



## Performance Qualification

### • Step Accuracy: STD Gradient\_3

#### • Instruments and Fluidics

Instrument Name	Model	Supplier's Name	Serial Number
Pump	HPG-3400RS	Thermo Scientific	8125299
UV Detector	DAD-3000RS	Thermo Scientific	8043573
Chromeleon Datasystem	V. 6.80 SR16 Build 5387	Thermo Scientific	40640

Accessories	Description
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-mars-24  
 Next Qualification: 2020-sept

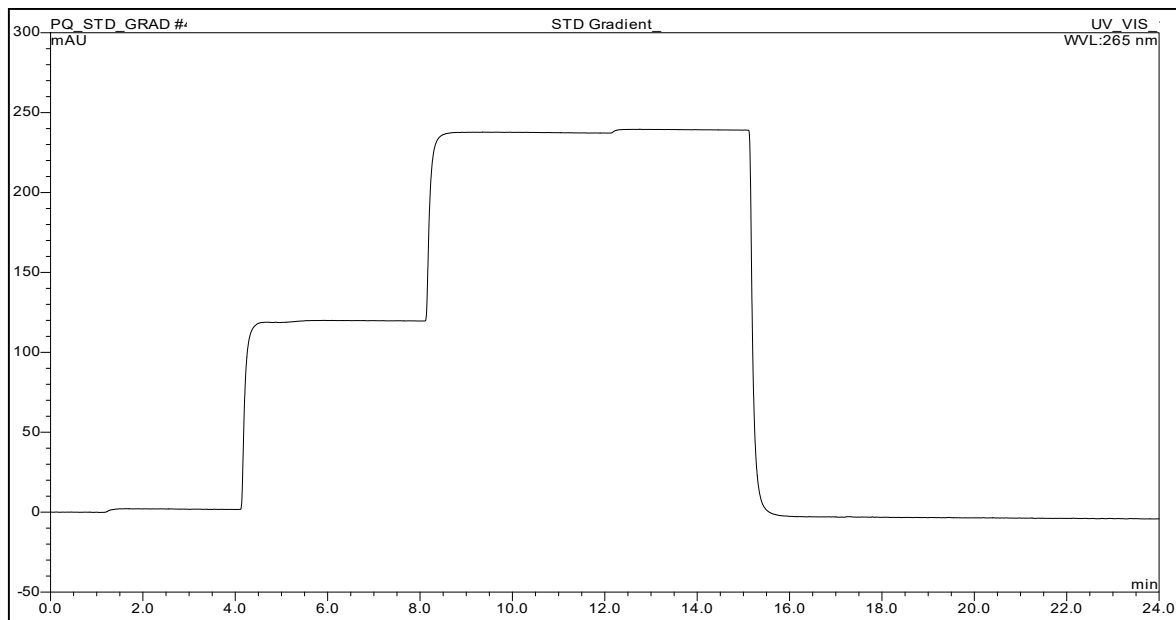
#### • Limits and Test Results

	Limit	Observed max. Deviation	Result of all Steps
Step Accuracy	<= 0,500 %	0,063 %	Test passed
Step Ripple	<= 0,500 %	0,043 %	Test passed

#### • Signatures

	Signature	Date
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**

Observed Value [mAU]	Expected Value [%]	Calculated Value [%]	Abs. Critical Deviation [%]	Calculated Deviation [%]	Result
0,00	0,00	0,000	0,500	0,000	ok
2,32	1,00	0,961	0,500	-0,039	ok
121,01	50,00	50,063	0,500	0,063	ok
239,29	99,00	99,000	0,500	0,000	ok
241,71	100,00	100,000	0,500	0,000	ok

• **Ripple of STD Gradient\_3**

Step [%]	Ripple [mAU]	Calculated Ripple [%]	Critical Ripple [%]	Result
1,00	0,102	0,042	0,500	ok
50,00	0,092	0,038	0,500	ok
99,00	0,104	0,043	0,500	ok

**Definition:**

Sample Name: **STD Gradient\_3**  
 Gradienttype: **STD**                      1                      0                      0                      1

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	-0,129	1,429	118,817	235,802	237,304
STD Gradient_2	-0,375	1,386	119,283	236,826	238,328
STD Gradient_3	-0,056	1,720	119,674	237,231	239,100

**Calculated Steps [%]**

	STD A-B	LON	STD C-D	C-D (1.0 ml/ml)	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	0,358	0,239	0,054	0,240	0,114
STD Gradient_2	0,174	0,163	0,084	0,169	0,108
STD Gradient_3	0,102	0,092	0,104	0,082	0,242

**Determination of Pump Unit for Dionex DGPs**

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

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

CM-Version:	Flow:
CM6:	2,000 (Pump)
CM7:	2,000 (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 Variable Name)**

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 Variable Name)**

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 Variable Name)**

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.
	n.a.	n.a.	n.a.	n.a.	n.a.
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**

<b>CM-Version:</b>	<b>%D(0.1):</b>	<b>%D(2.1):</b>	<b>%D(8.1):</b>	<b>%D(23.1):</b>	<b>%D(36.1):</b>	
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:**

<i>S/m</i>	<i>Signal Start mAU</i>	<i>Signal Step 1 mAU</i>	<i>Signal Step 50 mAU</i>	<i>Signal Step 99 mAU</i>	<i>Signal Step 100 mAU</i>	<i>Signal Step End mAU</i>
<i>UV</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>	<i>UV_VIS_1</i>
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
-6	1,816	118,791	-5,948	n.a.	n.a.	n.a.
-5	1,699	119,261	-4,869	n.a.	n.a.	n.a.
-4	2,048	119,658	-4,023	n.a.	n.a.	n.a.

**with Micro Mixing Kit:**

<i>R/m</i>	<i>Ripple Step 1 mAU</i>	<i>Ripple Step 50 mAU</i>	<i>Ripple Step 99 mAU</i>
<i>UV</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.	0,358	0,239	0,054
n.a.	0,174	0,163	0,084
n.a.	0,102	0,092	0,104

**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>
<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>
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
-0,129	1,429	118,817	235,802	237,304	-6,123
-0,375	1,386	119,283	236,826	238,328	-4,963
-0,056	1,720	119,674	237,231	239,100	-4,195













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

<b>Slope m</b> mAU / min $m = (Y2-Y1)/(X2-X1)$	<b>Offset t</b> mAU $t = Y1 - m \cdot X1$	<b>Signal Step 5</b> mAU UV_VIS_1	<b>Signal Step 1</b> mAU UV_VIS_1	<b>Signal Step 50</b> mAU UV_VIS_1	<b>Signal Step 99</b> mAU UV_VIS_1
#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!
-0,264068313	0,135251218	0,000	2,350	120,794	238,836
-0,202091252	-0,173194931	0,000	2,367	121,073	239,424
-0,182334188	0,12633871	0,000	2,323	121,007	239,292













**Calculated Steps [%]**

<b>Signal Step 100 mAU</b>	<b>Signal Step 50 %</b>	<b>Signal Step 1 %</b>	<b>Signal Step 50 %</b>	<b>Signal Step 99 %</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>
241,130	0,000	0,975	50,095	99,048	100,000
241,533	0,000	0,980	50,127	99,127	100,000
241,709	0,000	0,961	50,063	99,000	100,000