HPLC RECORDS

(Ref. SOP LAB-090)

Calibration of HPLC

Date: _____ System: _____ Analyst signature:_____

1. Reproducibility Check

Sample Set Name: _____

Injection Volume: _____(μL)

Area % RSD: _____ **(should be less than 2%)**

Retention Time % RSD: _____ **(should be less than 1%)**

2. Detector Check

(A) Waters 996 Photodiode Array Detector

PDA Internal Diagnostic			
Internal Tests		**Pass (P) / Fail (F)**	**Test display/ Comments**
*	CPU		
*	Timer		
*	Shutter		
*	Lamp		
*	Wavelength Accuracy		
*	Communications		
*	Optics		
*	ROM		
*	RAM		
*	DSP		

(B) Waters 470 Scanning Fluorescence Detector

(i) Check the powering up displays
If: SELF DIAGNOSIS
LAMP EM POOR
is displayed, lamp radiation energy is low and Waters must be called for service.

(ii) Check the hours of lamp time used.
The lamp has an expected lifetime of 1,000 hours.

LAMP OPERATION TIME _____ HR

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(C) ELSD Detector Check

Diagnostic Test				Pass or Fail
	Current	Max.	Min.	
1. Optics Test (mV) Laser off: Laser on: Offset:				
2. Nebuliser Gas Pressure Test (psi)				
3. Flow Meter Test (L/min)				

COMMENT:_____

(D) ECD 464 Detector

To ensure good working condition maintenance should be performed every 6 months. Check chart on ECD detector.

Date working electrode cleaned: _____ Due date: _____

Date changed solution in reference electrode: _____ Due date: _____

Comments: _____

(E) Differential Refractometer 410

Internal Temperature (°C)_____

Auto zero performed_____ (conforms)

Comments: _____

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HPLC Calibration Log

SYSTEM NAME:

Date	HPLC in use- (Yes) or (No)	Date of Calibration	Calibration Pass or Fail	Analyst Signature	Comments

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Record of Performance Tests for HPLC Columns

Column Details: Type_____ Length_____ Internal Diameter_____

Supplier's Column Performance Details

Mobile Phase in HPLC Method (M1):

_____

Standard Solution used (S1):

_____

Product method Details

Product the Column has been dedicated to: _____

Mobile Phase in HPLC Method (M2):

_____

Standard Solution used (S2):

_____

Date	Analyst	Column Serial Number	HPLC System used	Sample Set name	Standard S1 or S2	Mobile Phase M1 or M2	Flow Rate mL/ min	Injection Volume µL	λ nm	Plate Counts-N 5 sigma	Capacity Factor k'	USP Tailing