**DESIGN QUALIFICATION**

**FOR**

**AIR HANDLING UNIT (AHU)**

**DOCUMENT NO: GK/HVAC/VPL/DQ/AHU**

**SUBMITTED TO:**

**CLIENT NAME:**

**Apotex Pharmachem India Pvt.Ltd**

**Plot No 1A, Bommasandra Industrial Area, 4th phase,**

**Bommasandra Industrial Estate (Post office),**

**Bengaluru, Karnataka 560099,India**

**SUBMITTED BY:**



**GK AIR SOLUTIONS**

**WS 50, KSSIDC Indl. Estate, Jigani Ambedkar Indl.**

**Area, Jigani, Anekal Taluk**

**Bangalore- 560105.**

**TABLE OF CONTENTS**

[1.0 INTRODUCTION: 3](#_Toc90892676)

[2.0 PURPOSE: 3](#_Toc90892677)

[3.0 SCOPE : 3](#_Toc90892678)

[4.0 RESPONSIBILITY: 4](#_Toc90892679)

[5.0 ABBREVIATIONS: 4](#_Toc90892680)

[6.0 AIR HANDING UNIT SYSTEM DESCRIPTION : 5](#_Toc90892681)

[7.0 BASIC ROOM DETAILS COVERED BY THE AIR HANDLING UNIT: 6](#_Toc90892682)

[9.0 AIR HANDLING SYSTEM DESIGN SUMMARY SHEET: 6](#_Toc90892684)

[10.0 SYSTEM DESCRIPTION – MAJOR COMPONENTS 7](#_Toc90892685)

[12.0 SUMMARY AND CONCLUSION: 9](#_Toc90892687)

[13.0 LIST OF ATTACHMENTS 9](#_Toc90892688)

[14.0 PROTOCOL POST APPROVAL: 10](#_Toc90892689)

# INTRODUCTION:

This document is to specify the design details of the Air Handling Unit (AHU) and its major components that shall be installed in APOTEX PHARAMACHEM INDIA PVT,LTD. In Bommasandra industrial area.

# 2.0 PURPOSE:

The design specifications and the data provided in this protocol provide the basis for installation qualification and other subsequent check.

The:

* ISPE Guidelines (international society for pharmaceutical engineers).
* ASHRAE standards (American society of heating, refrigerating & air conditioning engineers).
* Recommended practices of equipment suppliers.
* Guidelines on good manufacturing practices for HVAC by WHO (World health Organization).

# 3.0 SCOPE :

The protocol outlines the design specifications safety features and other parameters of the air handling unit AHU and its major components. The documents are prepared on the basis of the requirements listed in the User requirement specifications (URS)/Room Data Sheet (RDS) document.

# 4.0 RESPONSIBILITY:

|  |  |  |
| --- | --- | --- |
| **Sl. No.** | **Organization** | **Responsibility** |
| 1 | GK AIR SOLUTIONS | * + - To prepare the Protocol (as per QA Requirement of VPL Chemicals) checking the protocol for adequate & accuracy prior to approval.     - Review & confirm of specifications provided by Client / Consultant     - Preparation of DQ & Summary Report. |
| 2 | APOTEX PHARMACHEM  PVT LTD | * + - Review of DQ     - Providing guidance, whatever required to related documents. |
| * + - Approval of DQ     - Providing guidance, whatever required to related documents. |
| * + - Authorization of DQ     - Providing guidance, whatever required to related documents. |

# 5.0 ABBREVIATIONS:

|  |  |  |  |
| --- | --- | --- | --- |
| AHU | Air Handling Unit | µ | Micron |
| mm | Millimeter | ACPH | Air Changes Per Hour |
| RPM | Revolution per minute | URS | User Requirement Specification |
| CGMP | Current Good Manufacturing Practice | RDS | Room Data Sheet |
| Pa | Pascal | BOD | Basis of Design |
| CFM | Cubic feet per minute | NMT | Not More Than |
| CMH | Cubic meter per hour | GI | Galvanized Iron |
| Deg.C | Degree Celsius | GSS | Galvanized Steel Sheet |
| DQ | Design Qualification | MOC | Material of Construction |
| FPM | Feet per minute | VCD | Volume Control Damper |
| KW | Kilo Watt | Atm | Atmosphere |
| m/s | Meter per second | NC | NO CONTROL |
| Max | Maximum | CNC | Control Not Classified |
| Min | Minimum | HVAC | Heating Ventilation and Air Conditioning |
| NA | Not Applicable | VAV | Variable Air Volume |
| TR | Tonnage of Refrigerant |
| FPI | Fins Per Inch |
| SS | Stainless Steel |
| F. S | Full Scale |
| WC | Water column |
| G | Gauge |
| RH | Relative Humidity |
| Temp | Temperature |
| UC | Unclassified |

