POLICY ON AREA CLASSIFICATION OF FACILITY& HVAC DESIGN

INTRODUCTION:

To provide a Guideline for Classification of facility / manufacturing area based on process activity, dosage form and HVAC Design.

SCOPE :

Applicable to areas and clean air devices to be classified for classification of air cleanliness ISO class, European Commission grade (EC) and Controlled Not Classified (CNC), wherever applicable. Also, applicable to all sterile /Non-sterile dosage form facility across …….. unit and its associated units.

POLICY DETAILS:

1. Area Classification:

Table 1: LIQUID INJECTION & LYOPHILISATION FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
A	**Aseptic Area Activity**	
1	Vial Filling Under LAF	Grade A (ISO 5)
2	Vial Plugging / Rubber stoppering, Under LAF	Grade A (ISO 5)
3	Sterile to Sterile (S2S) connectors, Under LAF	Grade B (ISO 7)
4	Rubber stopper loading, Under LAF	Grade A (ISO 5)
5	Aseptic connection, Under LAF	Grade A (ISO 5)
6	Material Transfer in double wrapped conditions, Under LAF	Grade B (ISO 7)
	Material Transfer without double wrapped conditions, under LAF	Grade A (ISO 5)
7	Area under Extended LAF outside filling cabinet (where no aseptic manipulation involved)	Grade B (ISO 7)
8	Vial Transfer from Rubber stoppering station to Capping Station (Rubber Stoppered Vials), Under LAF	Grade A (ISO 5)

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DOCUMENT NAME	**AREA CLASSIFICATION POLICY AND HVAC DESIGN**
DOCUMENT No.	**1035-Policy-072**
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Table 1 (Contd): LIQUID INJECTION & LYOPHILISATION FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
A	**Aseptic Area Activity**	
9	Vial Transfer from Filling to Lyo Loading area, Under LAF	Grade A (ISO 5)
10	Product Loading / Unloading to & From Lyo, Under LAF	Grade A (ISO 5)
11	Vial Transfer from Lyo area to Capping Station, Under LAF	Grade A (ISO 5)
12	Cap Sealing, Under LAF	Grade A (ISO 5)
	Cap Sealing Under LAF, where machine installed with Missing / raised stopper detector	Grade B (ISO 7)
13	Sterilized material unloading from Autoclave, (Without double wrapped) and storage under LAF	Grade A (ISO 5)
	Sterilized material unloading from Autoclave (Double wrapped sealed condition) and storage Under LAF	Grade B (ISO 7)
14	Transfer of material through mobile LAF (Class of area under Mobile LAF)	Grade A (ISO 5)
	Transfer of double wrapped material	Grade B (ISO 7)
15	Filtration aseptic connections, Under LAF	Grade A (ISO 5)
	Filtration S2S connections, Under LAF	Grade B (ISO 7)
16	Aseptic Manufacturing process, Under LAF	Grade A (ISO 5)
17	Material transfer in sealed conditions from compounding to Filtration, unloading from Pass box, Under LAF	Grade B (ISO 7)
18	Classification of all background areas (outside LAF) for Vial Filling, Cap sealing, Lyophilisation loading & unloading, cool zone and filtration	Grade B (ISO 7)
19	Classification of Corridors and other ancillary areas connected to Grade B/ISO 7 classified processing areas Entry / exit change room attached to Grade B / ISO 7 classified corridor / Processing Areas	Grade B (ISO 7)

