

Equipment Specification Data Sheet

Equipment Name: Hot Air Oven

Document No.: DS-HAO 01


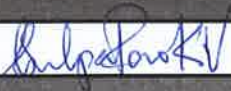

Revision: 03

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity(L)	Quantity
Q1	Admin QA&QC	Q1-HAO 01	400	1
G1	Animal House	G1-HAO 01	200	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Kiran Kumar M S	Engineer - Process		8/6/15
Checked by			
Ms. Shilpa Rao	Senior Engineer - Process		8/6/15
Approved by			
Mr. Vikas Katial	GM - Projects(SME) & Head COC Vaccines		9/6/15

Equipment Specification Data Sheet

Equipment Name: Hot Air Oven




Document No.: DS-HAO 01


Revision: 03


Project No.: 120310


Project Name: Integrated Vaccines Complex,
Chengalpattu


HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
SANJEEV KUMAR R	Manager		15/6/15
K. YASUNITHA REDDY	Deputy Manager	K. YASUNITHA REDDY	15/6/15
Polima Sreenath	Deputy Manager	Polima	12/6/15
Approved by			
V. Sivaganesan	Manager		19/6/15
Dr. K. A. Arul Anand	MANAGER	K. A. Arul Anand	19/6/15
Dr. Suresh Babu	DM	Dr. Suresh Babu	22/6/15
Authorized by			
Raman K. Ramachandran	CEO		24/6/15

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Chennai	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Hot Air Oven
	Document No.	DS-HAO 01
	Revision No.	03
		
1	Process requirements	
1.1	It is used for Dry Heat Sterilisation and Drying of Glassware.	
2	Equipment ID	
2.1	Q1-HAO 01	
2.2	G1-HAO 01	
3	Technical Specification	
3.1	Model	cGMP
3.2	Type	Table Top/Floor Mounted
3.3	Quantity	2 nos.
3.4	Temperature Range	Ambient +5 to 300 °C
3.5	Accuracy	± 2 °C
3.6	Control and Display	Timer Digital temperature setting with an accuracy of one degree, DS control with integrated timer 0 to 99.99 hrs.
3.7	Power Requirement	To be compatible with standard Indian power supply sockets.
4	Material of Construction	
4.1	Outer Body	SS 304/MS Epoxy powder coated reinforced by deep drawn ribbing with integrated and protected large area heating on four side exterior body alloy 304,rust - resistant and easy to clean.
4.2	Inner Body	Easy to clean interior,made of stainless steel SS316L.
4.3	Trays	SS 316L Perforated 3 or more adjustable.
5	Specific Equipment Requirements	
5.1	The gap between inner & outer walls of chamber should be fitted with high grade polyurethane foam (PUF), to ensure maximum thermal efficiency.	
5.2	Heating elements should be made of high grade chrome plated nicrome wire.	
5.3	Function set point/process delay function - process time should not start until the set temperature is reached.	
5.4	Ventilation forced air circulation by quite air turbine,adjustable in 10% increments, vent connection with restrictor flap.	
5.5	Sensors 2 PT 100 sensors Class A in 4 wire circuit,mutually monitoring the performance at the same temperature value.	
5.6	All the control switches & pilot lamps must be fitted on the front panel.	
5.7	Display resolution of display set point values 0.1 °C upto 99.9 °C, 0.5 °C from 100 °C and for actual values 0.1 °C (LED) solid state relays for low noise operation.Warm up timing to reach 150 °C in 40-50 min.	
5.8	Alarm Audio/Visual alarm for set temperature deviation,door open and other parameter deviation.	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
HLL Biotech Limited Chennai	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
	Equipment Name	Hot Air Oven	
	Document No.	DS-HAO 01	
	Revision No.	03	
5.9	Over Temperature protection additionally integrated over and under-temperature monitor,automatically following the set point valve at a preset tolerance range:alarm in case of over or under temperaure,heating is switched off in case of over temperature.		
5.10	Three or more adjustable perforated stainless steel racks must be provided.		
5.11	Control Adaptive multifunctional digital PID - Microprocessor controller with 2 high - definition TFT- colour display,self diagnostics for fault analysis parameters adjustable and control temperature(Celsius or Fahrenheit), fan speed, air flap position, programmable timer, time zones.		
5.12	Appropriate floor clearance to be provided with adjustable caster wheels for floor mounted type equipment for easy cleaning.		
5.13	Equipment shall be compatible for cleaning with all standard disinfectants.		
5.14	Ventilation port and validation port must be provided.		
6	Other Requirement		
6.1	Training / Demo for the users on operation and cleaning to be provided.		
7	Regulatory Aspects		
7.1	The equipment shall be as per cGMP standards.Validation services with complete qualification packages.General compliance services,hardware and system suitability.		
7.2	CE certification.		
8	Safety Requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Appropriate closure of all parts.		
8.2	Proper earthing is necessary.		
8.3	CE certification,error detection and display with audio visual alarm system for output signal, voltage fluctuations, process, temperature devation.		
9	Documents		
	Following documents, but not limited to these, must be provided by the vendor as part of the supply package in hard copy as well as editable electronic file.		
9.1	IOQ documents.		
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.		
9.3	Warranty letter for 1 year the date of supply.		
9.4	List of standard spare parts with ordering information.		
9.5	Calibration certificate of critical instruments with respect to traceable national reference standard instrument and their procedure.		
10	Timelines		
10.1	Not Applicable		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED (A subsidiary of HLL Lifesciences Limited) (A Government of India Enterprise)</small>
	Equipment Name	Hot Air Oven	
	Document No.	DS-HAO 01	
	Revision No.	03	
11	Preferred list of Makes		
11.1	Binder, Memmert, Thermo Scientific,		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.		

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				
	Equipment Name	Hot Air Oven			
	Document No.	DS-HAO 01			
	Revision No.	03			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-HAO 01	Admin QA&QC	FumeHood + Hot air ovens	Q1S024	3150×3450	2400
G1-HAO 01	Animal House	Wash area (Testing)	G1G100	11400×5100	2700
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2014	Kiran Kumar M S	00	-	New document	
27-10-2014	Kiran Kumar M S	01	All	Updated as per comments received from HBL dated 10-10-2014	
06-01-2015	Kiran Kumar M S	02	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
06-05-2015	Kiran Kumar M S	03	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					