GL3000 純化分離系統驗證方案(IQ, OQ, PQ)

GL3000 purification and separation system verification program (IQ, OQ, PQ)

目錄 Content

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成都格萊精密 Gelai Precision Co.			

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批准人 Approved by：

部門 Department	姓名 Full name	簽名 Signature	日期 Date

生效日期 Effective Date：

1. 目的 Purpose

經由對 GL3000 純化分離系統確認，證明該設備運行的可靠性，主要運行參數的穩定和結果的重現性，
設備各項性能指標符合設計及生產使用要求.

Through the qualification of the GL3000 purification separation system to prove the reliability of the equipment operation the stability and result reproducibility of main operating parameters, and all equipment performance specification meet the design and production requirements.

2. 範圍 Scope

本方案適用于成都格萊精密儀器公司生產的 GL3000 型純化分離系統安裝，運行確認.

The program applies to the installation and operation qualifications

of GL3000 type purification and separation system produced by Gelai Precision instruments co.

3.概述 Overview

3.1 設備概述：Equipment summary

GL3000 型純化分離系統, 是一款製備型的高效液相層析純化分離系統.

The GL3000 type purification and separation system is a preparative high performance liquid chromatography separation systems.

It is constituted by the pump liquid delivery system, UV detector, preparative chromatography column system， fraction collector, control software system.

Its working principle is:

The mobile phase A and mobile phase B in containers are pumped respectively by pump A and B to delivery into the system and mixed in the mixer.

Sample solution is transmitted by the injection pump C, that combine and load into it into the front end of chromatography column (stationary phase). The sample experiences continuous adsorption-desorption partition process between the two phases.

Since the various components of the sample solution have different distribution coefficients between the two phases, so they are separated into individual components that flows out of the chromatography column without overlaping.

The component absorption value, when passing the UV detector that is set to the maximum UV absorption wavelength

for the component, is converted into a digital signal continuously, and became workstation recorded chromatogram. The Fraction collector will collect the desired sample component into specified container channel, according to the time position or peak signal voltage setting.

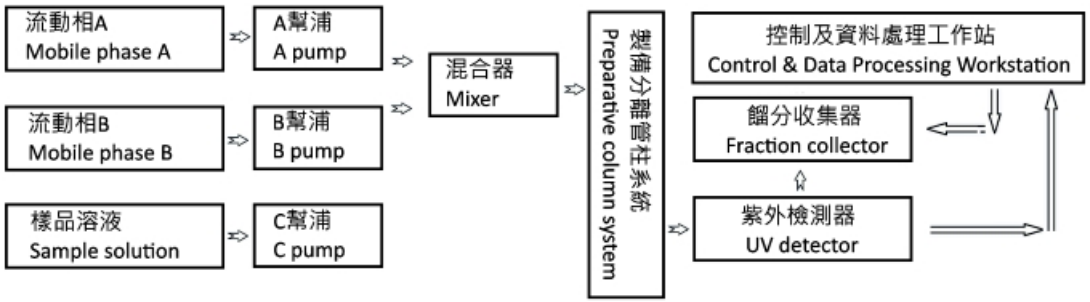
驗證主要技術參數為：液體輸送幫浦流量設定值誤差 SS, 流量穩定性誤差 SR, 梯度誤差 GC,紫外檢測器波長示值誤差, 波長重複性, 基線雜訊, 基線漂移.

The main technical verification parameters:

The pump flow rate setting error SS, the flow rate stability error SR, Gradient error GC, UV detector wavelength indication error, wavelength repeatability, baseline noise, and baseline drift.

該型號層析儀的連接示意圖如下：

The schematic diagram of the chromatography instrument is as follows:



層析儀的連接示意圖
The chromatography instrument connection diagram

4. 驗證小組成員與職責 Verification team members and responsibilities

成都格萊精密儀器公司 Gelai Precision Instruments：

提供驗證方案及服務, 協調小組的行動. 跟進確認方案的審批流程, 組織驗證資料並形成報告.

Provide verification scheme service and group action coordination.

Follow-up approval process of qualification program, organize verification data and generate reports.

