

# USER REQUIREMENT SPECIFICATION

## HPLC

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## 1. Objective

This document describes the User Requirements Specification of Liquid chromatography for obtaining exact and reproducible results of our analytical data at Sina Darou Pharmaceutical site. It contains detailed of HPLC description.

## 2. Scope

This document is applicable on Liquid chromatography Specification, working steps and additional devices & options at Sina Darou Pharmaceutical site.

## 3. Description of Equipment / System

This document defines the minimum user requirements for the Liquid chromatography to be installed in QC laboratory.

## 4. Instrument Specification

### 4.1- Solvent Management

- **Number of solvents:** one to four
- **Solvent conditioning:** Vacuum degas, two operating modes, four chamber, <500 µL internal volume per chamber
- **Flow rate range:** 0.01 to 10.000 mL/min (0.050 to 5.000 mL/min typical) in 0.001 mL/min increments
- **Compressibility compensation:** Automatic and continuous
- **Dwell volume (total system):** ≤1.145 mL
- **Plunger seal wash:** Integral, active, programmable
- **Gradient profile:** 11 gradient curves (including linear, step, concave, convex)
- **Dry prime/ Wet prime:** Automatic front panel control, System PREP function for automatic solvent(s) purge
- **Flow ramping:** time (0.01 to 30.00 min in 0.01 min increments) to reach maximum flow rate
- **Maximum operating pressure:** 5000 psi (345 bar [0.010 to 3.000 mL/min]) programmable upper and lower limits

- **Composition range:** 0.0% to 100.0%, in 0.1% increments
- **Composition accuracy:**  $\pm 0.5\%$  absolute, independent of backpressure (proportioning valve pair test, [degassed methanol: methanol/ propylparaben, 2.0 mL/min, 254 nm])
- **Composition precision:**  $\leq 0.15\%$  RSD or  $\leq 0.02$  min SD, whichever is greater, based on retention time (60:40 degassed methanol: water dial-a-mix, 1 mL/min, six replicates, Phenone mix, 254 nm)
- **Flow precision:**  $\leq 0.075\%$  RSD or  $\leq 0.02$  min SD, six replicates, based on retention time or volumetric measure (0.200 to 5.000 mL/min), isocratic premix
- **Flow accuracy:**  $\pm 1\%$  or 10  $\mu\text{L}/\text{min}$ , whichever is greater, 0.200 to 5.000 mL/min, (degassed methanol at 600 psi backpressure)

#### 4-2- sample management

- **Number of sample vials:** 120 vials, configured in five carousels of 24 vials each
- **Number of sample injections:** 1 to 99 injections per sample vial
- **Sample delivery precision:** typically  $< 0.5\%$  RSD, 5 to 80  $\mu\text{L}$  (using standard 250  $\mu\text{L}$  syringe), 60:40 degassed methanol/water dial-a-mix\*, 1 mL/min, six replicates, Phenone mix, 254 nm; typically  $< 0.3\%$  RSD, 5 to 60  $\mu\text{L}$  (using standard 100  $\mu\text{L}$  optional syringe), 70:30 degassed methanol/water dial-a-mix, 1 mL/min, six replicates, Caffeine, 273 nm;
- **Sample carryover:** sample carryover  $\leq 0.0025\%$  for caffeine, under specified conditions injection needle wash integral, active, programmable
- **Injection accuracy:**  $\pm 1$   $\mu\text{L}$  ( $\pm 2\%$ ) (50  $\mu\text{L}$ , N=6), sample: 100% degassed water, analytical solvent: 100% degassed methanol
- **Standard sample vial:** 2 mL
- **Advanced operations:** priority samples, auto additions, auto standards
- **Injection volume range:** 0.1 to 100.0  $\mu\text{L}$ , standard; 0.1 to 2000.0  $\mu\text{L}$ , with optional sample loop
- **Injector linearity:**  $> 0.999$  coefficient of deviation (1.000 to 100.000  $\mu\text{L}$ )
- **Minimum sample required:** 10  $\mu\text{L}$ , using low volume inserts
- **Sample temperature control (optional):**
  - Ambient  $-25^\circ\text{C}$  or  $4^\circ\text{C}$  (whichever is greater) to  $40^\circ\text{C}$  in  $1^\circ\text{C}$  increments
  - $\pm 3^\circ\text{C}$  temperature accuracy
  - 60-min time limit from lab ambient to heating set-point
  - 90-min time limit from lab ambient to cooling set-point
- **Column heater:**  $20^\circ\text{C}$  to  $65^\circ\text{C}$ , in  $1^\circ\text{C}$  increments ( $5^\circ\text{C}$  above ambient)
- **Column heater/cooler:** ambient minus  $15^\circ\text{C}$  or  $4^\circ\text{C}$  (whichever is greatest) up to  $65^\circ\text{C}$ , in  $1^\circ\text{C}$  increments

\*solvents are mixed using the solvent manager's programmable proportioning of up to 4 solvents (not premixed solvents).

#### 4-3- Instrument control

- **Communications:** IEEE-488, RS-232, Ethernet
- **Event inputs:** Three, TTL or switch closure
- **Programmable event outputs:** six, contact closure

#### 4-4- Electrical specifications:

- **Power requirements:** 950 VA (maximum)
- **Voltage range:** 100 to 240 VAC
- **Frequency:** 50 to 60 Hz

### 5- UV/Visible Detector

#### 5-1- Operating specifications:

- **Wavelength range:** 190 to 700 nm
- **Bandwidth:**  $\leq 5$  nm
- **Wavelength accuracy:**  $\pm 1$  nm (via patented Erbium filter)
- **Wavelength repeatability:**  $\pm 0.1$  nm
- **Linearity:**  $\leq 5\%$  at 2.5 AU, propylparaben, 257 nm, analytical flow cell
- **Baseline noise, single wavelength:**  $\leq 35 \times 10^{-6}$  AU peak to peak, 230 nm, 1 point/s, 2.0 s, 30-s segments, dry analytical flow cell
- **Drift:**  $\leq 1 \times 10^{-4}$  AU/hour, 239 nm, 2 pints/s, 1.0 s, 30-s segments, dry analytical flow cell
- **Measurement range:** 0.0001 to 4.0000 AU
- **Sampling rate:** up to 80 points/s

#### 5-2- Optical components specifications

- **Light source:** Deuterium arc lamp
  - Warranty: 2000 hours or 1 year (whichever comes first)
- **Path length:** 10 mm (analytical cell)
- **Cell volume:** 16.3  $\mu$ L (analytical cell)
- **Pressure limit:** 1000 psi (analytical cell)

#### 5-3- electrical specifications

- **Power requirements:** 100 to 240 VAC
- **Linear frequency:** 50 to 60 Hz
- **Power consumption:** 195 VA (nominal)
- **Inputs:** four event inputs
- **Outputs:** four outputs (2 analog, 2 event)

## **6. Warranty**

At least 2 years guarantee and 10 years warranty

## **7. Testing/Documentation/Training**

### **7.1. Testing**

FAT and SAT

### **7.2. Documentation**

IQ/OQ/PQ protocols should be done by supplier on site.

### **7.3 Training**

Training course should be performed by supplier on site.

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