User Requirement Specification for Open Front containment Station

TABLE OF CONTENTS

S.No		Description
1.	Approvals	
2.	Change history	
3.	Purpose	
4.	Scope	
5.	Specifications	
	5.1.	Description of equipment/ system
	5.2.	Equipment identification number and location
	5.3.	Intended use
	5.4.	Intended type of material to be handled
	5.5.	Construction
	5.6.	Capacity
	5.7.	Electrical construction
	5.8.	Control Parameters
	5.9.	Acceptable tolerance for control parameters
	5.10.	Type of control
	5.11.	Parameters must be feasible to be set.
	5.12.	Parameters to be indicated by control system
	5.13.	Available utilities
	5.14.	Any limitation constraints
	5.15.	Regulatory requirements
	5.16.	Delivery address
6.	Safety	
7.	Vendors scope	
	7.1.	Maintenance
	7.2.	Spare part
	7.3.	Support
	7.4.	Validation support
8.	Documentations	
9.	Reference	

User Requirement Specification for Open Front containment Station

1 Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2 Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

This document is generated under the authority for the purpose of specifying the user requirement for Open Fronted Containment Station. The URS is also provided to the Supplier to provide a price quote for the Open Fronted Containment Station including the design and manufacture of the machine.

4. Scope:

The User Requirements Specification (URS) is applicable for the Open Fronted Containment Station.

5. Specifications:

5.1. Description of the Equipment/ System: The Open Fronted Containment Station is required for dispensing / sampling, transfer and closing of pharmaceuticals in protected environment.

The down flow air produced within the booth's safe work zone area forces the HEPA Filtered air over operator's head and shoulders and downward towards the low-level exhaust system.

The down draught prevents airborne dusts caused by weighing and dispensing operations rising into the operator's breathing zone. The air forced downwards is extracted at low level into the booth's filtration system where dust particles are contained at each level of filtration prior to being re-circulated back into the booths' air stream.

Part of recirculatory air is exhausted through HEPA Filter in the room, thus ensuring negative pressure with in working zone. This provides the HEPA filtered coverage for material exposed as well as safety for operator.

5.2. Equipment identification number and location

S.No	Equipment Name	Equipment Identification number	Working size in Inches (W x D x H)	Location	Remarks
1	Open Fronted Containment Station	S/001	72 x 48 x 84	Dispensing Area	2 No stand alone SS perforated platform complete SS body on vibration isolation. Sodium vapor lamp shall be provided.
2	Open Fronted Containment Station	S/002	48 x 48 x 84	Sampling Booth	2 No stand alone SS perforated platform complete SS body on vibration isolation.

5.3. Intended Use

The Open fronted contamination booth will be used for Dispensing of excipients and non sterile active ingredients / and sampling of excipients and active ingredients. The equipment should be designed for continuous run and shall not experience any major breakdown because of workmanship. The equipment is intended to be in operation one shifts daily 6 days a week.

5.4. Intended type of material to be handled: This equipment shall be used for dispensing / sampling / weighing excipients and non sterile active ingredients

5.5. Preferred material of construction:

5.5.1. Preferably the entire equipment be made out of SS 304 quality material & provide with adequate arrangement such as coving etc. for easy smooth cleaning.

5.5.2. Supply air must be filtered through HEPA, EU-13 or equivalent filter. Filter must be provided with adequate arrangement for mechanical damage.

5.5.3. SS 304 protection grills must be provided for mechanical damage on return/suction filter.

5.5.4. Bleed filter bank for 10% of the total air displacement for slight negative pressure in workplace. The exhaust air must be filtered through HEPA, EU13 or equivalent filter.

5.5.5. DOP port: DOP introduction port to be provided for upstream challenge of the HEPA filter.

5.5.6. Air sampling port at the down stream side of the scavenging pre filter and intermediate filter.

5.6. Capacity: Not applicable

5.7. Electrical construction: Enclosed clean room lighting units capable of producing approximately 300 lux.

Unit must be provided with following facilities

Tag No. S/001- 3 nos. 5 amp. Capacity switch/socket

- Independent operation/control for lighting & blower.

Tag No. S/002- 2 nos. 5 amp. Capacity switch/socket.

- Independent operation/control for lighting & blower.

Either of above units must be provided Sodium Vapor Lamp.

