USER REQUIREMENT SPECIFICATION (URS)

FOR

GAS CHROMATOGRAPH

Department	:	Quality Control
URS no.		……
Supersede	:	Nil

USER REQUIREMENT SPECIFICATION

Name of Item: Gas Chromatograph	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 6

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Issued to mfg / supplier by purchase department _____

1.0 Approval:

Activity detail	Name of person	Designation	Signature	Date
Prepared By				
Reviewed By				
Approved By				

2.0 Change History:

Revision number	Revision details	Date of revision

3.0 Purpose:

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

4.0 Scope:

4.1 This document is applicable for Gas Chromatograph to be procured for quality control lab at manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5.0 Specifications:

5.1 Description of equipment / system:

The Gas Chromatograph shall have following components.

- Column oven
- Head space auto sampler
- Programmable split / split less injector
- Flame Ionization Detector
- Data handling software

The detail description of the components is as follows;

5.1.1 Column oven:

- Must be capable for analyzing the samples in the range 30°C to 400°C.
- Temperature programmable column oven.

5.1.2 Headspace Auto sampler

- It shall have built in syringe auto sampler.
- All control parameters shall be controlled through software.
- Sample vial must return to same position after the analysis is over.
- It shall have minimum 10 or more vial overlapping thermo stated facility to reduce the analysis time.
- It should have built in method storage facility.

5.1.2 Injector

- Programmable automatic injectors
- Split/Split less capillary injector shall have facility for programming and shall have pneumatic controls.
- Provision for attaching packed and capillary column.
- Required temperature range: 50 to 400°C.
- Split ratio must be easily adjustable in split/Split less capillary injector.
- Static headspace injector shall be equipped with thermostatically controlled sample heating chamber and automatic injection device with the facility to adjust sample volume.

5.1.3 Detectors

- Gas chromatograph shall be provided with Flame Ionization Detector (FID).
- Detector control parameters shall be pneumatically controlled.
- FID shall have auto ignition facility.
- Hydrogen and airflow shall be pneumatically controlled.
- FID range: 80°C to 400°C

5.1.4 Data Handling Software

- Shall have complete control on GC.
- Software should have streamlined series of operations like method preparation, sequence set up, acquiring, processing, reporting, and printing of data.
- System suitability calculation according to BP/USP/Ph.Eur.
- Facility of multiple user log in, authorization for privileges, audit trail.

5.1.5 Gas purification system

- Gas Purification system shall be provided with (but not limited to) molecular Sieve, Silica Gel, Activated Charcoal, Pressure Regulator, and filter gel for all gases, De-oxy trap in case of carrier line with suitable housing.

5.2 Identification number and location:

Equipment Name	Identification Number	Location
Gas Chromatograph	……..	Instrument room

5.3 Intended use:

5.3.1 Operation of equipment depends upon the production output.
5.3.2 The equipment should be designed to work continuously for 3 shifts per day.
5.3.3 Shall be used for quantitative quality control analysis of drug compounds, organic volatile impurities and method validation work.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms

5.5 Construction:

Not Applicable

5.6 Capacity:

Not applicable

5.7 Electrical construction:

Not applicable

5.8 Control parameters:

Carrier gas pressure, air-hydrogen flow, injector, detector and headspace shall be pneumatically controlled.

5.9 Acceptable tolerance for control parameters:

Flow rate ± 1 ml/min of set value
Oven Temperature: ± 5% of set temperature

5.10 Type of control System:

It should have Programmable Pneumatic control system.
Software for complete control on Gas Chromatograph.

5.11 Feasible parameters to be set:

Temperature, time and pressure functions.

5.12 Parameters to be indicated by control systems:

Carrier gas pressure, split flow ratio, flow rates (set value and actual value)
Temperature of all the streams (set value and actual value)
Flame out message
Analysis details during current run.

5.13 Available utilities:

Dedicated room for keeping GC.
Utilities required for electric connection shall be provided.
Gas purification system shall be provided
Chemicals and solvents shall be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

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

5.16 Delivery Address:

…..

6.0 Safety:

Pressure control devices, Proper equipment earthing.

7.0 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
  Vendor must provide familiarization and training.
- 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.
- Technical Support
  Technical support shall be available as and when required.

8.0 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Qualification documents	Paper
4.	Spare parts list	Paper
5.	List of users	Paper
6.	Certificate for compliance	Paper

9.0 References:

Unite State pharmacopoeia
British pharmacopoeia
In house