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Table 1 (Contd): LIQUID INJECTION & LYOPHILISATION FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
B	**Aseptic Area Change Room process**	
1	Wearing of Body Covering Suit & Head Gear / Comfort primary garment.	Controlled Not Classified (CNC)
2	Connecting area between CNC (Wearing of body covering suit & Head Gear) and Grade C (Wearing hand gloves & inner garments)	Grade D *
3	Wearing of 1st pair of Hand gloves and Inner garments	Grade C (ISO 8)
4	Wearing of sterile Garments & Goggles	Grade B (ISO 7)
5	Wearing of Final pair of Hand gloves	Grade B (ISO 7)
6	Airlock / Change room between sterile area and Degowning area	Grade B (ISO 7)
7	Removal of Inner and sterile Garments	Grade C (ISO 8)
8	Removal of Body covering suit and Head Gear / Comfort primary garment	Controlled Not Classified (CNC)
C	**Compounding area and subsequent Change Room Activity**	
1	Manufacturing / Compounding Under LAF	Grade C (ISO 8)
2	Man, material movement outside LAF in Compounding Area	Grade C (ISO 8)
3	Wearing of Body Covering Suit & Head Gear	Controlled Not Classified (CNC)
4	Connecting area between CNC (Wearing of body covering suit & Head Gear) and Grade C (Wearing hand gloves & final garments)	Grade D *
5	Wearing of second suit of Garment (Autoclaved) Wearing of Final Hand Gloves	Grade C (ISO 8)

Note: Grade D * : 'At rest' meets ISO 8

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Table 1 (Contd): LIQUID INJECTION & LYOPHILISATION FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
D	**Component Preparation area and subsequent Change Room Activity**	
1	Component / Garment preparation Under LAF,	Grade C (ISO 8)
2	Component Final Rinse under LAF	Grade C (ISO 8)
3	Component / Garment Loading in Autoclave Under LAF	Grade C (ISO 8)
4	Man and material movement outside LAF in Component Preparation Area	Grade C (ISO 8)
5	Storage of Clean Equipment and Spares	Grade C (ISO 8)
6	Deactivation and / or Washing of the used equipment / accessories / Component	Grade C (ISO 8)
7	Wearing of Body Covering Suit & Head Gear	Controlled Not Classified (CNC)
8	Connecting area between CNC (Wearing of body covering suit & Head Gear) and Grade C (Wearing hand gloves & final garments)	Grade D *
8	Wearing of second suit of Garment (Autoclaved) Wearing of Final Hand Gloves	Grade C (ISO 8)
E	**Vial Washing area and subsequent Change Room Activity**	
1	Vial Washing and Change room for Vial washing	Grade D *
F	**Other Area & Activity**	
1	Primary Gowning area for classified area Entry	Controlled Not Classified (CNC)
2	Corridor approaching all classified area after Primary Gowning area. Material airlock, Entry Exit airlock attached to the corridors.	Controlled Not Classified (CNC)
3	Area under Sampling / Dispensing RLAF / LAF	Grade C (ISO 8)
4	Man and material movement outside RLAF/LAF in Sampling / Dispensing Area	Grade D *

Note: Grade D * : 'At rest' meets ISO 8

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Table 1 (Contd): LIQUID INJECTION & LYOPHILISATION FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
F	**Other Area & Activity**	
5	Vial collection, Empty Vial Inspection, Filled Vial Inspection, Quarantine Storage, Terminal sterilization, Lyophilisation service area, Secondary Packing, RM Store, RM Quarantine, PM store, Vial & Plug store, Bottle store, FG store	Controlled Not Classified (CNC)
6	Primary Gowning area for Controlled unclassified area and Unclassified Area Entry.	Unclassified
7	Corridor approaching to Controlled unclassified area and Unclassified area.	Unclassified

Table 2: EYE DROP FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
A	**Aseptic Area Activity**	
1	Filling Activity, Aseptic connections, Direct product exposure activity under LAF	Grade A (ISO 5)
2	Sterilized material unloading from Autoclave, (Without double wrapped) and storage under LAF	Grade A (ISO 5)
3	Sterilized material unloading from Autoclave (Double wrapped sealed condition) and storage Under LAF	Grade B (ISO 7)
4	Classification of all background areas (outside LAF) for Filling, Suspension Manufacturing, and Cool zone	Grade B (ISO 7)
5	Classification of Corridors and other ancillary areas connected to Grade B/ISO 7 classified processing areas Entry / exit change room attached to Grade B / ISO 7 classified corridor / Processing Areas	Grade B (ISO 7)
6	Area under Extended LAF (where no aseptic manipulation involved)	Grade B (ISO 7)
7	Wash & SIP area	Grade B (ISO 7)
8	Transfer of material through mobile LAF (Class of area under Mobile LAF)	Grade A (ISO 5)
	Transfer of double wrapped material	Grade B (ISO 7)