客戶公司 Customer company：

審核及批準該方案, 負責確認過程中各部門協調工作, 組織實施確認過程的監督,

協調調查確認過程中的偏差及方案變更.

Review and approve the scheme, responsible for coordinating each department in the qualification process.
Organize supervision for the implementation of the qualification process, and coordinate to investigate the deviation and scheme changes in the qualification process.

5. 術語與縮略語 Terms and Abbreviations :

HPLC：高效液相層析儀 HPLC: high performance liquid chromatography instrument

6. 參考文獻：References

《藥品生產驗證指引》(2XXX 版) Drug production-verification Guidelines" (2XXX edition)
《藥品生產品質管制規範》(2010 年修訂) "Pharmaceutical production quality control specifications" (2XXX Amendment)
《設備確認管理程式》 "Equipment Qualification Management Program"
《JJG 705-2002 液相層析儀計量檢定規程》"JJG 705-2002 liquid chromatography verification procedures"

7. 確認前準備： Qualification preparation

7.1 人員培訓確認：Training personnel qualification

7.1.1 確認方法：查閱培訓記錄及培訓賬冊. Qualification Method: Check training records and training accounts

7.1.2 可接受標準：所有參與人員均應培訓本方案並考核合格

Acceptance criteria: All personnel participating in the program should be trained and pass the assessment.

7.1.3 記錄表：Record table:

姓名 Full name	部門 Department	培訓內容 Training content	考核結果 Assessment results	簽名 Signature	日期 Date	備註 Remark
		本確認方案 The qualification scheme				
標準 Criteria	所有參與驗證人員均應培訓考核合格. All personnel participating in the verification should be trained and pass the assessment.					
結論	結論 Conclusion					
備註Remark						

檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

7.2 主要儀器儀錶校驗確認：Main instrument and gauge calibration qualification

7.2.1 確認方法：

對照校驗證書, 記錄儀器編號, 校驗證書編號, 校驗有效期, 證書影本作為本方案的附件.

Qualification Method: Check for consistence of calibration certificate, including the instrument number of records, calibration certificate number, valid date of the certificate, and copy of certificates as annexes of this program.

7.2.2 可接受標準：所有相關儀器儀錶均在校驗有效範圍內.

Acceptance criteria: All instruments are within the calibration validity.

7.2.3 記錄表：Record sheet

名稱 Name	自定編號 Internal defined ID	校驗有效期 calibration valid date	證書編號 Certificate No	結果 Result

結論 Conclusion				
備註 Remark				
檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date		

7.3.3 記錄表：

7.3 設備資訊確認： Device Information qualification

7.3.1 確認方法：現場檢查. Qualification Method: Site inspection

7.3.2 可接受標準：設備有唯一識別資訊. Acceptance Criteria: The device has a unique information for identification.

7.3.3 記錄表：Record sheet

設備名稱 Device Name	設備型號 Device Model	出廠編號 Serial number

所屬部門 Departments	安裝位置 Installation location	
備註 Remark		

檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

7.4 文件資料確認：Confirmtion of documents

7.4.1 確認方法：現場檢查設備供應商提供的文件資料, 應包括產品合格證, 使用說明書, 材質證明.

Qualification Method: Check on-site the documents from equipment suppliers.

It should include product certification, manual, material proof.

7.4.2 可接受標準：所有文件資料完整存在, 方便可得.

Acceptance criteria: All documents is completely and readily available.

7.4.3 記錄表：Record sheet

設備編號 Device ID			
文件資料名稱	數量	齊備	備註

Documental name	Quantity	Are complete	
結論 Conclusion	□ Pass □ Fail，本測試有___個偏差 This test has ___deviation		
備註 Remark			
檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

7.5 材料/物料確認: Material/Substance qualification

7.5.1 確認方法：檢查來料證書或標籤，並記錄資訊

Qualification Method: Check source certificates or labels, and record the information

7.5.2 可接受標準：所有材料/物料名稱，規格，供應商，批號及有效期資訊完全，且有效期能覆蓋其使用時間.

Acceptance criteria: All documents is completely and readily available.

