Structural Solutions Private Limited

No: 0709

Technology News

May, 2007



Pharma Chambers



Weiss Umwelttechnik GmbH, Germany is one of the most important producers of standard testing chambers and special test systems for environmental simulation worldwide. The product range comprises temperature and climate testing systems as well as test systems for simulated exposure to weather, temperature shock, corrosion and for long-time testing in various test chamber volumes. To constantly maintain high quality and stability of pharmaceutical and medical products Weiss Umwelttechnik GmbH offers a standard range of stability test chambers in any size depending on your requirement. Walk-in /drive-in chambers and process-integrated plants for environmental simulation and biology and stability chambers are designed, produced and installed in accordance with customer specifications. Weiss Umwelttechnik is certified according to DIN EN ISO 9001.

Structural Solutions Private Limited is the authorized exclusive Indian representative of "Weiss Umwelttechnik Gmbh". Structural Solutions Private Limited is a professional Engineering Company engaged in offering high-end technology-intensive products and systems solutions for the complete range of "Environmental Chambers".

The Weiss Pharmaceutical Chambers has been developed with special features to fulfill the requirements of test laboratories in the pharmaceutical industry with three different sizes of Pharma 600, Pharma 1300, Pharma 2000 and Table Top Chambers of 34,100,120

The range of working for these chambers meets the requirements of the ICH Guideline Q1A and also permits the implementation of tests with other specifications in the performance range of respective system.

Temperature and humidity is controlled with highly precise sensors in combination with specially designed control unit. This specially designed control system responds very quickly and corrects the set-point variations caused by the influence of the cabinet's conditions and the external influences.

Standard Features:

- Micro-processor monitoring and control MINCON/32*
- Software Safety temperature limiter to protect the chamber against overheating
- Serial interface RS 232 C
- Lockable doors
- Door Contact Switch
- Transportable on wheels
- 4 castors, 2 of which with brakes
- Water tank, 19 l with automatic and manual water supply of demineralized Technical Data humidification water.
- Air Cooled refrigeration unit with low noise emission
- Patented vapour humidification system (Sterile Steam System)
- Capacitive humidity sensor
- Entry port, Ø 50mm, in the right side panel
- Control panel with LCD display and key pad for entering of set-point values
- Adjustable specimen protection tmin / tmax as independent temperature limiter.
- Calibration of 2 temperature and 2 humidity values.
- Best accuracies due to Uniflow Stainless steel Interior fittings

Options:

- S!MPATI* Pharma software package for recording and processing of measurement values.
- Networking of several test Systems
- Colour touch panel
- Centronics printer interface
- Registration of temperature and humidity
- Additional temperature and humidity sensor
- Lockable Glass door, heated
- Water cooled refrigeration unit
- Acoustic and optical warning signal
- Demineralization unit with exchangeable cartridges for connection to domestic water supply.
- Additional shelves
- Height adjustable feet
- Additional entry ports
- Qualification documentation for Pharma test chamber and S!MPATI* Pharma Software
- Special voltages
- Calibration Protocols
- Remote alarms by telephone



Туре	PHARMA 600	PHARMA 1300	PHARMA 2000
External dimensions (mm) Height Width Depth	1975 ¹⁾ /2030 ²⁾ 740 1050	1975 ¹⁾ /2030 ²⁾ 1460 1050	2067 ¹ /2112 ²) 2155 1050
Interior dimensions (mm) Height Width Depth	1300 620 685	1300 1340 685	1300 2034 685
Shelves (pieces) standard (650 x 530 mm) Storage area (m²) standard	6 ³⁾ 2.07 ³⁾	12 ³⁾ 4.14 ³⁾	18 ⁹⁾ 6.21 ⁹⁾
Climate working range Temperature working range Humidity range Humidity fluctuation, in time Dew point temperature range Temperature fluctuation, in time Temperature fluctuation, spatial Temperature gradient ⁴	°C % r.h. % r.h. °C K K K	+10 +50 20 90 ±1 ±2 +5 +40 ±0.1 ±0.5 ±0.5 ±1.0 1 2	
Electrical supply Max. installed load (kW)	1/N/PE AC 230 V ±10%/50 Hz Safety plug 2.5 3 3.5		
Noise level ⁵⁾	dB(A) 52	52	52
Humidity water	demineralised water pH-value 6-7 conductivity 5 to 20 Microsiemens/cm		
Weight (kg)	150	250	350

with castors 2) with height-adjustable feet 3) possible additions 4) according to IEC 60068-3-5

5) free field, 1 m distance from the front, as per DIN 45635, part 1, accuracy class 2

The performance values refer to an ambient temperature of +25 °C.

