

**DATA SHEET**

**HLL BIOTECH LIMITED, CHENNAI**

<b>nne pharmaplan®</b>	<b>REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR</b>		 <b>HLL BIOTECH LIMITED</b> <small>(Subsidiary of HLL Lifecare Limited)          (A Government of India Enterprise)</small>
	<b>Kjeldahl Apparatus</b>		
	<b>PROJECT NO :</b>	<b>110831</b>	
	<b>EQUIPMENT ID :</b>	<b>Annexure 1</b>	
	<b>DOCUMENT NO :</b>	<b>DS-KJA-01</b>	

<b>1</b>	<b>Process requirements</b>	
1.1	It is used to estimate the protien, nitrogen content in pharma grade samples. It shall be placed in IPQC room.	
<b>2</b>	<b>Technical Specifications</b>	
	Kjeldahl apparatus containing 1 no of digestion system, 1 no of distillation unit and 1 no of titration system.	
	<b>Total Quantity : 03 No.s</b>	
<b>2.1</b>	<b>Digestion System</b>	
2.1.1	Model	cGMP
2.1.2	Type	Portable
2.1.3	Operating temperature	50 °C - 480 °C
2.1.4	Temperature setting repeatability	1°C
2.1.5	Kjeldahl flask or Tube volume	100 ml
2.1.6	Temperature stability at 100°C	± 5°C
2.1.7	Temperature stability at 400°C	± 2°C
2.1.8	Time setting per step	1 - 1199 min
2.1.9	Power requirement	Vendor to specify
2.1.10	Weight, kg	10 to 15 kg <b>or Vendor to specify</b>
2.1.11	Dimension (W X D X H) mm	(310 x 540 x 620) mm <b>or Vendor to specify</b>
<b>2.2</b>	<b>Distillation Unit</b>	
2.2.1	Model	cGLP
2.2.2	Type	Portable
2.2.3	Pressure Range	Vendor to specify
2.2.4	Operating temperature	5-40 °C
2.2.5	Relative humidity	80 % (Maximum)
2.2.6	Display	LC display, monochrome
2.2.7	Distillation time	Vendor to specify
2.2.8	Distillation capacity	Vendor to specify
2.2.9	Pumps	NaOH, H <sub>3</sub> BO <sub>3</sub> , H <sub>2</sub> O
2.2.10	Measuring range	0.1 – 200 mg Nitrogen
2.2.11	Reproducibility (RSD)	1% RSD (including the digestion step)
2.2.12	Recovery	> 99.5% at nitrogen levels between 1 – 200 mg N
2.2.13	Reagent pump volumes	0 – 150 ml in steps of 10 ml
2.2.14	Power requirement	Vendor to specify
2.2.15	Utility requirement (If any)	Coolig water ( <b>Vendor to specify any other requirement</b> )
2.2.16	Weight, kg	25 to 30 kg <b>or Vendor to specify</b>
2.2.17	Dimension (W X H X D), mm	(430 x 660 x 520) <b>or Vendor to specify</b>
<b>3</b>	<b>Material Of Construction</b>	
3.1	Distillation unit	SS 316 with epoxy coated <b>or Vendor to specify</b>
3.2	Digestion System	SS 316 <b>or Vendor to specify</b>
3.3	Doors	Polypropylene <b>or Vendor to specify</b>

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**4 Specific requirements**

**4.1 Digestion System**

- 4.1.1 The Digestion Unit should be insulated to minimise the heat transfer to the surroundings and allow fast, even heating, thus giving good working conditions as well as saving energy.
- 4.1.2 It should have provision for measurement of actual temperature using external temperature probe .
- 4.1.3 Touch screen should be LED/ LCD digital display for temperature readout and heater indication.
- 4.1.4 It should have text in display for heater warning.
- 4.1.5 It should have inbuilt protection over temperature.
- 4.1.6 Samples size of solids/ liquids should be specified by PIIC.
- 4.1.7 Digestion unit should have water jet pump to absorb H<sub>2</sub>SO<sub>4</sub> fumes.
- 4.1.8 It should have provision for digestion of multiple samples, minimum 4 samples at a time.

**4.2 Distillation Unit**

- 4.2.1 Distillation system should be compact, Automatic, programmable distillation unit with menu-controlled programming.
- 4.2.2 It should be equipped with integrated Boric acid, NaOH and water pump for automatic dosing of alkali, acid and water
- 4.2.3 It should have bellow pumps for accurate dispensing of reagents.
- 4.2.4 It should have Alkali resistant Poly Propylene Plastic Splash head for long life time.
- 4.2.5 Distillation operation should not start without closing the safety door.
- 4.2.6 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.
- 4.2.7 There should be inbuilt automatic steam generator for steam distillation.
- 4.2.8 There should be automatic aspiration of the sample and receiver solution after distillation.
- 4.2.9 Self adjusting cooling water control should be there to save water and reduces costs.
- 4.2.10 Cooling water should be used only during analysis.
- 4.2.11 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.
- 4.2.12 System should have removable safety door.
- 4.2.13 There should be provision for tube emptying/ Waste collection.

**5 Other requirements**

- 5.1 Cleaning shall be able done manually.
- 5.2 Vendor to give code numbers for each component
- 5.3 All parts of the machine exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants for cleaning. (If any)
- 5.4 The heat given off by the unit must be stated (inside the room).
- 5.5 The software should support routine GLP functions such as password protection, results memory (ml consumption) etc.
- 5.6 System should have reagents alarms.
- 5.7 Training for the technical persons to be included to handle and to operate system.

- 5.8 Optionals:
  - Level sensors for monitoring the level in different tanks
  - Titration set
  - Acid resistant pump
  - External dosage devices for back titration

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**6 Regulatory Aspects**

6.1	21 CFR Part 11: Current Good Manufacturing Practice for finished Pharmaceuticals
6.2	CE certification.
6.3	RS 232 interface is required to transfer the data as well as to take the print out.

**7 Safety requirements**

7.1	The equipment should be integrated with audio or visual alarm in case of any failure.
7.2	All electrical wiring should be concealed for proper earthing.
7.3	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.
7.4	All bolts, nuts on the exterior part of equipment will be with cap head or cap nut.

**8 Documents**

	<b>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</b>
8.1	IOQ Protocol.
8.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.4	All equipment warranty should be valid for one year from the date of completion.
8.5	Vendor should provide list of standard spare parts with ordering information.
8.6	Vendor should provide list of change parts (if applicable) with ordering information

**9 Timelines**

NA

**NOTE:** Accurate size and technical specification need to be mentioned by the vendor.

	AFI Approved for Enquiry		AFO Approved for Ordering		
01	2015-10-01	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO

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**TABLE NO: 1**

Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-KJA 01	Diphtheria	1	IPQC	B1G057	2200 x 3310	3000
B2-KJA 01	Tetanus	1	IPQC	B2G026	3200 x 5335	3000
M1-KJA 01	Sterile media preparation and microbiology	1	Lab	M1G039	3020 x 5050	3000

	AFI Approved for Enquiry					Sheet 2/2
01	2015-10-01	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked by	AFI	AFO	