USER REQUIREMENT SPECIFICATION

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Name of Instrument: FTIR

Document Reference Number:

Effective Date:

1.0 Approval:

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	**Signature**	**Date**
Checked By	**Signature**	**Date**
Reviewed By	**Signature**	**Date**
Approved By	**Signature**	**Date**

2.0 Table of Contents:

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a FTIR. The URS is provided to aid the user through the important components.

The URS is provided to the supplier to provide a price quote for the FTIR including design and manufacture of the equipment.

The URS will be recognized as the integral part of the procurement agreement with the selected instrument vendor. The instrument supplier or vendor will abide by the information and condition set forth by this document as well as purchasing and delivery terms and condition of the Client.

The FTIR shall be installed in Instrument room of QC Department.

The utilities and space involved needs to be discussed prior to the purchase of the equipment.

4.0 OVERVIEW DEFINITION:

4.1 The FTIR shall have the following features:

4.1.1. The FTIR should have software for the operation.

4.1.2. The FTIR should have in build heater for the removal humidity.

4.1.3. The FTIR should have operating range from 4600 to 400 cm-1.

4.1.4. The FTIR should be interface with PC and should have auto validation facility.

4.1.5. The FTIR should design to meet the requirement of IP, BP, USP.

4.2 The FTIR shall be used for:

Identification test of raw material as well as finished goods

4.3 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Hardware	
Interferometer	Michelson interfermeter (30 degree indident angle) Advance dynamic alignment system Sealed and desiccated interferometer with an automatic dryer
Optical system	Single beam optics
Beam splitter	Germanium – coated KBr plate for Middle IR (Standard) Germanium – Coated CaF2 plate for Near IR (Optional) Silicon-coated CaF2 plate for Near IR (Optional)
Light Source	Air cooled ceramic for Middle / Far IR with 3 years guarantee (Standard) Tungsten lamp for Near IR (Optional)
Detector	DLATGS detector with temperature control for middle / Far IR (Standard) MCT (Hg-Cd-Te) detector with liquid nitrogen cooling for Middle IR (Optional) InGaAs detector for Near IR (Optional)
Wavenumber range	7,800 – 350 cm^{-1} 12,500 – 240 cm^{-1} (Optional. See figure for detail)
Resolution	0.5 cm^{-1}, 1 cm^{-1}, 2 cm^{-1}, 4 cm^{-1}, 8 cm^{-1}, 16 cm^{-1}, (Middle/Far IR) 2 cm^{-1}, 4 cm^{-1}, 8 cm^{-1}, 16 cm^{-1}, (Near IR)
S/N ration	40,0000 : 1 or higher (4 cm^{-1}, resolution, 1 minute accumulation, around 2,100 cm^{-1} , peak –to-peak)
Gain control	Automatic or manual from x 1 – x 128
Sample compartment	Automatic accessory recognition 200 (W) x 230 (L) x 170 (H) mm Center Focus
Dimensions	600 (W) x 680 (L) x 290 (H) mm
Weight	54 Kg

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ITEM	SPECIFICATIONS				
Scan Range	Light Source	Beam Splitter	Detector	Scan Range (cm^{-1})	Necessary Parts
	Tungsten	CaF2	InGaAs	12,500-3,800	NIR Kit (206-72015-91)
	Ceramic	KBr	DLATGS	7,800-350	Standard
			MCT	5,000-720	MCT Kit (206-72017-91)
		Csl	DLATGS	5,000-240	FIR Kit (206-72016-91)
Software					
Operational System	Microsoft Windows 200				
Data Processing	Addition, Multiplication, Abs to % T conversion, Normalization, Baseline Correction, Log conversion, Smoothing, Derivative, ATR correction, Kubelka - Munk conversion, Kramers – Kronig analysis, Wavenumber/ Wavelength conversion, Peak detection, Peak area calculation.				
Quantitative processing	Multipoint calibration curve with peak height/ area/ratio, Multinear regression (MLR method)				
Spectrum search	Search parameters, Search library creation				
Print processing	Report generator				
Display	High wavenumber compression, Zooming, Auto scaling, Overlay, Shift display				
Edit	Cut Copy Paste				
Others	Customizable graphical user Interface (GUI)				
Optional Software	PLS qualification, Curve fitting, Mapping, Macro platform				
Audit Trail	Container function with stored interferogram/background interferogram, operation history Password protection Log recording				

ITEM	SPECIFICATIONS
	FDA 21 CFR Part 11 compliance with Electronic signature (Note 1)
Accessory Detection	Automatically recognize installed Quick start accessory. Then sets up scan parameters and runs macro program (Note 1 : IR solution Agent software is needed to dully comply to FDA 21 CFR Part 11)
Another	
Installation site	Ambient temperature : 15-30^{o}C Ambient humidity : 70 % or less to avoid condensation
Power requirement (Note 2)	AC 100/120/220/230/240 V, AC 50/60Hz, 240 VA Standby power 4.5 VA (Note 2) PC requires additional power

4.4 The machine is to be used at the following environmental conditions:

4.4.1 Temperature **:** NMT 24 °C

4.4.2 Relative Humidity**:** NMT 55%

4.5 Base Utilities Available:

Electrical: Single Phase, 230V $\pm$ 10 % 50 HZ

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The instruments operation shall be safe, smooth both from user and environmental standpoint.

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5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall shut off automatically and acquire operator involvement to restart.

5.3 SAFETY FEATURE:

The instrument should produce warning or safety symbols to protect the instruments against damage.

5.4 ALARMS AND WARNINGS:

Warning labels should attached at several locations in the instruments for the correct and safe operation.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

The Supplier shall utilize controller that shall include a communication port.

UTILITIES:

The Supplier shall specify utility requirements. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

6.2 MATERIAL OF CONSTRUCTION:

Metal and plastic

7.0 MAINTENANCE:

Do's and Don'ts to be provided

7.1 Preventive maintenance system and checks to be provided (Maintenance and Operation manuals of vendor equipment)

7.2 A comprehensive lubrication list and recommended lubrication schedule

7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)

7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals., DQ, Electrical drawing

8.0 DELIVERY:

The FTIR with all options, equipment, and the documentation listed below, shall be delivered to the Client. Delivery should be confirmation of the purchase order.

9.0 DOCUMENTATION:

9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting "as-built" condition with final delivery.

9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect "As-Built" condition.

9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:

9.4 Design qualification

9.5 Installation Qualification

9.6 Operational Qualification

9.7 Maintenance and service manuals

9.8 Instrument listing

9.9 Material of construction