

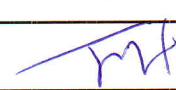

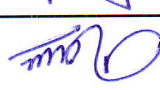

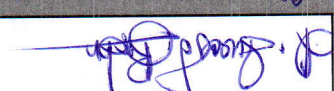
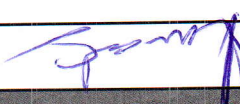




one pharmaplan 				
Equipment Specification Data Sheet Equipment Name: Fourier Transform Infrared Spectroscopy (FTIR) Document No.: DS-FTI 01 Revision: 01				
Project No.: 120310 Project Name: Integrated Vaccines Complex, Chengalpattu				
Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-FTI 01	-	1
NNE Pharmaplan India Limited				
Name	Designation	Signature	Date	
Prepared by				
Ms. Niharika Ruhela	Engineer - Process		01/03/2016	
Checked by				
Mr. Sridhar Babu	Senior Engineer - Process	K. Sridhar Babu	01/03/2016	
Approved by				
Dr. Harshad Mali	Lead Engineer - Process		01/03/2016	
HLL Biotech Limited				
Name	Designation	Signature	Date	
Reviewed by				
User department: QA Department	Manager	Siv	03/03/2016	
Project / Engineering department	Manager	A. Jothi	03/03/2016	
QA Department	Sr. Manager, QA		03-03-2016	
Approved by				
Head of the department (Quality control)	Manager		03/03/16	
Head of the department (QA)			08-03-16	
Authorized by				
Project Authority			05/03	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
 HBL BIOTECH LIMITED A Division of HLL Group Limited (Incorporated in India Company)	INTERGRAATED VACCINES COMPLEX,CHENGALPATTU		
	Fourier Transform Infrared Spectroscopy (FTIR)		
	Equipment Name:		
	Project # 120310		
Document # DS-FTI-01			
1			
Process requirements			
1.1 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			
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 CO2.,			
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			
KBr Press			
3.18 Operation			
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, Reduce/Interpolate, Frequency Convert, X Adjust, Time-Temperature Conversion, Peak Pick, Film Thickness, Data Calculation, Purify, Deconvolution, FFT, ATR Correction, Peak Split, Atmosphere Correction, 3D Reprocess, Extract, Kramers Kroni, Kubelka Munk			

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
me pharmaplan® Equipment Name: Fourier Transform Infrared Spectroscopy (FTIR) Project # 120310 Document # DS-FTI-01	INTERGRAATED VACCINES COMPLEX,CHENGALPATTU		
			
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,KBr dye,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		


Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
 <small>HLL BIOTECH LIMITED A Division of HLL Group of Companies A Government of India Enterprise</small>	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
Q1-FTI 01	Admin QA&QC	Chemical Lab / Bio Chemistry	Q1S022	6250×7350
				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				