



USER REQUIREMENT SPECIFICATION

Name of Item: FTIR Spectrometer

Protocol No.:.....

Functional Area: Quality Control

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USER REQUIREMENT SPECIFICATION (URS)
FOR
FTIR Spectrometer

Department :

URS no.

Supersede :



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3. Purpose:

The purpose of the user requirement for FTIR Spectrometer is:
To define the instruction for selection of FTIR Spectrometer for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

- 4.1 This document is applicable for FTIR Spectrometer intended to use at manufacturing plant.
- 4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5. Specifications:

5.1 Description of equipment / system:

The FTIR Spectrometer shall have following components.

- Detector
- Data handling software
- Dryer
- Beamsplitter
- HATR
- Diffuse Reflectance

The detail description of the components is as follows;

5.1.1 Detector:

- The instrument must have a high linearity detector.
- All control parameters shall be controlled through software.
- It should have built in data storage facility.

5.1.2 Data Handling Software

- Should have complete control of FTIR.
- Software should have operations like reporting, reviewing and approving data.
- Data integrity should be maintained.

5.1.3 Dryer

- The instrument should have with dryer for Mortar crusher, Kbr and Kbr Die set.
- The temperature for Dryer should be 25°C to 105°C



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5.1.4 Beamsplitter

- The instrument must have Znse Beamsplitter.
- Basic and advanced data manipulation routines and Beer's law predictions.

5.1.5 HATR

- Instrument must have HATR Combo for Liquid and Solids sample Analysis.

5.1.6 Diffuse Reflectance

- Simplifies analysis of difficult solid materials.
- Automatic sample positioning for better sensitivity.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
FTIR Spectrometer		Instrument room

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable

5.5 Construction:

Not Applicable

5.6 Capacity:

The FTIR Spectrophotometer must be capable for routine laboratory analyses as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase. Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Znse Beam splitter the system is switched on only during analysis hence source and laser gun life is increased by 3 to 4 times.

Sample Compartment: Patented wishbone optics with open architecture design. Can accommodate any type of cells and accessories because of open architecture.



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Detector and auxiliary parameters must be controlled.

The instrument must comply USP tests to be performed.

5.9 Acceptable tolerance for control parameters:

Automatically detector with the range of 7800-500 cm^{-1}

Resolution should be 0.7 cm^{-1}

The noise level should be better than 25000:1 RMS

5.10 Type of control System:

It should have Programmable Pneumatic control system.

Software for complete control on FTIR Spectrometer.

External Lamp On, OFF Switch.

Purge tubes of sample compartment allows purge in a few seconds thereby minimizing in the time and liquid nitrogen comes as a standard to eliminate the effects of CO_2 and H_2O in the sample.

Methods can be transferred to any other instrument of the same model

The instrument Works Up to 65% Humidity

5.11 Feasible parameters to be set:

Name of users.

5.12 Parameters to be indicated by control systems:

% Transmission, Wavelength cm^{-1}

Time and date formatting.

Formatting Format for recording data with company's name in header.

Analysis details during its run.

5.13 Available utilities:

Dedicated room for keeping FTIR Spectrometer.

Utilities required for electric connection can be provided.

Primary Reagent (Kbr) can be provided.

5.14 Limitations / constraints:

Not Applicable



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5.15 Regulatory requirements:

Software employed for having a control on FTIR Spectrometer, must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

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6 Safety:

Pressure Gauges, Pressure switches for Nitrogen Flushing.
Proper equipment earthing shall be provided.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.
- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support
Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.
- Training
User training shall consist of equipment training by a qualified trainer. Certificates of training shall be provided for each person completing the training program.
- Post Start-up Support
Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.



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- **Technical Support**
Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References: