


DATA SHEET


HLL BIOTECH LIMITED, CHENNAI

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

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| 1 | Process requirements | |
| 1.1 | It is used to estimate the protien, nitrogen content in pharma grade samples. It shall be placed in IPQC room. | |
| 2 | Technical Specifications | |
| | Kjeldahl apparatus containng 1 no of digestion system, 1 no of distillation unit and 1 no of titration system. | |
| | Total Quantity : 03 No.s | |
| 2.1 | Digestion System | |
| 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 or Vendor to specify |
| 2.1.11 | Dimension (W X D X H) mm | (310 x 540 x 620) mm or Vendor to specify |
| 2.2 | Distillation Unit | |
| 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 ₃ BO ₃ , H ₂ 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 (Vendor to specify any other requirement) |
| 2.2.16 | Weight, kg | 25 to 30 kg or Vendor to specify |
| 2.2.17 | Dimension (W X H X D), mm | (430 x 660 x 520) or Vendor to specify |
| 3 | Material Of Construction | |
| 3.1 | Distillation unit | SS 316 with epoxy coated or Vendor to specify |
| 3.2 | Digestion System | SS 316 or Vendor to specify |
| 3.3 | Doors | Polypropylene or Vendor to specify |

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| 4 | Specific requirments |
| 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 ₂ SO ₄ 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 adujusting 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: <ul style="list-style-type: none"> 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 | | | | | |
| | 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 | | | | | |
| 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 | Sheet 1/2 |

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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 | |