



## Performance Qualification

### • **Step Accuracy: STD Gradient\_3**

#### • **Instruments and Fluidics**

<b>Instrument Name</b>	<b>Model</b>	<b>Supplier's Name</b>	<b>Serial Number</b>
Pump	LPG-3400A	Thermo Scientific	8002568
UV Detector	DAD-3000RS	Thermo Scientific	8043573
Chromeleon Datasystem	V. 6.80 SR16 Build 5387	Thermo Scientific	40640

<b>Accessories</b>	<b>Description</b>
Back Pressure Device	Capillary (L:15 m; ID:0,18 mm)
Solvent A	Water (HPLC-Grade)
Solvent B for Gradient	Water + 0.1% Acetone

#### • **Additional Information**

Customer: Customer's Name  
 Operator: Operator's Name  
 Operator's Jobtitle  
 Execution Date: 2020-mai-27  
 Next Qualification: 2020-nov

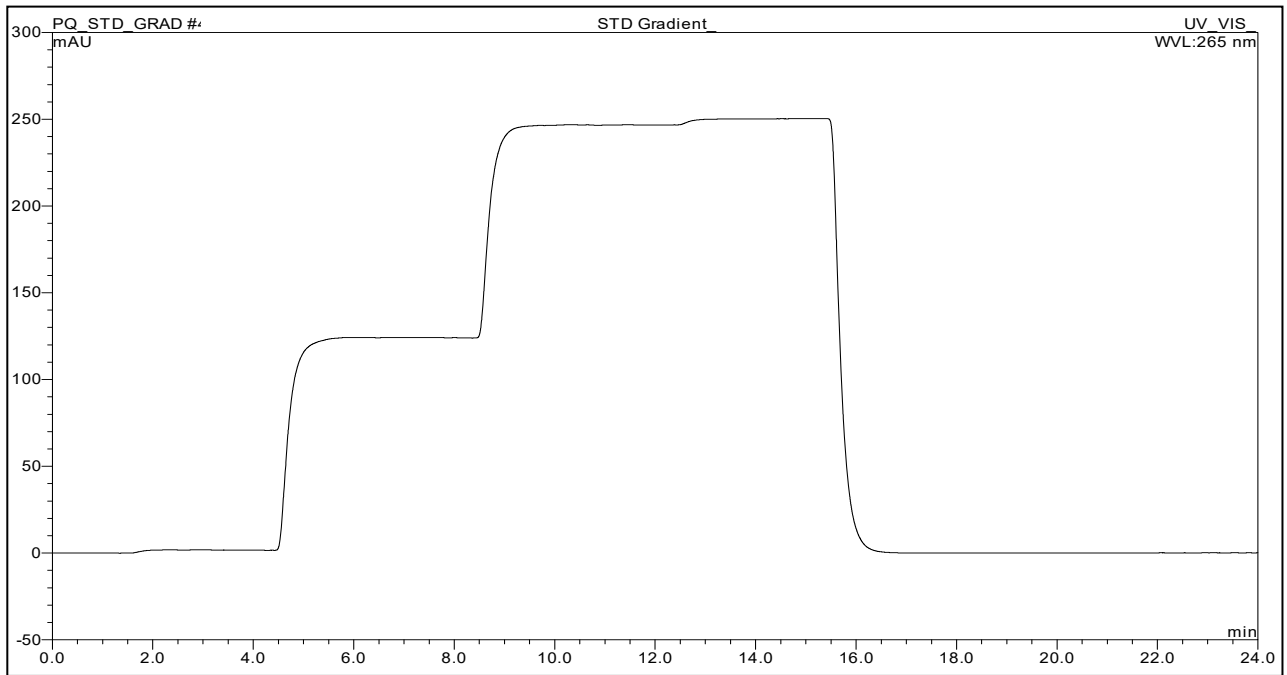
#### • **Limits and Test Results**

	<b>Limit</b>	<b>Observed max. Deviation</b>	<b>Result of all Steps</b>
<b>Step Accuracy</b>	<= 2,000 %	0,438 %	<b>Test passed</b>
<b>Step Ripple</b>	<= 0,500 %	0,039 %	<b>Test passed</b>

#### • **Signatures**

	<b>Signature</b>	<b>Date</b>
Submitter / Operator:	{seq.submitOperator.userName}	{seq.submitTime}
Reviewer:	{seq.reviewOperator.userName}	{seq.reviewTime}
Approver (e-sig. only):	{seq.approveOperator.userName}	{seq.approveTime}

