADESH

Inspection Check List
(As per new Schedule M)
Separate comments sheets may by used if space is inadequate

Date of Inspection	Name of Licensee	Address of firm
Firm's representative		License No.: /2010
Inspected by		Telephone No.
		Email :

Constitution of the Firm	
Purpose of Inspection	
Any Certificates held by the firm (ISO, WHO etc,)	
Categories of drugs manufactured	
Last two years turn over of the firm (1) Govt. Supply (2) Trade	

1) Location and surroundings		
	Whether the factory building is so situated and have such measure to avoid risk of contamination from external environment including open sewage, drain public laboratory or any other factory which produces disagreeable obnoxious, odour, fumes, excessive soot, dust smoke, chemical or biological emissions.	
	2.Building and premises	
2.1	Whether the building has been designed, constructed and maintained to suit the manufacturing operations so as to production of drug under hygienic conditions.	
2.2	Whether the building conform 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 personnel so as 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 ceilings)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 microbial growth.	

3.2	Whether water tanks 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 ware housing areas have good storage conditions. Are they clean and dry and maintained with in acceptable temperature limits.	
5.3	Whether proper rack, 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 3-1lactum, sex hormones and cytotoxic substances or any special category of product.	
5.9	Whether the 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 and 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 colors 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 the ancillary areas are adequate in area as per rules in every section of 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 isotopes testing areas.	
9	**Personnel:-**	
9.1	Whether the manufacturing and testing of drug is conducted under approved technical staff.	
9.2	Whether personnel for Quality Assurance has been designated.	
9.3	Whether number of personnel employed is adequate and indirect proportion to the work load.	
9.4	Whether the personnel are provided with regular in service training.	
9.5	Name of the technical staff	
9.6	Whether head of Q.C is independent of manufacturing unit.	

10	**Health, clothing and sanitation of workers:-**	
10.1	Whether personnel handling Betalactum antibiotics are tested for penicillin sensitivity before employment.	
10.2	Whether personnel's in handling if sex hormones, cytotoxic and other potent drugs are periodically examined for adverse effect. They should be moved out by rotation.	
10.3	Whether all personnel's 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 personnel cleanliness such as wash basin and dryers, towels disinfectant are provided.	
11	**Manufacturing operations:-**	
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 storage of manufacture along with signature of technical staff.	
11.2	Whether products not prepared under asceptic 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 check list and records.	
12.4	Whether packaging lines are independent and are adequately segregated.	
12.5	Whether segregated and secured area is provided for recalled, rejected and reprocessed materials.	

13	**Sanitation in the manufacturing area**	
13.1	Whether the premises are cleaned and maintained is an orderly manner so as to free from accumulated waste, dust and any other material along with maintenance of a validated cleaning procedure.	
13.2	Whether the manufacturing areas are used as the general through-fare	
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 stored as per their status_ Under test, Approved, and Rejected.	
14.4	Whether integrity of the containers of raw materials is intact.	
14.5	Whether approved vender list is provided.	
15	**equipment**	
15.1	Whether the equipment are designed aiming to minimize risk of error and permit effective cleaning ir order to avoid cross contamination, build up of dust and provided with log book wherever necessary	
15.2	Whether balance 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 equipment that come in to 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 the finished products during which all relevant data's should be radily 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 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 as 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 packaging 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 SOP's are available for sampling, inspecting, testing of raw materials, finished 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 procedures validated before they are adopted for routine testing.	
20.5	Whether Pharamacopeias, reference standards working standards and technical books as required are available.	
21	**Specifications: are available**	
21.1	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 formulae records**	
	Whether the unit has maintained master formulae records relating to all manufacturing procedures and batch sizes as per rules	
23	**Packaging records:**	
	Whether authorized packaging instructions for each product, pack size and type are maintained and complied with as per rules.	
24	**Batch processing records:**	
	Whether the batch processing records for each products on the basis and type are maintained and complied with as per rules.	
25	**Standard operating procedures and records:**	
	Whether SOP's and records are being maintained and complied with as per rules. Check whether following SOP'S are available. (a) SOP for receipt of materials	
	(b) SOP for internal labeling, quarantine, storage, packaging material and other material	
	(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	
	(j) SOP for training and hygiene for the personnel	
	(k) SOP for retaining reference sample	
	(i)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 SOP's for Recall operations	
28	**Complaints and adverse reactions:**	
	Whether the unit has maintained review system for compliments concurring the quality of products along with Sop's	
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		
1.2	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.	
1.3	Whether the unit has taken precaution to avoid contamination of fiber shedding materials like wood	
1.5	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.	
1.3	Whether metal detector provided	
2		
2.1	Whether mixing, sifting and blending equipment's are fitted with dust extractors unless operated as a closed system	
2.3	Whether critical operating parameter like time and temporature for each mixing and drying operation are recorded in BPR	

