



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Gas Chromatography	Protocol No.:.....
Functional Area: Quality Control	Page No.: 1 of 7

Name of Equipment: Gas Chromatography

Document Reference Number:

Effective Date:.....



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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



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3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for a GC. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional Gas chromatography that meets the User Requirement in the most cost effective method.

The URS is provided to the supplier to provide a price quote for the gas chromatography, 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 Client.

The GC shall be installed in INSTRUEMNT ROOM of Q.C Department.

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

4.0 OVERVIEW DEFINITION

4.1 The GC shall have the following features:

- 4.1.1. The GC should have software for the operation.
- 4.1.2. The GC should have two injections port one for the capillary column and second for the packed column.
- 4.1.3. The Gas chromatography system have touch screen for the manual operation.
- 4.1.4. The Gas chromatography should have the FID detector.
- 4.1.5. The gas chromatography should provided facility for the programming of method as per the requirements.

4.2 The GC shall be used for:

For the analysis of organic volatile impurities and solvent analysis



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4.3 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS	
Gas Chromatograph		
Temperature range	10°C above ambient to 450°C or – 99°C to 450°C with sub ambient accessory	
Column overheat protect	User settable up to 450°C	
Temperature programmer	3 ramp, 4 plateaus	
	Range	Minimum Increment
Initial temperature	up to 450°C	1°C
Initial time	0 to 999 min	0.1 min
Rate	0.1 to 45°C/min	0.1°C
Plateau time	0 to 999 min	0.1 min
Final oven temperature	up to 450°C	1°C
Col-down time	250°C to 50°C : 4.8 min 200°C to 50°C : 3.8 min 50°C to 0°C : 2.6 min 50°C to –30°C : 3.4 min with liquid CO ₂	
Sample Capacity	manual injection	
Precision	Typically <5% RSD of peak area from 1µl - 10µl	
Carryover	Typically <0.05%	

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 ± 10 % 50 HZ



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5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

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

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:

Instruments shall produce warning if any parameter goes out site of the acceptable criteria. The instrument should capable to produced sound alarms in case of any deviation.

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 stainless steel

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



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- 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 and DQ.

8.0 DELIVERY:

The GC with all options, equipment, and the documentation listed below, shall be delivered to Client site. 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