

Equipment Specification Data Sheet

Equipment Name: Fourier Transform
Infrared Spectroscopy (FTIR)


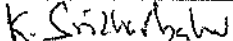

Document No.: DS-FTI 01

Revision: 01

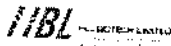
Project No.: 120310


Project Name: Integrated Vaccines Complex,
Chengalpattu


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

NNE Pharmaplan India Limited			
Name	Designation	Signature	Date
Prepared by			
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Checked by			
Mr. Sridhar Babu	Senior Engineer - Process		01/03/2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process		01/03/2016

HBL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
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Project / Engineering department Felix	Manager	A. Sathish	03/03/2016
QA Department Felix	Sr. Manager, QA	Felix	03-03-2016
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Head of the department (QA) Dr. Sridhar Babu	QA	Dr. Sridhar Babu	03-03-16
Authorized by			
Project Authority		Prasanth	05/03

DATA SHEET		
HLL BIOTECH LIMITED, CHENNAI		
INTERGRATED VACCINES COMPLEX, CHENGALPATTU		
Fourier Transform Infrared Spectroscopy (FTIR)		
Project #		120310
Document #		DS-FTIR-01
nne pharmanplan		
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-FTIR-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	50,000:1 or higher
3.5	Wavelength Range	650-4800 cm-1
3.6	Resolution	0.5cm-1 or higher
3.7	Operating Temperature	5-40 °C
3.8	Light source	High energy air-cooled ceramic light source
3.9	Beam Splitter	KBR
3.10	Detector	High sensitivity with Excellent stability
3.11	Mirror Speed	vendor to specify
3.12	Prism	KBR with Pressure sensor
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	Wavelength Precision	0.01cm-1
3.17	Wave length accuracy	0.1cm-1 or better
3.18	Dessicant	Dessicant provide internally
3.19	Wave number accuracy	0.1cm-1 or better
3.20	ATR Type	Diamond
3.21	Background scan	One time
3.22	Software	A single software compliant with data (Spectra) library of standards
3.23	Power required	240 VAC, 50/60Hz
	Kbr Press	
3.24	Operation	Hydraulic press with electrical drive
3.25	Max. hydraulic pressure	15 ton or better
3.26	Temperature	vendor to specify
4	Material of Construction	
4.1	Body	Epoxy powder coated corrosion resistant

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HLL BIOTECH LIMITED, CHENNAI						
nne pharmaplan	INTERGRATED VACCINES COMPLEX, CHENGALPATTU					
	Fourier Transform Infrared Spectroscopy (FTIR)					
	Project #		120310			
	Document #		DS-FTIR-01			
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, Purity, Deconvolution, FFT, ATR Correction, Peak Split, Atmosphere Correction, 3D Reprocess, Extract, Kramers Kroni, Kubelka Munk					
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	NIST Traceable polystyrene film to be provided					
5.7	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.					
7.6	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					
	AFI Approved for Enquiry			AFO Approved for Ordering		
0	13-03-2014	KNKS	SRKV	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 1

Equipment Specification Data Sheet						
HLL Biotech Limited, Chennai						
nne pharmaplan	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	6250×7350	2400	
Table-2: Change Log						
Date	Name	Revision	Section	Change/Comments		
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						