



Hindustan Apparatus Manufacturing Co.

12/2, Patel Industrial Estate, Gokhiware, Behind Range Office, Vasai (East), Dist: Palghar-401 208

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STABILITY CHAMBER GMP MODEL – PREMIUM SERIES:



CERTIFICATIONS	OUR CHAMBERS ARE “CE” Certified Chambers . We as company is ISO 9001:2008 Certified Company.
FEATURES	Consist of Chamber (Hamco 44 series) + Ethernet Based Connectivity + HMI PLC (7” Touch Screen PLC Display) + DS (Door Access System) + SOFTW-21 (Web browser based Software Part 11 21 CFR) + S.REF-1 (Standby Refrigeration System) + SH-1 (Standby Humidification system) + SCN-44 (4 Temp + 4 RH sensor) + GSM (Mobile SMS Alert) + VAL (Validation)
RANGE/ ACCURACY / UNIFORMITY	Temperature Range 10°C to 60°C , Temperature Accuracy +/- 0.2°C , Temperature Uniformity : +/- 1°C . Humidity Range 40% to 95% RH , Humidity Accuracy +/- 2% RH, , Humidity Uniformity : +/- 3% RH.
CONSTRUCTION GMP MODEL	Double walled , gap between walls filled with PUF Insulation. Inner Body made of SS 304 Mirror Finished, Outside SS 304 Matt Finished. Double door : Inner full Viewing door and outer door insulated with lock and key arrangement. 50mm Validation Port with silicon rubber seal to insert sensor for validation purpose. 3” Thick CFC Free Puff Insulation. Stainless steel Trays. Adjustable Tray Height adjustment. Unit Mounted on castor wheels with front lock arrangement. Stainless steel Rod Trays. Adjustable Tray Height adjustment.
LIGHTING	Floroscent Light are provided , which automatically On when we open the door.





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CHAMBER PRINCIPLE	Air circulation by Circulation Motor & Fan will continuously sucks the air from the chamber and Passes it through Air heater, Evaporator and injected steam and through it back to chamber and same air will be recirculated to achieve desired Temperature and Humidity stability inside chamber. Our design reduces the power consumption by 50% and water consumption by 70%.
ICH GUIDELINES	<p>Fully Suitable to carry out Stability Studies For Conditions Such As :</p> <ul style="list-style-type: none"> • 25°C / 60% RH • 30°C / 65% RH • 30°C / 75% RH • 40°C / 75% RH <p>Also Suitable for Low Humidity ICH conditions Laid out for drug Products packed in Semi-Permeable Containers Such As :</p> <ul style="list-style-type: none"> • 25°C / 40% RH • 30°C / 35% RH • 30°C / 65% RH • 40°C / NMT 25% RH <p>Other Than this cycle Please Mention it before order.</p>
APPLICATIONS	<p>Application includes Shelf Life Testing , Stability Testing , Expiration Date testing , Accelerated Aging and testing for Pharmaceutical , Packing , Life science , Medical Storage & R&D activity.</p> <p>Testing of Stability Sample Done :-</p> <ul style="list-style-type: none"> • To Provide evidence of how the quality of drug product Varies with time under the influence of a variety of Environmental Factors Such as Temperature , Humidity & Light. • To establish the shelf Life and storage condition of the drug Product. • To Confirm that drug products are assured For their Quality , Safety and efficiency in Marketed packs throughout the cycles of Warehousing , distribution , storage & use. • To Monitor the impact of Product quality due to changes in established Manufacturing Process. • In Support of Product registration in different Markets.