Acceptance Criteria: Information of all materials/substance name, specification, supplier, lot number and expiration date is

completely provided, and the valid date covers the time to use.

7.5.3 記錄表：Record sheet

名稱 Name	規格 Specification	供應商 Supplier	批號 Lot number	有效期至 Valid until	Pass/Fail
結論	□ Pass □ Fail，本測試有___個偏差 This test has ___deviation				
結論 Conclusion					

檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

8. 安裝確認 Installation Qualification(IQ)

確認專案 Qualification Project	確認標準 Qualification criteria	確認結果 Qualification results
儀器主體安裝確認 The instrument installation qualification	各部件完好，外觀整潔，無污跡，內外表面光亮，平整，無擦痕.儀器安裝平穩牢固. All components is intact, neat appearance, no stains, inside and outside surface is bright and smooth, no scratches. The Instrument is installed stably and firmly.	
電源電纜連線 Power cable connection	檢測器，液體輸送幫浦，層析分離管柱，分離管柱溫箱與電腦，印表機的電源連接正常，並接入 UPS 電源，電腦與儀器，電腦與印表機的網線連接正常，IP 位址設置正確. Access to UPS power supply and connect properly to detector, liquid delivery pump, chromatography column, column thermostat cab and computer. The cable for computer and printer communication is connected properly, and IP addresses if necessary set correctly.	
管路 Pipes	溶劑瓶，液體輸送幫浦，分離管柱溫箱，檢測器與廢液瓶之間溶劑管路連接正確，各管路均有標識，溶劑瓶上有標示盛裝溶劑名稱或代碼.	

	Pipes are properly connected for solvent bottle, liquid delivery pump, chromatography column, the detector and the waste container, and are identified with tabs, and the solvent bottles are labeled with name or code of solvents contained.	
電腦安裝檢查 Computer installation Check	打開電源開關，電腦應能順利啟動 WINDOWS OS. Turn the power switch On, the computer should be able to successfully start WINDOWS OS.	
儀器控制軟體連接 Instrument Control Software connection	啟動程式，儀器應能與控制軟體順利連接. 在控制軟體中可對幫浦，檢測器等各模組進行參數設置, 各模組依據設置的指令作相應的動作，可順利完成進樣，採集資料. Start the software, the instrument should be able to successfully connect with control software. In the control software, parameters can be set for control pump, detector, and other modules. Each module actions in accordance with the requested instructions and can successfully complete the sample loading and data collection.	
結論 Conclusion：		

檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

9. 運行確認：Operation qualification：

項目 Item	測試方法與可接受標準 Test methods and acceptance criteria	確認結果 Qualification results
幫浦運行測試 Pump operation test	在工作站各幫浦模組中, 開啟幫浦後, 幫浦應自動完成自我檢測並啟動. 設置流速與各溶劑的比例, 幫浦可按設置運行. 點擊關閉幫浦, 幫浦停止動作, 恢復至初始狀態. Turn On each pump module on the workstation. The pumps should automatically finish self-test and start. Set the flow rate and ratio of the solvents, and pump can run accordingly. Click Stop pump that pump should be stopped and restore to its initial state.	
檢測器 Detector	在工作站中可實現對檢測器的開, 關控制. 開啟後, 氖燈應可點亮並通過自我檢測.可設置檢測波長. The detector On and Off control can be realized in the workstation.	

	When it is turned on, the Deuterium lamp should be lit and pass self-testing successfully. The detection wavelength can be set.	
壓力報警 Pressure alarm	設置最高壓力為 100bar, 逐步增加流速, 當壓力超過 100bar 時, 幫浦停止運行或降低流速保持在 100bar 內運行, 保護系統. Set the maximum pressure of 100bar and gradually increasing the flow rate. When the pressure exceeds 100bar, the pump is stopped or the flow rate is reduced to remain pressure within 100bar to protect system.	
結論 Conclusion：		

檢查人/日期 Checker/ Date		客戶確認/日期 Customer qualification/Date	

10. 性能確認 Performance Qualification

10.1 泵流速準確度及精密度 The accuracy and precision of pump flow rate

10.1.1 測試方法：分別設定幫浦 A, B, C 幫浦的流速為最大流速的 10%, 50%, 90%.

