CDP
SAMPLING AND WEIGHING POWDER CONTAINING BOOTH

ARTICLE DESCRIPTION
CDP 48
CDP 72

CODE
n. SI083029960
n. SI083029340

1.0 GENERAL DESCRIPTION OF THE SYSTEM

The scope of this document is the technical description of the CDP cabinet for powder containment in sampling and dispensing operations.

The CDP cabinet is a containment solution for the weighing, the handling and the dosing of chemical and pharmaceutical active products with the operator outside the LAF (laminar air flow) area.

This CDP cabinet is a vertical laminar flow of Class M 3.5 (Fed. Std. 209 E) air, with a vertical return grid on the frontal side supplied with absolute filter on recovery and recirculation air. The cabinet is designed with part of the air recirculated and quote of air exhausted outside, after absolute filtration.

The equipment is not designed to work in ex-proof classified room and in tropical climatic condition (more than 50°C).

2.0 OPERATING PRINCIPLE

The CDP cabinet is a containment solution for the handling and dosing of non sterile products (including medium/low active ingredients and excipients) with the operator outside the LAF (laminar air flow).

The identified and carefully estimated factors considered as essential, with particular reference to process and safety requirements, are:

- protection of the product;
- protection and safety of the operator;
- containment of handled product;
- cleanness of working area;
- ergonomic factors.

2.1 Main design features

The operator and product protection by cross contamination between environmental/product and vice versa will be obtained with a physical containment into handling area powder, with a slight negative pressure inside the cabinet and a airflow barrier at level of front working aperture.

The air front barrier is designed to permit an aspiration equal to 30% of the total air with a minimum air frontal velocity of 0.40 m/s and recirculation of the remaining 70% of the air on the working area in laminar air flow condition equal to a velocity of 0.45 m/s +/-20%.

The sterility – cleanness of working area is guaranteed by a filtration of the air by absolute HEPA filter H14 and velocity of 0.45 m/s +/-20%.

As far as product protection from the operator is concerned, it also relies on the down-flow of the HEPA filtered air, as well as on the appropriate personal protection devices like individual garments including mask, headgear, white coat, gloves and compliance with all the sanitary and safety regulations recommended in the Operating Manual of the CDP cabinet and in the user safety procedures (like cGMP).

3.0 TECHNICAL FEATURES
The cabinet is made by a self supporting structure press-bent metal sheet of stainless steel AISI 304L with scotch brite finishing with radius of about 3 mm curvature.

The physical surrounding containment of working chamber is made of aluminium anodised structure and stainless steel blind panel in the lower part of the structure and safety glass side walls.

The hinged front window is made of stratified glass with gas springs fitted outside the working area. The lightning system is made of fluorescent lamps on the front part outside the working area.

The part of the structure under the working surface is equipped with 2 doors for an easy access to the filters.

The electrical control board is located on the front panel with the electrical components and board outside the contamination area for safe electrical service operations.

Ventilation system: ventilation is achieved by two centrifugal fans double inlet type LEMMENS mod. DD10/10 ECMd2 complete of microprocessor control regulation for automatic compensation of clogging pre-filters/filters, four poles, single phase 230V, 50 Hz, 0.75 Kw, with optimisation of the air ducts. Grade protection IP44.

Filtration system: the upper filtration area is shielded by a diffuser film made of inorganic material, supplied as integral part of HEPA filters.

Plenum: in textile material for a distribution of the air and reduction of noise. Designed in negative pressure to prevent escape and/or by pass of HEPA filter by contaminated air and/or dust.

Air treatment:
- pre-filtration stage by G3 Class Eurovent, 80% Arrestance;
- absolute filtration stage (total air), formed by H13 type HEPA filters
- absolute filtration stage (work area), formed by H14 type HEPA filters;
- absolute filtration stage (exhaust air), formed by H14 type HEPA filters.

4.0 OPERATION

4.1 Control panel, electric drives and alarms

The system control can be set into stand-by/ready for operating by turning on the main switch i.e. acting on the control panel where the following functions are foreseen:
- Power ON/OFF section switch;
- Light ON/OFF;
- Laminar air flow velocity (m/s) display;
- Green/Red indicator light for correct fan functioning;
- Green/Red indicator light for exceed of maximum filter pressure drop
- Red indicator light for non correct pressurisation of HEPA filters;
4.2 **Booth indicator gauges**

The booth is equipped with analogical differential pressure gauges placed on the vertical backside wall:

A pressure gauge is installed near the first pre-filtration stage and one over the control panel; they show respectively differential pressure at the pre-filtering bank and at the absolute filtering stage, therefore they highlight the progressive clogging and saturation of pre-filters and HEPA filters.

5.0 **SERVICING / PERIODICAL MAINTENANCE**

All the routine servicing and the extraordinary maintenance should be carried out by disconnecting the instrument from the main power. All maintenance can be carried out within the working area.