### • Chromatogram of STD Gradient\_3



Flow [ml/min]: 2,000

• **Data of STD Gradient\_3**

<b>Observed Value [mAU]</b>	<b>Expected Value [%]</b>	<b>Calculated Value [%]</b>	<b>Abs. Critical Deviation [%]</b>	<b>Calculated Deviation [%]</b>	<b>Result</b>
0,00	0,00	0,000	2,000	0,000	ok
1,74	1,00	0,697	2,000	-0,303	ok
124,08	50,00	49,591	2,000	-0,409	ok
246,61	99,00	98,562	2,000	-0,438	ok
250,20	100,00	100,000	2,000	0,000	ok

• **Ripple of STD Gradient\_3**

<b>Step [%]</b>	<b>Ripple [mAU]</b>	<b>Calculated Ripple [%]</b>	<b>Critical Ripple [%]</b>	<b>Result</b>
1,00	0,038	0,015	0,500	ok
50,00	0,096	0,039	0,500	ok
99,00	0,071	0,028	0,500	ok

**Definition:**

**Sample Name:** STD Gradient\_3

**Gradienttype:** STD

Sample Number: 4  
 First Solvent: A Solvent Help: Grad  
 Second Solvent: B

**Calculation of Gradient accuracy and -precision:**

**Observed Values for Pumps with Standard Mixing Chamber:**

Name	Signal Start mAU	Signal Step mAU	Signal Step 50 mAU	Signal Step 99 mAU	Signal Step 100 mAU
	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1
Solvent change	n.a.	n.a.	n.a.	n.a.	n.a.
STD Gradient_1	0,010	2,045	124,549	246,978	250,529
STD Gradient_2	0,008	1,778	124,136	247,038	250,461
STD Gradient_3	-0,033	1,735	124,101	246,662	250,282

**Calculated Steps [%]**

	STD A-B	LON	STD C-D	C-D (1.0 ml/min)	Current
Start	0,00	0,00	0,00	0,00	0,00
Step 1	1,00	1,00	0,00	0,00	1,00
Step 2	50,00	99,00	0,00	0,00	50,00
Step 3	99,00	0,00	0,00	0,00	99,00
End	100,00	0,00	0,00	0,00	100,00

**Calculation of Ripple:**

**Observed Values for Pumps:  
 with Standard Mixing Chamber:      with Mixing Kit 1 or 2:**

Name	Ripple Step 1 mAU	Ripple Step mAU	Ripple Step 99 mAU	Ripple Step 1 mAU	Ripple Step 50 mAU
	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1
Solvent change	n.a.	n.a.	n.a.	n.a.	n.a.
STD Gradient_1	0,095	0,096	0,052	0,105	0,027
STD Gradient_2	0,095	0,067	0,443	0,054	0,037
STD Gradient_3	0,038	0,096	0,071	0,095	0,029

**Determination of Pump Unit for Dionex DGPs**

Sequence name: PQ\_STD\_GRAD  
 Right end of the sequence GRAD  
 Pump's model number: LPG-3400A  
 Pump's model variant: LPG  
 Pump unit:

### Determination of Pump Flow (Full Qualified and Non-Full-Qualified Variable Name)

CM-Version:	Flow:	
CM6:	2,000	(Pump)
CM7:	n.a.	(Pump - DDK driver)
	n.a.	(MicroPump - DDK driver)
	n.a.	(LoadingPump - DDK driver)
	n.a.	(PumpLeft - DDK driver)
	n.a.	(PumpRight - DDK driver)
	2,000	(Pump)
	n.a.	(MicroPump)
	n.a.	(LoadingPump)
	n.a.	(PumpLeft)
	n.a.	(PumpRight)
Used Flow Rate	<b>2,000</b>	(= maximum flow rate)

### Determination of Gradient Composition (Full Qualified and Non-Full-Qualified Variab

CM-Version:	%B(0.1):	%B(1.1):	%B(4.1):	%B(8.1):	%B(12.1):	
CM6:	n.a.	n.a.	n.a.	n.a.	n.a.	
CM7:	0,0	1,0		50,0	99,0	100,0
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
Used %B	<b>0,000</b>	<b>1,000</b>	<b>50,000</b>	<b>99,000</b>	<b>100,000</b>	

### Determination of Gradient Composition (Full Qualified and Non-Full-Qualified Variab

CM-Version:	%B(0.1):	%B(2.1):	%B(8.1):	%B(23.1):	%B(36.1):	
CM6:	n.a.	n.a.	n.a.	n.a.	n.a.	
CM7:	0,0	1,0		99,0	0,0	0,0
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
Used %B	<b>0,000</b>	<b>1,000</b>	<b>99,000</b>	<b>0,000</b>	<b>0,000</b>	

### Determination of Gradient Composition (Full Qualified and Non-Full-Qualified Variab

CM-Version:	%D(0.1):	%D(1.1):	%D(4.1):	%D(8.1):	%D(12.1):	
CM6:	0,0	0,0		0,0	0,0	0,0
CM7:	0,0	0,0		0,0	0,0	0,0
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	0,0	0,0		0,0	0,0	0,0
Used %D	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	