以純水為移動相, 運行層析儀幫浦, 使純水不經過分離管柱, 直接流出至已知重量的空燒杯中.

收集 1 分鐘後稱量得出水重, 每個設定流速值測定 6 次, 計算實際平均流速與設定值間的相對標準差,

計算 6 個測定值間的 RSD 值.

Set the A, B, C pump to 10%, 30%, 50%, that is relative to the maximum pump flow rate respectively.

Run the pumps with purified water as mobile phase, without passing through the chromatography column, and flow directly to an empty beaker of known weight. Collect for 1 minute and get water weight.

Repeat 6 time for each specified flow rate value, and then calculate the relative standard deviation of the averaged actual flow rate with specified value, with RSD values calculated between the 6 measured values.

10.1.2 接受標準 Acceptance Criteria :

準確度 Accuracy：RE% ≤ 2.0%

精密度 Precision：RSD% ≤ 2.0%

10.1.3 計算公式 Formula

RE%= | $\bar{F}_M$ -FS | /FS×100%

$$RSD\%=\sqrt{\sum\left(F_M-\bar{F}_M\right)^2/(n-1)}/\bar{F}_M\times 100$$

F_M=W/ρ/T

NOTE：

RE%——泵流速準確度 - Pump flow rate accuracy

RSD%——泵流速精密度 - Pump flow rate precision

W——流動相重量（g）- Mobile phase Weight(g)

F_S——流量設定值（ml/min）- Flow rate set

F_M——泵流速測量值（ml/min）- Flow rate measured

$\bar{F}_M$——同一組泵流速測量值的算術平均值（ml/min）

- The arithmetic mean of measuring flow rates of same set of pump

ρ——實驗溫度下流動相的密度(g/cm3) - Mobile phase density at experimental temperature

T——收集流動相的時間（min）- Mobile phase collection time

10.1.4 記錄

幫浦編號 Pump Number		A 幫浦 Pump A		
流速設定值 Flow rate set				
第 1 次	移動相重 Mobile phase Weight			
1	實測流速 Measured flow rate			

第 2 次 2	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 3 次 3	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 4 次 4	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 5 次 5	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 6 次 6	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
結果計算 Result	相對標準差 Relative standard deviation			
Calculation	RSD%			
結論 Conclusion				
備註 Remark	純化水溫度為____ ℃, 對應純化水密度為_____ Purified water temperature____ ℃, Corresponding purified water density _____			

檢查人/日期 Checker/Date		客戶確認/日期 Customer qualification/Date	

幫浦編號 Pump Number		B 幫浦 Pump B		
流速設定值 Flow rate set				
第 1 次	移動相重 Mobile phase Weight			
1	實測流速 Measured flow rate			
第 2 次	移動相重 Mobile phase Weight			
2	實測流速 Measured flow rate			
第 3 次	移動相重 Mobile phase Weight			
3	實測流速 Measured flow rate			
第 4 次	移動相重 Mobile phase Weight			
4	實測流速 Measured flow rate			
第 5 次	移動相重 Mobile phase Weight			
5	實測流速 Measured flow rate			
第 6 次	移動相重 Mobile phase Weight			
6	實測流速 Measured flow rate			

結果計算 Result Calculation	相對標準差 Relative standard deviation		
	RSD%		
結論 Conclusion			
備註 Remark	純化水溫度為____ ℃, 對應純化水密度為_____ Purified water temperature____ ℃, Corresponding purified water density _____		
檢查人/日期 Checker/Date		客戶確認/日期 Customer qualification/Date	

幫浦編號 Pump Number		C 幫浦 Pump C		
流速設定值 Flow rate set				
第 1 次 1	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 2 次 2	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			

第 3 次 3	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 4 次 4	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 5 次 5	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
第 6 次 6	移動相重 Mobile phase Weight			
	實測流速 Measured flow rate			
結果計算 Result	相對標準差 Relative standard deviation			
Calculation	RSD%			
結論 Conclusion				
備註 Remark	純化水溫度為____ ℃, 對應純化水密度為_____ Purified water temperature____ ℃, Corresponding purified water density _____			
檢查人/日期		客戶確認/日期		

10.2 梯度精度 Gradient precision

10.2.1 方法：Method

設置階梯式的梯度沖滌程式，檢測器波長為 265nm，流速 600ml/min，移動相 A 為純化水，移動相 B 為含 5%丙酮的水溶液，移動相 B 經由 5 個階梯從 0 變到 100%，如下圖所示.