# 6.0 AIR HANDING UNIT SYSTEM DESCRIPTION :

The complete system is consisting of air handling unit, air distribution network, filtration system and necessary control and monitoring mechanisms. Double skin air-handling unit, horizontal floor mounted type mainly comprises of Pre filter G4, fine filter EU5, DX type cooling coil, centrifugal type belt driven blower.

The blower sucks the air through G4 and EU5 grade air filter. After filtration this fresh air and pass over cooling coil to cool the air to required temperature. This filtered air further passed through duct. Thus, conditioned air is passed through insulated ducts to respective rooms to maintain desired conditions.

The supply air is fed from ceiling fitted HEPA Modules through condition space and return air is being sucked by raiser. Temperature is achieved by circulation of refrigeration in cooling coil. The quantity of air is controlled by volume control dampers are provided in the supply and return air ducts which will control the air volume as per the requirement.

Outdoor refrigeration unit of desired capacity is installed connecting to respective AHU. This cooling system modulates w.r.t room air conditions and ensures desired conditions within connected areas. Magnehelic gauges are mounted on the unit across the pre filters and fine filters to indicate the pressure difference across these filters for monitoring the cleaning / replacement frequency of the filters.

# 7.0 BASIC ROOM DETAILS COVERED BY THE AIR HANDLING UNIT:

# Design Conditions:

| **Sl. No** | **Room Description** | **Grade** | **Room Volume in Cu. Mts.** | **Temp. (°C)** | **RH (%)**  **NMT** |
| --- | --- | --- | --- | --- | --- |
| 1. |  |  |  |  |  |
| 2. |  |  |  |  |  |
| 3. |  |  |  |  |  |
| 4. |  |  |  |  |  |
| 5. |  |  |  |  |  |
| 6. |  |  |  |  |  |
| 7. |  |  |  |  |  |
| 8. |  |  |  |  |  |

**8.0 REFERENCE DOCUMENTS LIST IN COMMON REFERENCE FILE:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Annexure No** | **Description** | **Reference Document no** | **No. of Pages** |
| Annexure No. 1 | Room data sheet (RDS) |  | 1-1 |

# 9.0 AIR HANDLING SYSTEM DESIGN SUMMARY SHEET:

|  |  |  |
| --- | --- | --- |
| **Season** | **Temperature (ᵒF)** | |
| **Dry Bulb** | Wet Bulb |
| Summer | 104 | 86 |
| Monsoon | 82 | 78 |
| Winter | 58 | 54 |