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Table 2 (Contd): EYE DROP FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
B	**Aseptic Area Change Room process**	
1	Wearing of Body Covering Suit and Head Gear and Removal of Factory Garment and Factory shoes	Controlled Not Classified (CNC)
2	Pass through corridor or change room	Grade D *
3	Wearing of 1st pair of Hand gloves and sterile Inner Garments	Grade C (ISO 8)
4	Wearing of sterile Garments, Hand gloves and Goggles	Grade B (ISO 7)
5	Wearing of Final pair of Hand gloves	Grade B (ISO 7)
6	Airlock / Change room between sterile area and Degowning area	Grade B (ISO 7)
7	Pass through corridor or change room	Grade C (ISO 8)
8	Removal of Inner and sterile Garments	Grade D*
9	Removal of body covering suit & head Gear	Controlled Not Classified (CNC)
C	**Manufacturing Area and subsequent Change Room Activity**	
1	Manufacturing Under LAF	Grade C (ISO 8)
2	Wash area	Grade C (ISO 8)
3	Man, material movement outside LAF in Manufacturing Area	Grade C (ISO 8)
4	Removal of Factory shoes.	Grade D *
5	Wearing of Sterilized Garment (Autoclaved) and Wearing of Hand Gloves	Grade C (ISO 8)
D	**Unit Preparation area**	
1	Unit Preparation, Wash, Autoclave loading Area	Grade D *

Note: Grade D * : 'At rest' meets ISO 8

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Table 2 (Contd): EYE DROP FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
E	**Other Area & Activity**	
1	Primary Gowning area for classified area Entry	Controlled Not Classified (CNC)
2	Corridor approaching all classified area after Primary Gowning area, Material airlock, Entry Exit airlock attached to the corridors.	Controlled Not Classified (CNC)
3	Area under Sampling / Dispensing RLAF / LAF	Grade C (ISO 8)
4	Man and material movement outside RLAF/LAF in Sampling / Dispensing Area	Grade D *
5	Secondary Packing, RM Store, RM Quarantine, PM store, FG store, Water System	Controlled Not Classified (CNC)
6	Primary Gowning area for Controlled unclassified area and Unclassified Area Entry.	Unclassified
7	Corridor approaching to Controlled unclassified area and Unclassified area.	Unclassified

Table 3: FORM FILL SEAL (FFS) FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
A	**Suspension Area Activity and subsequent Change Room Activity**	
1	Suspension Manufacturing, Direct product exposure activity, under LAF	Grade A (ISO 5)
2	FFS Suspension Manufacturing area outside LAF	Grade B (ISO 7)
3	Removal of factory garment	Grade D *
4	Wearing of sterilised inner Garment	Grade C (ISO 8)
5	Wearing of sterilised Garment, Hand gloves, Goggles	Grade B (ISO 7)
6	Wearing of Second pair of Hand gloves	Grade B (ISO 7)

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Table 3 (Contd): FORM FILL SEAL (FFS) FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
B	**Suspension Area Activity and subsequent Change Room Activity (Facility with S2S Connection)**	
1	Suspension Manufacturing, Direct product exposure activity	Grade C (ISO 8)
2	FFS Suspension Manufacturing area	Grade C (ISO 8)
3	Removal of factory garment	Grade D *
4	Wearing of sterilised Garment, Hand gloves, Goggles	Grade C (ISO 8)
5	Wearing of Second pair of Hand gloves	Grade C (ISO 8)
C	**FFS Filling Area Activity and subsequent Change Room Activity**	
1	FFS Filling, Direct product exposure activity, under LAF	Grade A (ISO 5)
2	Air sampling of Fill Zone, Under LAF	Grade B (ISO 7)
3	Sterilized material unloading from Autoclave, Under LAF	Grade B (ISO 7)
	Sterilized material unloading from Autoclave (Double wrapped sealed condition), Under LAF	Grade C (ISO 8)
4	Man and Material movement outside LAF area (FFS Filling area, Filtration area, Cool Zone area, Clean corridor)	Grade C (ISO 8)
5	Removal of factory garment, Factory shoes & Wearing of snood	Grade D *
6	Wearing of sterilised Garment, Hand gloves, Goggles	Grade C (ISO 8)
7	Wearing of Second pair of Hand gloves	Grade C (ISO 8)