將液體輸送幫浦和檢測器連接(以 2M PEEK 管代替層析分離管柱)，首先以 100%移動相 A 沖洗系統，待檢測器基線平穩後開始執行梯度程式，記錄移動相 A 與 B 在各梯度比例時的檢測器輸出信號值.

Setting stepped gradient elution program, with detector wavelength of 265nm, the flow rate is 600ml/min.

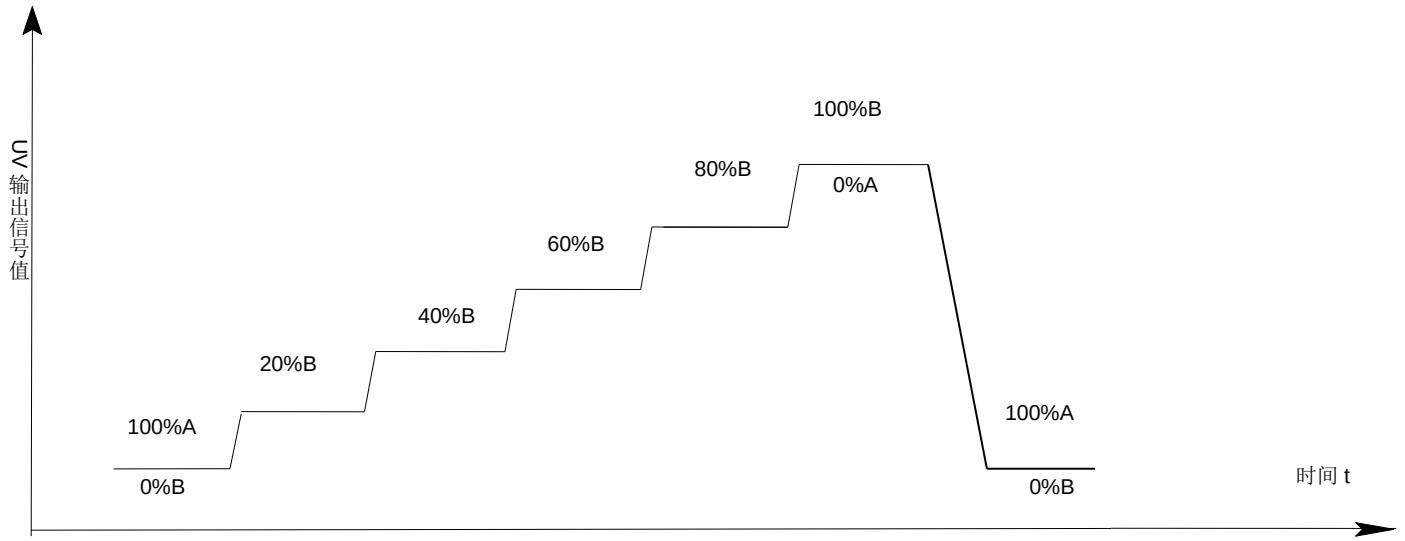
The mobile phase is purified water, mobile phase B is 5% acetone water solution.

The ratio of mobile phase B changes from 0 to 100% in five steps, as figure shown below.

Connect the liquid pump and detector (go through a 2M PEEK pipe instead of chromatography column),

and elute with 100% mobile phase A in the system.

After the detector baseline is steady, start the gradient program and record the detector output signal values at various mobile phase A and B gradient proportions.



