

Equipment Specification Data Sheet

Document No.: DS-FTI 01

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-FTI 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Ms. Niharika Ruhela	Engineer - Process	<i>[Signature]</i>	01/03/2016

Prepared by

Name	Designation	Signature	Date
Mr. Sridhar Babu	Senior Engineer - Process	<i>[Signature]</i>	01/03/2016

Approved by

Name	Designation	Signature	Date
Dr. Harshad Malli	Lead Engineer - Process	<i>[Signature]</i>	01/03/2016

Reviewed by

User department	Project / Engineering department	QA Department	Head of the department (Quality control)	Head of the department (Quality control)	Head of the department (QA)	Date
QA Department	Project / Engineering department	QA Department	QA Department	QA Department	QA Department	03/03/2016
QA Department	QA Department	QA Department	QA Department	QA Department	QA Department	03/03/2016

Approved by

Head of the department (Quality control)	Manager	Signature	Date
QA Department	Manager	<i>[Signature]</i>	03/03/16

Authorized by

Head of the department (QA)	Head of the department	Signature	Date
QA Department	QA Department	<i>[Signature]</i>	03-03-16

Project Authority

Signature	Date
<i>[Signature]</i>	03/03

Equipment Specification Data Sheet		HLL Biotech Limited, Chennai	
INTERGRATED VACCINES COMPLEX,CHENGALPATTU		Equipment Name: Four Transform Infrared Spectroscopy (FTIR)	 <p>HBL HLL BIOTECH LIMITED Government of India Company</p>
Project # 120310		Document # DS-FTI-01	
Equipment ID		Q1-FTI 01	
Process requirements		<p>1 A Fourier Transform Infrared Spectroscopy is used in all applications where a dispersive spectrometer was used, FTIR is a method of measuring an infrared absorption spectrum</p>	
2	Equipment ID		
2.1	Q1-FTI 01		
3	Technical Specification		
3.1	Model	cGLP model	
3.2	Optical system	Single beam optics	
3.3	Interferometer	Michelson Type	
3.4	S/N Ratio	30,000:1 or higher	
3.5	Wavelength Range	7,800 to 500 cm-1	
3.6	Resolution	0.9cm-1 or higher	
3.7	S/N ratio	30,000:1 or higher	
3.8	Light source	High energy air-cooled ceramic light source	
3.9	Beam Splitter	ZnSe or KBr	
3.10	Detector	High sensitivity with Excellent stability	
3.11	Mirror Speed	Vendor to specify	
3.12	Prism	Made of Zinc Selenide (ZnSe) with pressure sensors	
3.13	Sample compartment	Automatic Accessory Recognition capability to enable the FTIR to automatically recognizes the accessory type and ID number and optimum scan parameters	
3.14	Atmosphere correction	Must be incorporated to reduce influences of water vapor and CO ₂ .	
3.15	Interface	USB	
3.16	Software	A single software compliant with data (Spectra) library of standards	
3.17	Power required	240 VAC, 50/60HZ	
3.18	Kbr Press	Hydraulic press with electrical drive	
3.19	Max. hydraulic pressure	15 ton or better	
3.20	Temperature	Vendor to specify	
4	Material of Construction		
4.1	Body	Epoxy powder coated corrosion resistant	
5	Specific Equipment requirement		
5.1	Data manipulation Arithmetic,Normalize, Baseline Correction, Smoothing, Datapoints, Data Calculation, Purity, Deconvolution, FFT, ATR Correction, Peak Adjust, Time-Temperature Conversion, Peak Pick, Film Thickness, Data Calculation, Purity, Deconvolution, FFT, ATR Correction, Peak Split, Atmosphere Correction, 3D Reprocess, Extract, Kramers Kroni, Kubelka Munk		

Equipment Specification Data Sheet	
HLL Biotech Limited, Chennai	
 HLL BIOTECH LIMITED Division of HLL Group 15, Convent Road, Chennai	
INTERGRAATED VACCINES COMPLEX,CHENGALPATTU	Equipment Name: Fourier Transform Infrared Spectroscopy (FTIR)
	Project # 120310
	Document # DS-FT1-01
me pharmapan®	
5.2	Single-Reflection ATR : To measure the spectrum of a liquid, Powder, Moldings Thin Films, Rubbers on the prism, with incidence angle is 45°, Prism made of ZnSe, respective prism is equipped with a pressure sensor
5.3	Password security should be provided for data
5.4	Automatic temperature compensation should be provided to corrects readings 18°C to 40°C for pure sucrose solution
5.5	Automatic temperature equilibration detection software should be provided to ensure that the sample and prism temperature is stable and should provide accurate and precise measurements.
5.6	Extensive diagnostics, error detection and display with audio visual alarm system for deviation
6	Other requirement
6.1	Accessories required : Hydraulic press,KBrdye,pellet holder,Liquid demountable cell for KBr
6.2	It shall have capacity to save the data for 100 measurements.
6.3	2 USB port shall be provided for access
6.4	LCD display shall be provided for process monitoring and alarm indicator.
6.5	Download the Data to your computer or printer
7	Regulatory guidelines / standards
7.1	The equipment shall be as per cGMP standards,
7.2	All measurements are made automatically, which eliminates the need for operator judgment.
7.3	Calibration with fluids traceable to NIST and calibration data securely stored and available for review.
7.4	Operator Traceability, full 21 CFR Part 11 compliant password system.
7.5	Verification step with electronic signature
8	Safety
8.1	CE Certification and Proper earthing should be given for the instrument.
8.2	Adjustable down stopper to prevent accidental damage to slides
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	Operation and maintenance manuals, with trouble shooting tips (Both soft and Hard copies) and IQ,OQ Documents,
9.2	One year Warranty.
9.3	List of standard spare parts with ordering information.
9.4	Calibration and inspection certificates.
9.5	Training for the technical persons to be included to handle the equipment, Compliance and calibration certificates, instrumentation and control wiring drawings, complete IQ,OQ,PQ documents for hardware (soft and hard copies), accessories and spare parts list, procedures for calibration and cleaning etc.
10	Timelines
	Not Applicable
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

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HLL Biotech Limited, Chennai					
		INTERGRATED VACCINES COMPLEX, CHENGALPATTU		Equipment Name: Fourier Transform Infrared Spectroscopy (FTIR)	
				Project # 120310	
				Document # DS-FTI-01	
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-FTI 01	Admin QA&QC	Chemical Lab / Bio Chemistry	Q1S022	6250x7350	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2016	Ms. Niharika Ruhela	00	-	New document	
01-03-2016	Ms. Niharika Ruhela	01		Updated as per comments given by HBL dated 26-02-2016	
Table-3: Annexure					
Not applicable					