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Table 3 (Contd): FORM FILL SEAL (FFS) FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
D	**FFS Manufacturing Area Activity and subsequent Change Room Activity**	
1	FFS solution Manufacturing room	Grade C (ISO 8)
2	Autoclave & DHS loading area, suspension loading area,	Grade C (ISO 8)
3	Wash area, Day Store	Grade C (ISO 8)
4	Removal of shoes and Wearing Feet Covers	Grade D *
5	Wearing of sterilised Garment and hand gloves	Grade C (ISO 8)
E	**Other Area & Activity**	
1	Primary Gowning area for classified area Entry	Controlled Not Classified (CNC)
2	Corridor approaching all classified area after Primary Gowning area. Material airlock, Entry Exit airlock attached to the corridors	Controlled Not Classified (CNC)
3	Area under Sampling / Dispensing RLAF / LAF	Grade C (ISO 8)
4	Man & material movement outside RLAF / LAF in Sampling / Dispensing Area	Grade D *
5	Deflashing & Leak Testing, Secondary Packing, Raw Material Store, Raw Material Quarantine, Packing Material store, Finished Good store, Water System	Controlled Not Classified (CNC)
6	Primary Gowning area for Controlled unclassified area and Unclassified Area Entry.	Unclassified
7	Corridor approaching to Controlled unclassified area and Unclassified area.	Unclassified

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Table 4: NASAL FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
A	Nasal Filling, Nasal Manufacturing, Direct product exposure activity, under LAF	Grade C (ISO 8)
B	Sterilized material unloading from Autoclave, Under LAF	Grade C (ISO 8)
C	Nasal Filling, Nasal Manufacturing, Cool zone area, Clean Corridor, Wash Area	Grade C (ISO 8)
D	**Nasal Filling Change room**	
1.	Removal of factory gown and Factory shoes	Grade D *
2.	Wearing of sterilised Garment, Hand gloves, Goggles	Grade C (ISO 8)
3.	Wearing of Second pair of Hand gloves	Grade C (ISO 8)
E	**Nasal Manufacturing Change room**	
1.	Removal of Factory shoes and wearing of foot cover	Grade D *
2.	Wearing of sterilized Garments and hand gloves	Grade C (ISO 8)
F	Vial Wash & sanitisation, Vial Inspection, Autoclave Loading Area, Entry airlock.	Grade D *
G	**Other Area and Activity**	
1	Primary Gowning area for classified area Entry	Controlled Not Classified (CNC)/
2	Corridor approaching all classified area after Primary Gowning area, Material airlock, Entry Exit airlock attached to the corridors.	Controlled Not Classified (CNC)
3	Area under Sampling / Dispensing RLAF / LAF	Grade C (ISO 8)
4	Man & material movement outside RLAF/LAF in Sampling / Dispensing Area	Grade D *
5	Secondary Packing, Raw Material Store, Raw Material Quarantine, Packing Material store, Finished Good store, Water System, Deboxing area	Controlled Not Classified (CNC)
6	Primary Gowning area for Controlled unclassified area and Unclassified Area Entry.	Unclassified
7	Corridor approaching to Controlled unclassified area and Unclassified area.	Unclassified

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Table 5 : METERED DOSE INHALERS (MDI) FACILITY		
S.No.	**Activity / Area**	**Area Classification**
		In Operation
1	Area Under LAF (Direct product exposure, over filling machine)	Grade C (ISO 8)
2	Area Under LAF (Sampling & dispensing)	Grade C (ISO 8)
3	**Note :- Option I** - If Filling is done under LAF Filling area, Manufacturing area, Process area, day store area, collection area, Change room I & II, Clean accessories	Grade D *
4	**Note: - Option II** - If no LAF installed in Filling area Filling area, Manufacturing area, Process area, day store area, Change Room II	Grade C (ISO 8)
	Collection area, Change room I, Clean accessories	Grade D *
5	Primary Gowning area for classified area Entry	Controlled Not Classified (CNC)
6	Man and material movement outside RLAF/LAF in Sampling / Dispensing Area	Grade D *
8	Secondary Packing, Raw Material Store, Raw Material Quarantine, Packing Material store, Finished Good store	Controlled Not Classified (CNC)
9	Primary Gowning area for Controlled unclassified area and Unclassified Area Entry.	Unclassified
10	Corridor approaching to Controlled unclassified area and Unclassified area.	Unclassified