梯度誤差驗證示意圖 Schematic diagram of gradient error verification

梯度誤差驗證測試程式： Gradient error verification test program:

時間 Time (min)	%A	%B	流量Flow rate (ml/min)	檢測波長 Detection wavelength
0	100	0	幫浦最大流量值的50%	265nm

3	100	0	50% of the maximum pump flow rate	
3.1	80	20		
7	80	20		
7.1	60	40		
11	60	40		
11.1	40	60		
15	40	60		
15.1	20	80		
19	20	80		
19.1	0	100		
23	0	100		
26	100	0		
29	100	0		

10.2.2 可接受標準：Gci 不超過±3.0% Acceptance criteria: Gci not exceed ±3.0%

10.2.3 計算方法：Calculation method

以移動相 B 的含量及對應的輸出信號值，按以下計算式，計算梯度誤差 Gci,

取 Gci 最大者作為儀器梯度誤差：

The detector output signal values corresponding to each mobile phase B content ,
is calculated with the following formula to get error value, Gci, for every gradient step.
The gradient step with greatest Gci value is used as the instrument gradient error.

公式: Formula

$$G_{ci} = (\overline{L}_i - \overline{L}_m)/\overline{L}_m \times 100\%$$

式中：G_{ci} —— 第 i 段梯度误差（%）；

$\overline{L}_i$ —— 第 i 段输出信号值（或记录仪读数）平均值；

$\overline{L}_m$ —— 各段输出信号（或记录仪读数）平均值的平均值。

Gci = (Li-Lm)/Lm x 100%

其中: Wherein

Gci = 第 i 段梯度的誤差(%) , i-th step gradient error(%)

Li = 第 i 段檢測器輸出訊號的平均值, Detector output signals mean value of gradient step i.

Lm = 全部各段 Li 的平均值, Average of all steps' Li(s)

10.2.4 記錄 Records

梯度段移動相含量(B%) Mobile phase B content of gradient step(B%)	0%～20%	20%～40%	40%～60%	60%～80%	80%～100%
梯度誤差Gradient error Gci					
結論：Conclusion					
測試人/日期 Test person/Date :		客戶確認/日期 Customer qualification/Date			

10.3 檢測器波長準確性 Detector wavelength accuracy

10.3.1 方法 Method：

已知萘在 275nm 有特徵吸收，故配置 0.1mg/ml 萘的甲醇溶液．注入檢測器，直到有流出檢測器出口後，用實心塞子封住檢測器出口．依次設定檢測器波長,在 270-280nm 記錄吸收度，並比較各波長下吸收度大小，找到吸收最大點.

The naphthalene has known characteristic absorption at 275nm, and 0.1mg/ml naphthalene solution in Methanol is prepared and injected into the detector until eluted over the flow cell outlet. Close the outlet with solid plug.

Set the detector wavelengths sequentially in 270-280nm range and to record absorbance, and then compare to find the wavelength with maxima absorption.

10.3.2 接受準則: Acceptance Criteria

波長應在 275±nm 有最大吸收 The maximum absorption wavelength shoule be 275±nm

10.3.3 記錄 Record

設備編號 Device ID	
測定波長 Measured wavelength (nm)	
270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280	
最大吸收波長 The maximum absorption wavelength	nm
誤差 Error	nm
檢查人/日期 Checker/Date	客戶確認/日期 Customer qualification/Date

10.4 基線雜訊與基線漂移：Baseline noise and baseline drift

10.4.1 測試方法：Test method

以 100%甲醇為移動相, 以幫浦頭最大流量 50%流速沖洗檢測器流通池 3 分鐘, 停止流速.

波長設定為 254nm, 待基線穩定後記錄基線 20 分鐘並保存圖譜, 計算基線雜訊與基線漂移.

Elute detector flow cell for 3 minutes with 100% methanol as the mobile phase and 50% of the maximum pump head flow rate, and stop pump. After the detector baseline is steady, then record baseline for 20 minutes, save and calculate baseline noise and baseline drift.