We reserve the right to make technical alterations.

Photostability Test Chamber



The Weiss Photostability test chamber (Pharma 500-L) is portrayed by an ideal light, UV, temperature and humidity distribution and can thus guarantee absolutely reproducible light, UV and climatic conditions.

The lighting equipment of the chamber meets the requirements of ICH guideline Q1B Option 2and allows the photo stability test s to be carried out in less than 100 hours.

Homogeneous irradiation of the specimens is one of the most important requirements of the photostability tests. To achieve this, all the specimens are placed at same distance from the light source and the inhomogeneous emission of light by florescent lamps is compensated with the help of special light and UV filter systems.

Standard Features:

- 32-bit control system SIMCON/32*-NET with MINCON* Control Panel
- 2 shelves illuminated with UV light
- 2 shelved illuminated with white light
- Light and UV Timer
- Light and UV filter for optimum distribution (ideal homogeneity)
- Specially painted interior for ideal homogeneity
- Counter for total operating hours
- Lockable door
- Water tank 19 l, with possibility of manual automatic water supply
- Patented vapour humidification system (sterile steam system)
- Calibration certificate
- Serial interface RS 232 C

Options:

- Colour Touch panel
- UV and Lux sensors with automatic measurement value integration
- Analog line recorder
- Digital line recorder
- S!MPATI pharma software package complying with FDA 21 CFR Part 11
- Ethernet/ LAN interface (10/100 MBit) in connection with S!MPATI* for integration into a network
- **Oualification Documentation**
- DKD Calibration certificate
- Spatial measurements for temperature and humidity
- Mapping of light distribution
- Maintenance contracts with response time
- Access ports

Qualification Documentation:

Documentation Includes

- Analog line recorder
- Digital line recorder
- Digital line recorder, complying with FDA 21 CFR Part 11
- S!MPATI * Pharma software package complying with FDA 21 CFR Part 11 for connecting devices and test chambers to a PC.

Qualification Comprises:

FAT Factory Acceptance Test DKD (German calibration service) Calibration Certificates DQ **Design Qualification**

IQ Installation Qualification OQ. Operation Qualification PQ Performance Qualification

Limited Private

Volume

External dimensions

Temperature range Humidity range

Test space dimensions

Temperature gradient 1)

Illumination

UV energy

Light distribution

Electrical connection

UV distribution

Noise level²⁾

Humidity fluctuation, in time

Temperature fluctuation, in time

Temperature fluctuation, spatial

Technical Data Pharma 500-L

litres

οС

Κ

K

Κ

% r.h.

% r.h.

W/m²

% r.h.

% r.h.

dB (A)

2) free field, 1m distance from the front, as per DIN 45635, part 1, accuracy class 2

The performance values refer to an ambient temperature of +25 °C, 1) according to IEC 60068-3-5,

 $W \times H \times D mm$

 $W \times H \times D mm$

Sugnana, Ist Floor 9,Ist Main Road, Ganganagar Bangalore -560 032 Ph: 080-2354 8889 Fax: 080-2354 7505 Email:bangalore@stsols.com

51/3B, Karaya Road, First Floor, Kolkata Pin-700 019. Ph: 033-2247 2993 ,2283 6735, Fax: 033-2283 6734 Email:kolkata@stsols.com

gross approx. 700

net approx. 460

815 x 935 x 2070

595 x 600 x 1305

+10 ... +50

20 ... 90

±0.1 ... ±0.5

±0.5 ... ±1.0

1 ... 2

±1 ... ±2

max. 25000

max. 3.7

approx. ±6

approx. ±10

1N/PE AC 230 V ±10 %, 50 Hz

Saijothi, A-F1, 1,3rd Street, Satyavathi Nagar, Officer's Colony, Anna nagar West Extn., Padi Chennai -600 050 TeleFax 044 - 2654 9409. Email: chennai@stsols.com

Hyderabad (Head office)

301 & 303 - Eldorado Estate, 3-6-526 Himayath Nagar, Hyderabad-500 029 Ph:040-2763 6433, 2762 0569 Fax:040 -2763 6435 Email:sales@stsols.com

6478, Sector C, Pocket 6 & 7 Vasant Kunj, New Delhi-110 070 Ph: 011 - 5176 7790 Fax:011-51767791 Email:delhi@stsols.com



Block: II, Office No: 504, fifth Floor, Lloyds Chambers 409, Mangalwar Peth, Pune - 411 011.

Cell: 93733 13907, 9370658126, 9370659222

Email:pune@stsols.com