Note: Grade D * : 'At rest' meets ISO 8

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Table 6: OSD TABLET / HARD & SOFT GELATIN CAPSULE / TOPICAL-OINTMENT FACILITY / ORAL LIQUID FACILITY		
S.NO.	**Activity / Area**	**Area Classification**
		At Rest
1	RM/PPM Sampling Area, RM /PPM Dispensing Area, Manufacturing Area, Sifting Area, Binder Preparation, Solution Preparation, Blending Area, Compression Area, Coating Area, Inspection Area, Capsule Filling Area, Primary Packing Area (Tab / Capsule / Topical-Ointment), Encapsulation & Capsule Drying	ISO 8
2	Liquid Filling and Sealing, Seal Inspection, Clean Bottle area, Bulk Storage area, Mixing cubicle, Bottle Washing, Tankage, Clean equipment room.	ISO 8
3	RM/PM Dispensed Material Store, In process Store, Coating Day Store / Tool Room, IPQC, Manufacturing Spares, Production Corridor, Packing Corridor, Wash area connected to classified area, Packing Change part room inside classified area, Foil printing Area, Change room for classified area Entry, Used Equipment area, Clean equipment Area	ISO 8
4	Area under Sampling / Dispensing RLAF / LAF	ISO 8
5	Secondary packing Area, RM Store, RM Quarantine Area, PM Store, FG Store, Capsule store, QC Area, Water System Area, Accessories and Polybag store, secondary packing In-Process QC, spare part room / change part room outside classified area	Controlled Not Classified (CNC)
6	Bottle storage, Bottle Deboxing activity	Controlled Not Classified (CNC)
7	External Corridor, Primary Change room	Unclassified

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Table 7: MICROBIOLOGY LABORATORY FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
1	Sterility LAF, Sterility Testing Isolators	Grade A (ISO 5)
2	**For Sterility Testing performed under LAF:** Sterility Area and Other ancillary areas connected to Sterility area, Final Change Room for Sterility area,	Grade B (ISO 7)
	Sterility area change room for aseptic Gowning	Grade B (ISO 7)
	Sterility area Entry Change room 1 (for Inner Garment)	Grade C (ISO 8)
3	**For Sterility Testing performed under Isolator:** Sterility Area, and Other ancillary areas connected to Sterility area, Final Change Room for Sterility area.	Grade C (ISO 8)
	Sterility area Entry Change room 1	Grade D *
4	LAF / Biosafety cabinet of Microbiology Testing Area	Grade A (ISO 5)
	Microbiology Testing Area	Grade C (ISO 8)
	Microbiology Testing Area entry change Room 1	Grade D *
5	Biosafety cabinet for Culture Handling area.	Grade B (ISO 7)
	Area and attached Change rooms / Airlock	Grade C (ISO 8) / Grade D *
	Culture Handling Area entry change Room 1	Grade D * / Controlled Not Classified (CNC)
6	Media Preparation, BET Testing, Wash area, Deactivation Area, Incubation, Accessories storage area, Microbiology Corridor, Documentation area and Entry airlock	Controlled Not Classified (CNC)

Note: Grade D * : 'At rest' meets ISO 8

Table 8: API FACILITY		
S.No.	**Activity / Area**	**Area Classification In Operation**
1	Manufacturing Area, Fluid bed Dryer Area, Octagonal Blender Area, Jetmill Area, Crystallisation Area, Vacuum Tray Dryer Area, Centrifuge Area, Fuming Hood Area, Change Room, Packing Room, Store Room, Small volume manufacturing Area, RCVD Area, Wash area#, Clean equipment and accessories area, Material Entry airlock,	Controlled Not Classified (CNC)
2	Intermediate Area, Wash Area#, Accessories Store Area	Unclassified