### Determination of Gradient Composition (Full Qualified and Non-Full-Qualified Variab

CM-Version:	%D(0.1):	%D(2.1):	%D(8.1):	%D(23.1):	%D(36.1):	
CM6:	0,0	0,0		0,0	0,0	0,0
CM7:	0,0	0,0		0,0	0,0	0,0
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	n.a.	n.a.	n.a.	n.a.	n.a.	
	0,0	0,0		0,0	0,0	0,0
<b>Used %D</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	<b>0,000</b>	









**Observed Values for Pumps with Mixing Kit 1 or 2:**

Signal Start mAU	Signal Step 1 mAU	Signal Step 50 mAU	Signal Step 99 mAU	Signal Step 100 mAU	Signal Step End mAU
UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1	UV_VIS_1
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0	2,040	124,476	0,093	n.a.	n.a.
0	1,783	124,136	0,189	n.a.	n.a.
0	1,747	124,086	0,137	n.a.	n.a.

**with Micro Mixing Kit:**

Ripple Step 1 mAU	Ripple Step 50 mAU	Ripple Step 99 mAU
UV_VIS_1	UV_VIS_1	UV_VIS_1
n.a.	n.a.	n.a.
n.a.	0,095	0,096
n.a.	0,095	0,067
n.a.	0,038	0,096

**File Name) - STD Gradient A-B**

(Pump)
(Pump)
(MicroPump)
(LoadingPump)
(PumpLeft)
(PumpRight)
(Agilent ICF)
(= maximum %B)

**File Name) - LON Gradient A-B**

(Pump)
(Pump)
(MicroPump)
(LoadingPump)
(PumpLeft)
(PumpRight)
(Agilent ICF)
(= maximum %B)

**File Name) - STD Gradient C-D**

(Pump)
(Pump)
(MicroPump)
(LoadingPump)
(PumpLeft)
(PumpRight)
(Agilent ICF)
(= maximum %D)

**File Name) - Gradient C-D (Flow rate: 1.000 ml/min)**

(Pump)
(Pump)
(MicroPump)
(LoadingPump)
(PumpLeft)
(PumpRight)
(Agilent ICF)
(= maximum %B)







**Observed Values for Pumps with Micro Mixing Kit:**

<b>Signal Start mAU</b>	<b>Signal Step 1 mAU</b>	<b>Signal Step 50 mAU</b>	<b>Signal Step 99 mAU</b>	<b>Signal Step 100 mAU</b>	<b>Signal End mAU</b>
<i>UV_VIS_1</i>	<i>UV_VIS_1</i>	<i>UV_VIS_1</i>	<i>UV_VIS_1</i>	<i>UV_VIS_1</i>	<i>UV_VIS_1</i>
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0,010	2,045	124,549	246,978	250,529	0,128
0,008	1,778	124,136	247,038	250,461	0,167
-0,033	1,735	124,101	246,662	250,282	0,146













**Linear Drift correction:  $Y = m \cdot X + t$       Drift corrected Signal values:  $Y(\text{corr}) = Y(\text{obs}) - m \cdot X - t$**

Slope m mAU / min $m = (Y2 - Y1) / (X2 - X1)$	Offset t mAU $t = Y1 - m \cdot X1$	Signal Step 5 mAU UV_VIS_1	Signal Step 1 mAU UV_VIS_1	Signal Step 50 mAU UV_VIS_1	Signal Step 99 mAU UV_VIS_1
#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!
0,005215989	0,004336874	0,000	2,020	124,503	246,911
0,007003058	0,001022917	0,000	1,749	124,079	246,953
0,007908666	-0,041044766	0,000	1,744	124,079	246,608













**Calculated Steps [%]**

<b>Signal Step 100 mAU</b>	<b>Signal Step 99 %</b>	<b>Signal Step 50 %</b>	<b>Signal Step 1 %</b>	<b>Signal Step 1 %</b>	<b>Signal Step 100 %</b>
<b>UV_VIS_1</b>	<b>UV_VIS_1</b>	<b>UV_VIS_1</b>	<b>UV_VIS_1</b>	<b>UV_VIS_1</b>	<b>UV_VIS_1</b>
<b>#VALEUR!</b>	<b>#VALEUR!</b>	<b>#VALEUR!</b>	<b>#VALEUR!</b>	<b>#VALEUR!</b>	<b>#VALEUR!</b>
250,446	0,000	0,807	49,712	98,588	100,000
250,355	0,000	0,699	49,561	98,641	100,000
250,205	0,000	0,697	49,591	98,562	100,000