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<p>HEATING ,COOLING & HUMIDITY SYSTEM</p>	<ul style="list-style-type: none"> • Heating system: U shaped Nichrome wire heater in SS Sheathing. • Cooling system : Hermetically sealed CFC free Emerson compressor with R 134a refrigerant . • Humidity system : Non condensing type steam injection system with water level arrangement with insulation to save heat energy. • Air circulation : Flange Motor with Impeller and blower. Interior Illumination for working Area. There will be two nos of blower from 450 Ltr Onwards.
<p>DQ,IQ,OQ,PQ</p>	<p>To Help the customers to meet current regulatory requirements for the equipment , Hamco can provide DQ,IQ,OQ,PQ Protocols. This Protocol ensures that the system is properly installed, Operating as per our recommendations , Adequately documented and controlled according to regulatory requirements. Calibration certificate & Test certificate of critical components along with Operation , Maintenance Manual, Wiring diagram , chamber diagram, sensor position diagram provided. Operation Training of the instruments along with software installation and software Training is part of our Operation Qualification.</p>
<p>VALIDATION & CALIBRATION</p>	<p>Calibration of chamber is provided with Treacability against standard used. Hamco will give one cycle 24 hours Validation report offsite & 24 hours Validation report onsite one cycle . (Validation is putting temp & RH sensors at different position in the chamber confirming Uniformity at different places in the chamber.)</p>
<p>TEMPERATURE & HUMIDITY SENSOR</p>	<ul style="list-style-type: none"> • High Quality Temperature & Humidity Combo Sensor with 4-20 mA output with stable reading . Temperature resolution 0.1°C and Humidity resolution 0.1%RH.
<p>DISPLAY</p>	<p>HMI Display is 7" Color Touch Screen Display of Delta Make with display shows</p> <ul style="list-style-type: none"> • set & Process Value of Temp & Humidity • Active Alarm List • Status of Component. • Component running Hour display • Password Protected Display • Alarm List & its History. • Graph Display of Temperature & Humidity. • Limited Door Access through Password Protection. • Auto changeover of Refrigeration system on failure. • Auto changeover of Humidity system on failure. • Auto changeover of Sensor on failure.





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DOOR ACCESS SYSTEM (DS)	Limited Door access through Password protection. The person with Authorised password can only open the door with reason . In software we get the door access report which shows who open the door , when & for what reason with time stamp.
AUTO SENSOR CHANGEOVER (SAFETY-1)	In the case of Master Temp-RH sensor Fails , it switch over to Standby Temp-RH Sensor.
STAND BY COOLING SYSTEM (S.REF 1)	In case of Failure of Comp 1 , it switch over to Comp2 , thus reduces down time
STAND BY HUMIDITY SYSTEM (SH-1)	In case of Failure of Boiler 1, it switch over to Boiler 2 , thus reduces the down time
TEMPERATURE & HUMIDITY SCANNER (SCN 44)	4+4 Temp – Rh sensor including one Master Sensor Placed at different Position in the chamber to Study the distribution of conditions in the different locations of the chambers and thus helps in Auto- Validate the chamber and helps in easy detection of Drift in the sensor
MOBILE ALERT (GSM)	Only in Premium Model , You will get SMS Alert on critical utility paramenters like Temp High & Low Alarm, Humidity High & Low Alarm, Low water Level, Power Fail etc.
CONTROLLING SYSTEM	<p>The controlling system is Fully PLC Based , It consist of HMI Display , PLC Digital & Analogue cards, Relays, Contactors, Overload Trip devices, MCB. Separate Connection for Main & UPS (UPS will be on Buyer Scope). This helps in recording the chamber conditions even during Power fail and capture the event of Power Fail & Resume during the conditions. The control panel has below features.</p> <ul style="list-style-type: none"> • IP 22 Protection. • Data Storage of 30,000 Readings. If we set data interval of 30 Mins , it can save more than one year data. • Controls Temp & Humidity using PID Loops. • Captures all the events Like Power OFF / Resume , Water Level Low/OK , Door Open/Close , etc. • Operates as Safety Controller by cutting of Heating device on Over temperature , Cutting of Refrigeration device of Low Temperature, Cutting off Boiler on High Humidity etc and generates Alarms and transmit the same alarm to Multiple locations. • Ethernet Port for PC Connectivity.
	<p>Temperature Safety :-</p> <ul style="list-style-type: none"> • When Temperature deviates higher side than their prescribed limits , the Heater will be cut off by switchgears & if still go higher than by Thermostate. It generated alarm and horn the buzzer if it deviates. Once it reach within the range , the heating system reset automatically.