2.4	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	
3.4	Whether tablets are being inspected and checked for suitable pharmacopial parameters like apperance weigh variation, disintegration, hardness, friability and thickness and records maintained thereof.	
3.5& 3.6	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)**			
7.1	Whether rogue tablets and capsules are removed before packaging			
7.3	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			
7.4	Whether integrity of individual packaging strips is vaccum tested periodically to ensure leak proofness			
6	**Equipments and Area in the Tablet Section PART-II**			
	TABLET SECTION (GENERAL)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
3.1a3	Mass Mixer			
3.1a2	Drum Mixer			
3.1bi	Rotary Tablet Machine			
do	Rotary Tablet Machine			
do	Single Stroke Multi punch Machine			

3.1a5	Hot Air Oven Tray Drier			
3.1a5	Fluid Bed Dryer with thermal heat			
3.1a.1	Multi-mill			
3.1d2	Coating Pan			
3.1d3	Polishing Pan			
3.1a.1	Sifter			
3.1c.3	Counter Pan			
3.1b6	Tablets Disintegration Machine			
3.1b7	Dehumidifier			
3.1b6	Physical Balance			
do	Single Pan Balance			
do	Hardness Tester			
3.1b3	Deduster Machine			
	Stainless Steal Vessels			
	Stainless Steal Scoops			
3.1b4	Table Inspection Belt			
	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
3.1a3	Mass Mixer			

3.1a2	Drum Mixer			
3.1bi	Rotary Tablet Machine			
3.1a.5	Fluid Bed Dryer			
3.1a.1	Multi-mill			
3.1a.1	Sifter			
3.1b6	Tablets Disintegration Machine			
3.1b7	Dehumidifier			
3.1b6	Physical Balance			
3.1b4	Tablet Inspection Belt			
3.1b3	Deduster Machine			
	Air Handling Unit (Specification of filter and blower capacity)			
3.1c.1	Blister Packing Machine			
	TABLET SECTION (SEX HORMONES) SEPARATE SAMPLING AND DISPENSING BOOTH			
Sl.No.	Name	Make/Model	Number of machine	Total Area
	Roller Compactor			
3.1a.2	Drum Mixer			
3.1b.1	Rotary Tablet Machine			
3.1a.1	Multi-mill			

3.1a.1	Sifter			
3.1b.6	Tablets Disintegration Machine			
3.1b.7	Dehumidifier			
3.1b.6	Physical Balance			
3.1b.6	Single Pan Balance			
3.1b.6	Hardness Tester			
3.1b.3	Deduster Machine			
3.1b.4	Tablet Inspection Belt			
	Air Handling Unit (Specification of filter and blower capacity)			
3.1c.1	Blister Packing Machine			
7	**Equiments and Area in Capsule Section :-**			**PART-II**
	CAPSULE SECTION (BETALACTUM ANTIBIOTICS)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
5(1)	Rota Cube			
5(2)	Capsule Filling Machine			
	Sifter			
	Dehumidifier			
	Capsule Loading Machine			
5(3)	Counter Pan			
5(4)	Physical Balance			

5(6)	Capsule Polishing Machine			
	Blister Packing Machine			
	Air Handling Unit (Specification of filter and blower capacity)			
	CAPSULE SECTION (NON BETALACTUM)			
Sl.No.	Name	Make/Model	Number of machine	Total Area
	Sifter			25 Sq.mts. For basic installation And 10 Sq.mts. Ancilliary area
5.1	Rota Cube			
5.2	Capsule Filling Machine			
	Dehumidifier			
5.2	Automatic Casule Loading Machine			
5.3	Counter Pan			
5.4	Physical Balance			
5.2	Semi Atutomatic Capsule Filling Machine			
5.6	Capsule Polishing Machine			
	Air Handling Unit (Specification of filter and blower capacity)			