Key #: To be classified based on the adjacent area classification

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S.No.	Table 9: Activity / Area – API FACILITY (Stores)	Storage condition maintained		Area Classification
		Temperature (ºC)	RH (%)	In Operation
1	API sampling /Dispensing area	18-25	Below 70%	**CNC**
2	Raw material sampling dispensing	15-30	Below 70%	**CNC**
3	Primary Packaging materials sampling /Dispensing	Ambient	Ambient	NA
	Primary Packaging materials Storage	18-25	Below 70%	**CNC**
4	Raw material storage area	Ambient	Ambient	NA
5	Finished goods storage area	18-25	Below 70%	**CNC**
6	Tertiary Packaging Material Storage	Ambient	Ambient	NA
7	Solvent Storage area	Ambient	Ambient	NA

2. Viable Limit for Area Classification:

2.1 Area classification as per EC guideline in operation state for an area, should be considered for Viable limit as per SOP. For e.g. Compounding area of Liquid/Lyo injection facility.

2.2 For ISO 8 Area, the in-house limits set for ISO 8 should be considered.

2.3 For Dynamic passbox, located between areas of different grade, frequency of monitoring, sampling and limits should be as per higher grade area classification. E.g. if the passbox is between compounding area which is grade C and filtration area which is grade B, then the passbox should be classified as Grade B.

2.4 Garment cubicle should be classified as per the area in which it is located.

3. Non-Viable Particulate Count Limit for Area Classification:

All areas connected to classified area for regular operation, should be designed minimum for same class, even if, the requirement for the area is for lower classification. For example: Incase requirement for Vial Collection area is CNC and if this area is attached to a Corridor of Grade D * where all the man-material

movement is done through same corridor then this subsequent area should also be designed as per Grade D * classification.

All LAF which will be classified for Grade B classification, should be designed for ISO 5 air quality.

4. HEATING, VENTILATING AND AIR-CONDITIONING (HVAC) DESIGN:

Table 10:

S.No.	Class of Area (At Rest)	Class of Area (In Operation)	Temp & RH (°C) / (%RH) (Note 5)	Air velocity / Min ACPH (Note 6)	Filters in AHU (Note 1,2,3)	Terminal Filter (Note 3)
1	Grade A / ISO Class 5	Grade A / ISO Class 5	As per background Area	72 to 107 FPM at working Height	Should be FFM Design supply from AHU	H 13 /H 14
2	Grade B / ISO Class 5	Grade B / ISO Class 7	19 to 25 / 35 to 55	65	F6 / F7 + F8 / F9 + H13 /H14	H 13 /H 14
3	Grade C / ISO Class 7	Grade C / ISO Class 8	19 to 25 / 35 to 55	40	G4/ F6 / F7 + F7/ F8 / F9	H 13 /H 14
4	Grade D / ISO Class 8 (Sterile Facility)	Grade D * / NA	19 to 25 / 35 to 55	20	G4 / F6 / F7 + F8 / F9	H 13 /H 14
5	ISO Class 8 (General OSD)	NA	19 to 25 / 40 to 55	20	G4/F6 + F7/F8 /F9 + H 13 /H 14	NA
6	ISO Class 8 (Potent OSD process area)	NA	19 to 25 / 40 to 55	20	G4(Riser Terminal) + H 13 /H 14 (BIBO on Riser top) +	H 13 /H 14
7	CNC	CNC	15 to 25 / NMT 60/75	10	G4/ F6 / F7 + F7 / F8 / F9	NA
8	Unclassified	Unclassified	15 to 25 / NA	6	G4/ F6 / F7 + F7 / F8 / F9	NA

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Note :-

1. Final Filtration of HVAC for all classified area should be H13 / H14. For new design H14 filters to be selected.

2. Fresh air supply can be through separate Fresh air unit or can be through G4 filter, selection of filter or fresh air unit depends on facility design.