The routine maintenance of the CDP cabinet consists mainly in the replacement of the following components:

- HEPA filters;
- fluorescent tubes.

6.0 **SAFETY REQUIREMENTS**

The apparatus is designed, realised and installed according to the safety rules and standards into force, and particularly according to:

- DPR 547/55
- EN 392
- EN 292
- EN 60204-1

The apparatus is also manufactured according to:

- LOW VOLTAGE DIRECTIVE 73/23/EEC - 93/68/EEC

Contamination class: M3,5 "as built" according to FED 209E

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**IMPORTANT !!**

The apparatus we produce, according to the above statements, are manufactured in compliance with the laws on safety into force. Particularly, they are manufactured in compliance with Art. 6 Dlgs 626/94 and its modification (Italian law in compliance with European Directive EEC/89/391) on the DUTY OF DESIGNERS, OF MANUFACTURERS, OF SUPPLIERS AND INSTALLATORS.

The equipment are NOT submitted to the directive EEC 93/42 on Medical Devices, as indicated in the definition of “Medical Devices” reported in art. 1 point 2a of the Directive mentioned.

STERIL IS NOT responsible for damages to people and objects due to a non proper use of the equipment, and due to a fail to comply with the user instructions and maintenance that are always supplied with the cabinets.

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7.0 **APPROVAL TESTING AT MANUFACTURING PLANT (F.A.T.)**

After assembly, the machine is tested at the manufacturing plant in order to verify the product conformity to the warranted technical data.

Steril carries out the following functional tests:

- average air flow velocity;
- front opening air velocity;
- DOP/DOS test for the HEPA filters;
- cleanliness class of the work area according to Fed. Std. 209 E;
- noise level;
- luminosity;
- HEPA filter clogging threshold;
- measurements of current leakage and earth bond;
- as standard procedure, the Test Certificate is supplied.
8.0 AVAILABLE UTILITIES WITHIN BATTERY LIMIT

Electric power 230V/1/50 Hz Customer charge.

9.0 SUPPLY EXTENSION

9.1 Inclusions:
- all the components described in the present document;
- all the documents described in chapter 11.0;
- unit packaging (wooden cage).

9.2 Exclusions:
- delivery to the customer plant;
- unloading at the customer plant;
- transport inside the customer plant;
- building, mechanical, electrical, etc. works for the installation of the booth;
- equipment and components custody inside the customer plant;
- electrical installation;
- installation;
- site testing and start up.

10.0 DOCUMENTATION

The following documentation will be supplied:
- drawing of the assembled unit;
- electrical diagrams;
- operator and maintenance manual according to EEC 89 / 392 directive;
- test reports;
- declaration of conformity.

11.0 INSTALLATION, MOVEMENT AND SHIPMENT

Installation shall be done by qualified personnel.

Shipment and movement During shipment the booth is normally packed and laid onto pallets. The pack is formed by two wooden crates where the booth lies in three pieces, rolled up in propylene sheets.
The package requires lifting equipment to be moved.

12.0 TECHNICAL INFORMATION TABLE

<table>
<thead>
<tr>
<th></th>
<th>CDP 48</th>
<th>CDP 72</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall dimensions (LxDxH mm)</td>
<td>1400x2700x2800</td>
<td>1980x1532x2450</td>
</tr>
<tr>
<td>Work area (LxDxH mm)</td>
<td>1200x750x900</td>
<td>1800x822x800</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>300</td>
<td>400</td>
</tr>
<tr>
<td>No. of Motorfans 230 V, 50 Hz, 1.52 Kw</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>No. of Prefilters 80% Efficiency G3 (593x593x25 mm)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>No. of HEPA filters H13 (595x595x292 mm) CANISTER</td>
<td>1</td>
<td>/</td>
</tr>
<tr>
<td>No. of HEPA filters H13 (595x595x292 mm)</td>
<td>/</td>
<td>2</td>
</tr>
<tr>
<td>No. of HEPA filters H14 (762x1830x68 mm)</td>
<td>/</td>
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<tr>
<td>No. of HEPA filters H14 (762x1220x68 mm)</td>
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<td>/</td>
</tr>
<tr>
<td>No. of HEPA filters H14 (610x762x115 mm)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total air flow volume (m³/h)</td>
<td>2100</td>
<td>3230</td>
</tr>
<tr>
<td>Air flow volume with a 0.45 m/s LAF</td>
<td>1500</td>
<td>2260</td>
</tr>
<tr>
<td>Exhaust air flow volume (m³/h)</td>
<td>600</td>
<td>970</td>
</tr>
<tr>
<td>Voltage</td>
<td>230 V – 50Hz</td>
<td>230 V - 50Hz</td>
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<tr>
<td>Ampere (A)</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>No. of Fluorescent lights 58W</td>
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<td>2</td>
</tr>
<tr>
<td>No. of Fluorescent lights 30W</td>
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<td>/</td>
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