

Equipment Specification Data Sheet

Equipment Name: Kjeldahl Appartus

Document No.: DS-KJA 01

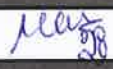
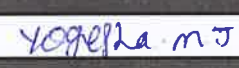
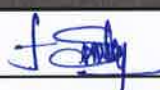
Revision: 02

Project No.: 120310


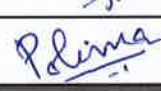

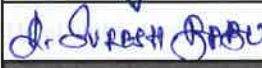
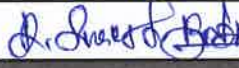

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA QC	Q1-KJA 01	-	1


NNE Pharmacplan India Limited


Name	Designation	Signature	Date
Prepared by			
Mr. Manohar M S	Engineer - Process		8/6/15
Checked by			
Mr. Yogesha M J	Engineer - Process		8/6/15
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		9/6/15


HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
Sanjeev Kumar R	Manager		12/6/15
Polima Sreenath	Deputy Manager		12/6/15
Approved by			
V. Swagamesh	Manager		19/6/15
	Done		22/6/15
Authorized by			
Ramona. K. Ramachandran	CEO		24/6/15

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HLL Biotech Limited, Chennai		
nne pharmanplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
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1	Process requirements	
1.1	It is used to estimate the protien, nitrogen content in samples.	
2	Equipment ID	
2.1	Q1-KJA 01	
3	Technical Specifications	
3.1	Kjeldahl apparatus containng 1 no of digestion system and 1 no of distillation unit.	
3.2	Digestion System	
3.3	Model	cGLP
3.4	Type	Portable
3.5	Operating temperature	Ambient to 420°C or more
3.6	Temperature setting repeatability	1°C
3.7	Kjeldahl flask or Tube volume	250 to 300 ml
3.8	Temperature stability at 100°C	± 5°C
3.9	Temperature stability at 400°C	± 2°C
3.10	Weight, kg	Vendor to specify
3.11	Dimension (W X D X H) mm	Vendor to specify
3.12	Program Library	Minimum 8
3.13	Temperature Ramping	Minimum 4
3.14	Way of Digestion	Infrared or block digestion
3.15	Display	LC display, monochrome
3.16	Timer range	0-99.99 min
3.17	Automatic lift Mechanisum	To be provided
3.18	SS Exaust Manifold	To be provided
3.19	Distillation Unit	
3.20	Model	cGLP
3.21	Type	Portable
3.22	Pressure Range	Vendor to specify
3.23	Display	LC display, monochrome
3.24	Distillation time	Vendor to specify
3.25	Distillation capacity	Vendor to specify
3.26	Pumps	NaOH, H ₃ BO ₃ , H ₂ O
3.27	Measuring range	0.1 – 200 mg Nitrogen
3.28	Reproducibility (RSD)	1% RSD (including the digestion step)
3.29	Recovery	> 99.5% at nitrogen levels between 1 – 200 mg N
3.30	Reagent pump volumes	0 – 150 ml in steps of 10 ml

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3.31	Steam power	30 to 100% Adjustable		
3.32	Programs	Minimum 8		
3.33	Tube & Door Sensor	To be provided		
3.34	Door	To be provided		
3.35	Power requirement	To be compatible to standard Indian Power supply socket.		
3.36	Utility requirement (If any)	Coolig water (Vendor to specify any other requirement)		
3.37	Weight, kg	Vendor to specify		
3.38	Dimension (W X H X D), mm	Vendor to specify		
4	Material of Construction			
4.1	Distillation unit	SS with epoxy coated		
4.2	Digestion System	SS		
4.3	Doors	Polypropylene		
5	Specific Equipment Requirements			
5.1	Digestion System			
5.2	Touch screen should be LED/ LCD digital display for temperature readout and heater indication.			
5.3	It should have text in display for heater warning.			
5.4	It should have inbuilt protection over temperature.			
5.5	Digestion unit should have to absorb fumes.			
5.6	Distillation Unit			
5.7	Distillation system should be compact, Automatic, programmable distillation unit with menu-controlled programming.			
5.8	It should be equipped with integrated NaOH,H ₃ BO ₃ and water pump for automatic dosing of alkali, acid and water			
5.9	It should have bellow pumps for accurate dispensing of reagents.			
5.10	It should have Alkali resistant Poly Propylene Plastic Splash head for long life time.			
5.11	Distillation operation should not start without closing the safety door.			
5.12	The Steam Generator must be made of glass and should be visible from outside, so that the operator will know when to clean the salt residues.			
5.13	There should be inbuilt automatic steam generator for steam distillation.			
5.14	There should be automatic aspiration of the sample and receiver solution after distillation.			
5.15	Self adjusting cooling water control should be there to save water and reduces costs.			
5.16	Cooling water should be used only during analysis.			
5.17	To ensure highest operator safety standards, the instrument should be equipped with a protective door sensor, cooling water flow sensor, sample tube sensor, front door sensor etc.			
5.18	System should have removable safety door.			
5.19	There should be provision for tube emptying/ Waste collection.			
5.20	Equipment shall be compatible for cleaning with all standard disinfectant.			
6	Other Requirements			
6.1	Cleaning shall be able done manually.			
6.2	Vendor to give code numbers for each component			
6.3	The heat given off by the unit must be stated (inside the room).			
6.4	System should have reagents alarms.			
6.5	Training/Demo for users on operation and cleaning to be provided.			
6.6	Digestion system should be provided with Tray and tube			
6.7	In case of block digestion digestion block to be provided			

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6.8	RS 232 / 485 interface is required to transfer the data as well as to take the print out.	
7	Regulatory Aspects	
7.1	CE certification	
8	Safety Requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	The equipment should be integrated with audio or visual alarm in case of any failure.	
8.2	All electrical wiring should be concealed for proper earthing.	
8.3	In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.	
8.4	All bolts, nuts on the exterior part of equipment will be with cap head or cap nut.	
8.5	Appropriate closure of all parts.	
9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file	
9.1	IOQ document.	
9.2	Operation and maintenance manuals shall be provided along with IOQ document during installation at site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	List of change parts with order information.	
9.6	MOC Certificate.	
10	Timelines	
10.1	NA	
11	Preferred list of Makes	
11.1	Buchi, Velp and Gerhardt	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-KJA 01	Admin QA QC	Chemical Lab / Bio Chemistry	Q1S022	6240 X 6805	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
28-02-2014	Manohar M S	00	-	New document	
09-01-2015	Yogesha M J	01	-	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
06-05-2015	Manohar M S	02	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					