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SAFETY	<ul style="list-style-type: none"> When Temperature deviates lower side than their prescribed limits , the Compressor will be cut off by switchgears & if still go lower than by Thermostate. It generated alarm and horn the buzzer if it deviates. Once it reach within the range , the Refrigeration system reset automatically. <p>Humidity Safety :-</p> <ul style="list-style-type: none"> When Humidity deviates higher side than their prescribed limits , the Boiler will be cut off by switchgears. It generated alarm and horn the buzzer if it deviates. Once it reach within the range , the Humidity system reset automatically. Low water level safety , In case of Insufficient water in boiler tank , the Boiler is Cut off and it generates the alarm and horn the buzzer . When it resumes, it starts automatically. <p>Human Safety :-</p> <ul style="list-style-type: none"> All the component has individual MCB for Overload and trip protection. The system has provided with proper earthing. <p>Sensor Safety :-</p> <ul style="list-style-type: none"> The system has been provided with Stand by Sensor, So in case Master sensor Fails, it switch over to Safety sensor thus reduces the down time possibility.
ALARM GENERATION	<p>Audio & Visual Alarms are generated for :</p> <ul style="list-style-type: none"> Temperature Deviation. Humidity Deviation. Sensor Failure. Component Failure. Mains Failure. Door Open Water Level Low Thermostate High
PC COMMUNICATION (ETH-1)	Ethernet Based Connectivity for High speed Data transmission.
SOFTWARE WEB – 21	<p>It is Web Browser Based Software(You can access the software from any PC Connected in LAN to Server PC). Having Below said Features .</p> <ul style="list-style-type: none"> All 21 CFR Part 11 Requirements are Met. LIVE SCREEN. GMP Compliant- Tamper Proof Documentation of Measured data. Can Connect 50 Chambers at a Time. Authorised Access Only. Auto Backup Facility. Password Expiry & Multi Wrong attempt of Password will block the User. Auto Logout for no activity during Prescribed Time. <p>Unlimited Users , Multiple login levels.</p>





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	<ul style="list-style-type: none"> • Can Created Data Log Report & Alarm for Temp & RH. • Scanner & Scanner Alarm Report for Temp & RH. • Event Log Report • Door Access Report. • HMI Audit Report Etc
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ORDERING INFORMATION :-

CONSISTS OF CHAMBER +ETH -1 (ETHERNET) + HMI PLC (7") + SOFTW WEB -21(WEB BROWSER BASED SOFTWARE)+DS.

MODEL NO.		CAPACITY		DIMENSIONS IN CM		SHELVES	WT IN KG		POWER	
Standard	GMP	Cu. Ft	Litre	Chamber	Over All		Unit	Packed in wooden case	VAC Hz	Watts
HAMCO44 PS-4	HAMCO44 PG-4	4	120	45x45x60	60x95x125	2	125	185	230,50	2000
HAMCO44 PS-8	HAMCO44 PG-8	8	200	60x60x60	80x110x125	2	170	240	230,50	2500
HAMCO44 PS-12	HAMCO44 PG-12	12	324	60x60x90	80x110x155	3	200	270	230,50	2500
HAMCO44 PS-16	HAMCO44 PG-16	16	450	60x60x125	80x130x175	4	275	355	230,50	4000
HAMCO44 PS-21	HAMCO44 PG-21	21	600	60x80x125	80x130x195	5	295	375	230,50	4000
HAMCO44 PS-28	HAMCO44 PG-28	28	800	80x80x125	100x130x210	5	325	415	230,50	4500
HAMCO44 PS-34	HAMCO44 PG-34	34	1000	80x80x155	100x130x220	5	350	450	230,50	4500
HAMCO44 PS-53	HAMCO44PG-53	53	1500	60X160X150	110X170X210	10	375	475	230,50	5000
HAMCO44 PS-70	HAMCO44 PG-70	70	2000	80X160X150	130X176X210	10	400	500	230,50	5500