10.4.2 接受標準與計算方法：Acceptance criteria and calculation methods

10.4.3 接受標準 Acceptance Criteria：

基線雜訊 Baseline noise $N_{d:} \leqq 2\times10^{-5}$ (AU)

基線漂移 Baseline drift: $N_m \leqq 1\times10^{-3}$ (AU/h)

10.4.4 計算方法：Calculation method

基線雜訊 N_d：即為圖譜中的最高峰高(峰谷到峰頂)(AU)

基線漂移 N_m 為 1 小時內基線偏離原點的數值(AU/h)

(即取圖譜中 20 分鐘內基線偏離原點的數值換算為 1h 內基線偏離原點的數值)

Baseline noise N_d: The maximum peak height(AU, valley to the peak) in the chromatogram.

The baseline variation the difference between continuously monitored level to the begin time baseline level, and is count for one hour of period.

It is derived from the variation monitored in 20 minutes period.

10.4.5 記錄表：Record sheet

測試項目 Test item	可接受標準 Acceptance criteria	測試結果 Test results
基線雜訊測試值 Baseline noise	≤2×10^{-5}（AU）	N_d：_____ AU
基線漂移測試值 Baseline drift test	≤1×10^{-3}（AU/h）	N_m：_____ AU/h
結論 Conclusion		
測試人/日期 Test person/Date		客戶確認/日期 Customer qualification/Date

10.5 系統耐壓性能及壓力穩定性 System pressure resistance and pressure stability

10.5.1 方法 Methods

將儀器的液體輸送系統，進樣器，層析分離管柱和檢測器連接好. 以甲醇-水(50-50)為移動相啟動儀器，調整流速，使壓力達到最大允許值的 80%，待壓力平穩後保持 3 分鐘，不斷觀察壓力值變化，記錄 3 分鐘內的最高壓力和最低壓力.

用濾紙檢查各幫浦系統及 DAC 軸向壓縮系統管路接頭處有無濕跡.

Correctly connect the liquid delivery systems, injectors, chromatography column and detector of the instrument.

Start the instrument with Methanol-water(50-50) mobile phase.

Adjust the flow rate to reach 80% of the maximum allowable pressure value.

After the pressure is steady, continue to monitor and record maximum pressure and minimum pressure values for 3 minutes

Touch with dry filter paper to check each piping joints of the pump and DAC axial compression system to see if any leakage and wetted spot found.

10.5.2 接受標準：各管路接頭處應無濕跡

Acceptance criteria: pipe joints should have no leakage

10.5.3 記錄 Record

壓力最大允許值 The maximum allowable pressure value	最大壓力值 The maximum pressure value	最小壓力值 Minimum pressure	設定流速 Flow rate used(set)
結論 Conclusion			

測試人/日期 Test person/Date		客戶確認/日期 Customer qualification/Date	

11.偏差追蹤：Deviation tracking

將測試過程中的偏差記錄在此, 並向 QA 申領《偏差處理表》.

Record the deviation for the testing process here, and to apply from QA for a "Deviation handling table.

流水號 Serial number	偏差描述 Description of deviation	偏差編號 Deviation No.	已關閉 Are Closed	確認人/日期 Confirmer/Date

12.附件登記：Annex Registration

將支援本方案測試過程的附件登記在此，並按“測試說明”的要求附在方案後.

Register here the annexes that supports testing process of this program, and according to the requirement of related test descriptions, to attach to the program report.

附件登記表 Annex Registration Form				
附件流水號 Annex serial number	設備編號 Device ID	涉及章節 Related sections	附件描述 Annex Description	附件頁數 Annex Pages

登記人/日期 Subscriber/Date				

13. 總結：Summary

記錄人/日期 Record person/Date:

客戶確認/日期：Customer qualification/Date

本測試有 ____ 個偏差 This test has ____ deviation			
對測試結果和原始資料進行審核, 偏差關閉情況如下： The test results and raw data is audited, the deviation is closed as follows: □已完全關閉 □ is completely closed □未完全關閉 □ is not completely closed 仍有 _____ (流水號)偏差需要修正. There still _____(serial number) deviations need to be amended.			
最終結論：Final Conclusion： □Pass □Fail			
備註Remark :			
測試人/日期 Test person/Date		客戶確認/日期 Customer qualification/Date	