

Check List for Lay out Plan Approval for Manufacturing Medical Devices

Sr. No.	Manufacturing Section	Area Provided	Area Required (minimum)	Other requirement
1.	Medical Devices (Sterile Devices for Single use) a) mfg area for each category b) Sterilization area c) Drug coating section (wherever applicable)		30 sq.mt 10sq.mt 10sq.mt	Air Handling Unit And Aseptic area
2.	Quality Control Chemical section (Physico -Chemical Section) Instrument Room Microbiology Sterility		20 sq.mts 10 sq.mts 10 sq.mts 10 sq.mts	Air Conditioned Airlock, Air Handling Unit, LAF Airlock and Air Handling Unit
3.	Office		10 sq mts	
4.	Workers Room Gents Ladies		8 sq mts 8 sq mts	
5	Raw Material		30 sq mts	A/C for Thermolabile Drugs Separate Area for Storage of Drugs
6	Quarantine raw Material		10 sq mts	
7	Finished Goods Store		20 sq mts	A/C for Thermolabile Drugs coated devices
8	Quarantine for finished product		10 sq mts	
9	Packing and Labelling		20 sq mts	Air Handling Unit for primary packing section
10	Packing Material		75% of Raw .Material Section	Air Conditioner and Air Handling Unit