5.8. Control parameters:

- Clean of cleanliness equal to or better than ISO-8 ref. ISO 14644-1
- Air flow pattern to ensure that smoke generate is scavenged towards return air grill.

5.9. Acceptable Tolerance for control parameters:

S.No	Parameter	Limits
1.	Air velocity	90 feet/minute ± 20 %
2.	Vibration	Adequate measure to be provided to isolate blower vibrations ensuing balance table is not disturbed.
3.	Noise	Less than 65 decibels @ 1 meter distance.
4.	Differential pressure	Should be minimum 5 Pa negative w.r.t. room.

5.10. Type of control:

The supplier shall provide all relays / switchgear of Siemens/ Telemechanique.

Power ON indicator light, Blower ON indicator, and light switch shall be provided.

5.11. Parameters must be feasible to be set: Not applicable

5.12. Parameters to be indicated by control system:

Differential pressure: 0-25 Magnehelic gauge (Dwyer make) to indicate differential pressure across HEPA filter with respect to atmosphere.

Differential pressure: 0 -25 Magnehelic gauge (Dwyer Make) to indicate differential pressure across intermediate pre filter to atmosphere.

5.13. Available Utilities: Electrical power 440-3 phase 50 Hz/ 220 1phase 50 Hz is available.

S.No	Equipment Name	Equipment Identification number	Location	Height from the floor for suspension
1.	Open Fronted Containment Station	S/001	Dispensing Area	3 meter
2.	Open Fronted Containment Station	S/002	Sampling Booth	3 meter

It shall operate within an environment temperature range of 23+/- 2°C.

5.14 Limitation and constrains: Not applicable

5.15 Regulatory Requirements:

5.15.1 The Open Fronted Containment Station shall be designed to meet the appropriate GMP regulations at the time of order.

5.15.2 The Open Fronted Containment Station shall meet the appropriate safety regulations. E.g.: OSHA regulations for the safety of operators of equipment with regards to safety, guarding and noise.

5.15.3 Manufacturer must provided at minimum following

- In-Situ HEPA installation leak test report.
- Air velocity measurement.
- Cleanliness clean verification using desecrate particle counter.
- Individual HEPA filter & fen certificate.
- Air flow visualization using suitable smoke test.

5.15.4 Wiring on the machine and in the control cabinets shall be terminated at both ends and match the numbering shown in the documentation.

5.15.5 Control components shall be identified with a tag number consistent with the documentation.

5.16 Delivery address:

The Open Fronted Containment Station with all options, equipment, along with the documentation shall be delivered to the User's receiving dock at the site.

6. Safety:

6.1. Safety related faults should be taken care of to alarm indication or machine stoppage in a logical manner.

6.2. The systems should not cause any emergency or hazardous situation, during correct operation/maintenance.

6.3. Audiovisual alarm for motor blower trip as safety features.

6.4. Multi functional digital timer for clean down for cGMP start up.

7. Vendors scope:

7.1. Maintenance

The equipment is to be designed for long maintenance free periods. The supplier shall provide list of maintenance items and duration interval. All the adjustment points shall be identified and must provide instructions for its adjustment. There must be good access for routine operation and maintenance.

7.2. Spare Parts

7.2.1. A suggested spare parts listing will be provided

7.2.2. The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.3. Support

7.3.1. Start-up Support shall consist of full assistance on the User's site for installation, start-up commissioning, and training.

7.3.2. The vendor shall provide suitable training for the users as appropriate.

7.3.3. Post start-up support shall be provided whenever required by the Site after the completion of commissioning activities.

7.3.4. Technical support shall be available via telephone / mail following the completion of commissioning.

7.4 Validation support: The Supplier shall provide full support during the Installation qualification (IQ), Operational qualification, (OQ).

8. Documentation:

8.1. All documents shall be in English language.

8.2. The validation documentation package should include comprehensive documentation for installation qualification (IQ) and Operational qualification (OQ). The supplier shall ensure that all the documents as may be required for qualification of the machine as per the current cGMP guide lines shall be provided by the supplier.

9. Reference guidelines:

9.1. ISO 14644-1 -Clean rooms and associated controlled environments-Part 1: Classification of airborne particulates.

9.2. WHO guide to good manufacturing Practices (GMP) requirements Part 2:

9.3. Annexure 15 to EU guide to Good Manufacturing Practices..

9.4. USFDA guideline 21 CFR part 211 section 63,65,67.