# 10.0 SYSTEM DESCRIPTION – MAJOR COMPONENTS

# AIR HANDLING UNIT:

| **Sl. No.** | **Parameter** | **Specification** |
| --- | --- | --- |
| **1** | **AHU** | |
| Make/Model | GK AIR SOLUTIONS/ AHU-6000/125 |
| AHU Capacity | 1500 CFM |
| Type of unit | DRAW THROUGH TYPE |
| Cooling Capacity | 13 TR |
|
| **2** | **Unit Body** | |
| Type | Double Skinned Insulated with thermal break profile with 25 mm, PUFF insulated. |
| Profile Type | Thermal Break PUF |
| Inner Sheet thickness | 0.6 mm |
| Outer Sheet thickness | 0.8 mm |
|  |  |  |
| **3** | **Supply Air Blower** | |
| Make | KRUGER |
| Fan type | CENTRIFUGAL FAN |
| CFM | 1CFM |
| Static Pressure | 140 mm WG |
|  |  |  |
| **4** | **Motor** | |
| Make | CG |
| Motor Efficiency | 90% |
| Capacity | 7.5 kW |
| RPM / Hz | 2576 /44Hz |
|  |  |  |
| **5** | **Cooling Section** | |
| Capacity | 13 TR |
| Coil Dimension | 980mm (H) x 980mm (L) |
| Tube Material | Copper |
| Tray Material | SS 304 |
| Fin Material | Aluminum |
| Number of rows | 6 RD |
| Tube Thickness | 0.41mm |
|  |  |  |
| **6** | **Pre-Filter** | |
| Grade | EU4 |
| Filter Media | Synthetic Media |
| Make | AAF |
| Size (H x W x D) / Qty | 610x610x 50 / 02 No’s and 610x300x 50 /02 No’s |
| Efficiency | 90 % down to 10µ |
|  |  |  |
| **7** | **Fine Filter** | |
| Grade | EU7 |
| Filter Media | Synthetic Media |
| Make | AAF |
| Size (H x W x D) / Qty | 610x610x 300 / 02 No’s and 610x300x300 /02 No’s |
| Efficiency | 95 % down to 5µ |
| Location | Blower Access Door |
|  |  |  |
| **8** | **Fresh Air Filter** | |
| MAKE & TYPE | AAF |
| EFFICIENCY | 90% Down to 10 microns, EU4 |
| SIZE (mm) & QTY | 250 x150x50 – 1 no |
|  |  | |
| **9** | **Bleed Air Filter** | |
| MAKE & TYPE | AAF |
| EFFICIENCY | 99.95% Down to 0.3 microns, H13 |
| SIZE (mm) & QTY | 250x150x50-1 no |
| **10** | **HEPA Module** | |
| Make | GK AIRSOLUTIONS |
| Module Size | 610 x 610 - 05Nos |
| 450 x 450 - 08Nos |
|  |  |  |
| **11** | **Outdoor Unit** | |
| MAKE & TYPE | VOLTAS & DUCTABLE TYPE |
| CAPACITY | 13 TR |
|  |  |
| **12** | **Magnehelic Gauges** | |
| MAKE & TYPE | DWYER |
| RANGE | 0-100 mmwc |

1. **DUCTING MATERIAL:**

|  |  |  |
| --- | --- | --- |
| **Sl. No.** | **Parameter** | **Specification** |
| 1. | Sheets | GI SHEETS |
| 2. | Make | JINDAL / TATA |
| 3. | Coating | 120 GSM GI |
| 4. | Connecting Termination | TDF Flanges with GI Clamps |

1. **DUCT INSULATION:**

|  |  |  |  |
| --- | --- | --- | --- |
| **SI. No.** | | **Parameter** | **Specification** |
| 1 | | Material | PE Cross Linked Foam |
| 2. | | Make | SUPREME |
| 3. | | Air conditioning SA ducts | 19 mm thick, with Al. Foil |
| 4. | | Air conditioning RA ducts | 13 mm thick, with Al. Foil |
| 12.0 SUMMARY AND CONCLUSION: All the user requirements are verified against design documents (technical specification) of proposed AHU as per protocol: GK/HVAC/VPL/DQ/AHU and following parameters/sections are considered for the design.   * AHU system description * AHU GA drawing * Room data sheet   There were no deviations identified during design qualification. Hence the equipment shall be cleared for future qualification activities. 13.0 LIST OF ATTACHMENTS  |  |  |  |  | | --- | --- | --- | --- | | ANEXTURE NO. | DOCUMENT NAME | DOCUMENT REFERENCE NO. | No. Of PAGE | | 1 | Room data sheet (RDS) |  | 1-1 | | 2 | AHU GA DRAWING |  | 1-1 | | 3 | AIRFLOW DRAWING |  | 1-1 | | 4 | DUCTING DRAWING |  | 1-1 | | | | |
| 14.0 PROTOCOL POST APPROVAL:  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **GK AIR SOLUTIONS** | | | | | | **Prepared by:** | **Name** |  | **Signature & Date** |  | | **Designation** |  | | **Reviewed by:** | **Name** |  | **Signature & Date** |  | | **Designation** |  | | **VPL CHEMICALS PVT LTD..** | | | | | | **Reviewed by:** | **Name** |  | **Signature & Date** |  | | **Designation** |  | | **Reviewed by:** | **Designation** |  | **Signature & Date** |  | | **Name** |  | | **Approved by:** | **Designation** |  | **Signature & Date** |  | | **Name** |  | | | | |