

**Check List for Lay out Plan Approval for Manufacturing
Allopathic Drugs**

Sr. No.	Manufacturing Section	Area Provided	Required Area (As per New Sch M Req.)	Other Requirement
1	External Preparation (Ointments, Emulsion, Creams, Lotions, Paste, Dusting Powder etc.)		30 sq.mt + 10 sq. mt Ancillary Area	Air handling system, Airlock, Air Conditioning & Air Supply through 20 Micron filler & Exhaust system
2	Liquid Orals (Syrups, Elixirs, Suspensions etc.)		30 sq. mt + 10 sq. mt Ancillary Area	Air handling system, Airlock, In primary packaging area 5-micron air supply & temp .below 30 degree Celsius.
3	Oral Powder		30 sq. mt	Air handling system, Exhaust system, and Separate Section. For Blending.
4	Tablets. A. Granulation B. Compression C. Packing D. Coating		60 sq. mt 20 sq. mt Anc. Area 30 sq. mt+ 10 sq. mt anc.	Air handling system, Dehumidifier & Air Conditioning as required and Suitable Exhaust system Cubicle for each tablet machine.
	E. Beta Lactum		Separate manufacturing & packing Section Area as required for general tablet section	Suitable Measures to avoid cross contamination, Air handling System
	F. Hypodermic Tablets		Separate manufacturing & Packing Section Area as required	
5	Capsule Section A General (Non		25 sq. mt +	Air handling system, Airlock Exhaust

	Penicillin)		10 sq. mt ancillary.	Dehumidifier & A/C
	E. Beta Lactum Group		25 sq. mt + 10 sq. mt ancillary.	Air handling system, Provisions to avoid Cross contamination
	C. Soft Gelatin Capsule		30 sq. mt	Air handling system, A/C, Dehumidifier
6	Surgical Dressings A. Surgical Bandages (Excluding Cotton wool) B. Medicated Dressings		30 sq. mt 30 sq. mt) Air handling) System
7	Ophthalmic Preparation (Eye ointments, Eye Lotions etc.)		25. sq. mt + 10 sq. mt. anc.	Sterile, Air conditioned Dehumidifier & Air Lock
8	Pesseries & Suppositories (if manufactured by Granulation & compression area required is as per tablet section)		30 sq. mt	Other requirement as per Tablet section
9	Inhalers, Vitroli		20 sq.mt	Air handling system
9 a	Metered Dose inhalers		As required	Air handling system With following subsections Change room, Container preparation bulk preparation & filling Quarantine spray testing
10	Basic drugs			
A	General		30 sq. mt	a .Construction above this is not allowed Air handling system 5 micron air supply
b	Sterile		30 sq. mt	All provisions required for manufacture of

				sterile formulation
11	Disinfectant / Phenyl Powder repacking		30 sq. mt 30 sq. mt	Air lock
12	Liquid repacking		30 sq. mt	Air handling system
14	Medicinal gases		30 sq. mt	
15	Cotton Wool		100 sq. mt	
16	Hard gelatin capsule		75 sq. mt	Air handling system
17	Mechanical contraceptives a. Condoms b. copper T c. Tubal rings		30 sq. mt 25 sq. mt 25 sq. mt	Air handling System Aseptic area
18	Bottle washing Cleaning		15 sq. mt	Air handling system
19	Parenteral Preparations (Following Sub-sections are required for Glass containers) a Water management area b Containers & closures prep. c Solution prep d Filling capping sealing e Sterilization f Quarantine g Visual inspection h Packing area		150 sq. mt	Air handling system Environmental Monitoring & other Special Provisions as per Sch M Part I A 100 sq. mt ancillary area for small volume parenteral 150 sq.mt. ancillary area 100 sq. mt for packing material store for large volume parietals
20 For parenteral preparation in plastic container Mfgd by FFS/BFS Technology for metered dose required				
	<ul style="list-style-type: none"> • Water management Area • Solution preparation Area • Container moulding, filling & sealing Area • Sterilization Area • Quarantine Area 		250 sq. mt	As per Sch M Part I Air handling unit, Environment monitoring & Special Provision 150 Ancillary Area 150 Packing material stores for LVP

	Visual inspection Area Packing Area			
20	Quality Control			
A	Chemical Testing		20 sq. mt	
B	Instrument room		10 sq. mt	Air conditioned
C	Microbiology		10 sq. mt	Air Lock Air handling unit LAF
D	Pyrogen Testing		15 sq. mt	Air conditioned
E	Sterility testing		10 sq. mt	Air Lock, Air handling unit LAF
F	Animal house		15 sq. mt	Air conditioned
21	Office		10 sq. mt	
22	Workers room		8 sq. mt for Gents 8 sq. mt for Ladies	
23	Raw material Section			<ul style="list-style-type: none"> • A/C for thermolabile drugs • Separate sampling area • Separate area for Sampling/ Dispensing & storing of Beta-lactum, cytotoxic & sex hormones
a	One/two section		30 sq. mt	
b	Three/four section		40 sq. mt	
c	More than Four section		50 sq. mt	
d	Receiving bay		As required & covered	
24	Quarantine Raw Material		10 sq. mt	A/C for the thermolabile drugs
25	Finished Goods Store			A/C for the thermolabile drugs
a	One section		20 sq. mt	
b	Each additional Section		10 sq. mt	
26	Quarantine for finished product		10 sq. mt	
27	Packing & labeling	Air handling system for primary packing section		
a	one section		20 sq. mt	
b	Two section		30 sq. mt	
c	Three or more		50 sq. mt	
28	Packing Materials		75% of the area required for raw material section	Air conditioned or air handling system as required.