

# HPLC SYSTEM SOP (GMP COMPLIANT)

SOP No: QC/HPLC/001

Effective Date: \_\_\_\_\_

Revision No: \_\_\_\_\_

## Approval Page

Prepared By	Checked By	Approved By

## Revision History

Revision No	Date	Change Description	Approved By

## **1. OBJECTIVE**

To define procedure for HPLC operation using Chemstation software.

## **2. SCOPE**

Applicable to QC laboratory HPLC systems.

## **3. RESPONSIBILITY**

QC Officer / Executive.

## **4. ACCOUNTABILITY**

QC Manager.

## **5. PROCEDURE**

Detailed procedure for operation, method creation, analysis and shutdown.

## **6. CALIBRATION**

Verification of system suitability, flow rate, wavelength accuracy.

## **7. CLEANING**

Routine cleaning of system components and flushing.

## **8. SAFETY**

Follow lab safety guidelines and solvent handling precautions.

## **9. DOCUMENTATION**

Maintain logs and records for audit compliance.

## **10. ABBREVIATIONS**

HPLC, SOP, UV, GMP definitions.

## Instrument Usage Log

Date	Instrument ID	Column	Mobile Phase	Flow Rate	Analyst	Remarks

## Calibration Log

Date	Parameter	Standard	Observed	Deviation	Status

## Cleaning Log

Date	Solvent Used	Column Flushed	Injector Cleaned	Done By	Verified By

## **Pre-Operation Checklist**

Ensure system cleanliness, mobile phase readiness, no air bubbles, column installed.

## **Post-Operation Checklist**

Flush column, save data, shutdown system properly.