3. Bleed air filter should be G4 for general exhaust, F9 for general OSD facility and H13/14 for potent drug handling facility.

4. Safe change Bag-in-bag out filter system should be considered in HVAC for potent drug handling facility.

5. Temperature / RH limits are specified for HVAC deign purpose, however Temperature & RH limits may vary as per:
    a. Product requirement, for eg. Low RH for hygroscopic product or low temperature for temperature sensitive products.
    b. Operation limits for area will be as per Temperature & RH limits as per Corporate / Unit level SOPs.
    c. Operational Temperature limits for Autoclave loading / unloading, water system, incubator area shall be up to 27 / 30 °C.

6. Proposed Air Changes per Hour are for designing the HVAC system, however operational limits may vary as per present installation, current controls, maintaining differential pressure, mutually agreed parameters, unit level / corporate level SOP.

7. The details provided in HVAC design Table are basic details for designing the HVAC system, however there may be variation in the filtration, Temperature and relative humidity limits as per present installation, project requirement, facility design and product / process requirement.

5. Other Factors which should be considered during designing of HVAC system:

5.1 Geographical conditions shall be Ambient.

5.2 Differential Pressure:

- For adjacent different class of area, shall maintain minimum 15 Pascal.
- For adjacent same class of area, shall maintain 05 to 10 Pascal.
- General dosage facility should be designed at Positive pressure with atmosphere.
- Potent facility should be designed with Negative pressure with atmosphere.

5.3 Airflow and Air Handling Units (AHU):

- Aseptic area AHU should be designed considering Aerial disinfection facility.
- Airflow of the area should be designed such that air should flow from higher class to lower class.
- Terminal HEPA Filter should be Gel type design, for zero side leakages.
- Area recovery should be within 15 minutes.
- For Fresh Air, the air changes per hour (ACPH) should be minimum 02 or Fresh air CFM should be 10% of Total CFM achieved in the area.

5.4 Facility Design:

- All entry / exit point of the building should have bubble type / sink type / cascade type airlock to avoid contamination to the process area and / or to the Environment.
- Door size, its opening (gap) and its Number of open / close movements.
- Any opening, cut-outs in the area, which may lead to bleed Cubic Feet per minute (CFM).
- Cooling and Heating Media should be available.
- Low level return riser should be considered for all clean area and should be distributed in area on all sides for proper air distribution.
- Flameproof (FLP) / Non-Flameproof (NFLP) design
- Occupancy.
- Sensible and Latent Heat load in the area.
- Point exhaust, if any.
- Condensate Drain should be appropriately located above ground level for easy maintenance.

AMENDMENT AND WAIVER :

POLICY ON AREA CLASSIFICATION OF FACILITY& HVAC DESIGN

The company reserves right to amend, alter and/or terminate this policy at any time.

DEFINITION :

Aseptic area / Critical area : An area designed to maintain sterility of sterile materials.

Aseptic area activity / Aseptic Processing : Handling sterile material in a controlled environment.

Aseptic manipulation : Intervention or activity that occurs within the critical area.

As-built: Condition where the cleanroom or clean zone is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present.

At- rest: Condition where the installation is complete with equipment installed and operating in a manner agreed upon, but with no personnel present.

Classification: Method of assessing level of cleanliness against a specification for a cleanroom or clean zone.

Clean room: Room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room.

Clean zone: Defined space in which the concentration of airborne particles is controlled and classified and which is constructed and operated in manner to control the introduction, generation, and retention of contaminants inside the space.

Controlled Area: An area within the facility in which specific environmental facility, conditions and procedures are defined, controlled, and monitored to prevent degradation or cross-contamination of the product.
Operational: Agreed conditions where cleanroom is functioning in the specified manner with the specified number of personnel present and working with machines runs under standard operating conditions.

ABBREVIATIONS:

AHU : Air Handling Unit
API : Active Product Ingredient
ACPH : Air Changes per Hour
CFM : Cubic Feet per Minute
CNC : Controlled Not Classified
HEPA : High Efficiency Particulate Air
LAF : Laminar Air Flow
NVPC : Non-Viable particulate count.

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