ThermoFisher
SCIENTIFIC

Performance Qualification

• Step Accuracy: STD Gradient_3

• Instruments and Fluidics

Instrument Name	Model	Supplier's Name	Serial Number
Pump	**LPG-3400RS**	**Thermo Scientific**	**8043253**
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-avr-15
Next Qualification:	2020-oct

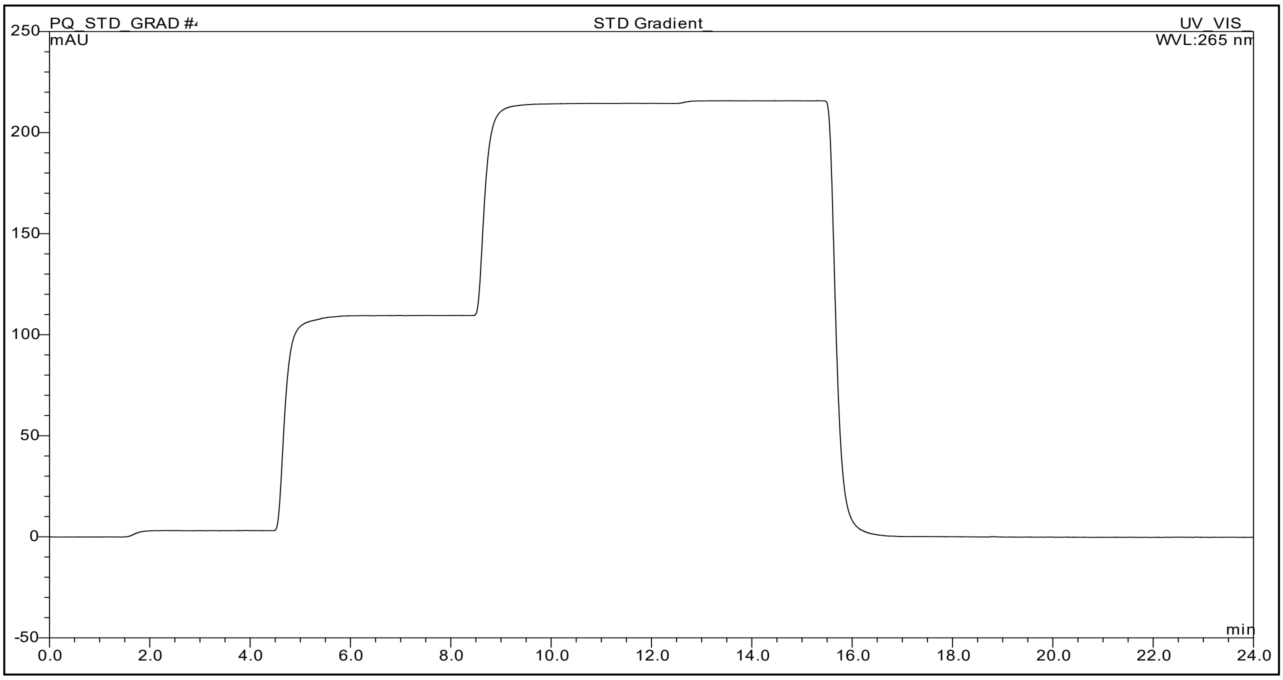
• Limits and Test Results

	Limit	Observed max. Deviation	Result of all Steps
Step Accuracy	<= 2,000 %	0,771 %	**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	2,000	0,000	ok
3,19	1,00	1,476	2,000	0,476	ok
109,65	50,00	50,771	2,000	0,771	ok
214,66	99,00	99,395	2,000	0,395	ok
215,97	100,00	100,000	2,000	0,000	ok

• *Ripple of STD Gradient_3*

Step [%]	*Ripple [mAU]*	*Calculated Ripple [%]*	*Critical Ripple [%]*	*Result*
1,00	0,094	0,043	0,500	ok
50,00	0,075	0,035	0,500	ok
99,00	0,067	0,031	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 Gradientaccuracy and -precision:

Observed Values for Pumps with Standard Mixing Chamber:

Name	***Signal Start mAU*** ***UV_VIS_1***	***Signal Step mAU*** ***UV_VIS_1***	***Signal Step 50 mAU*** ***UV_VIS_1***	***Signal Step 99 mAU*** ***UV_VIS_1***	***Signal Step 100 mAU*** ***UV_VIS_1***
Solvent change	n.a.	n.a.	n.a.	n.a.	n.a.
STD Gradient_1	0,059	3,466	109,936	215,004	216,248
STD Gradient_2	0,053	3,206	109,743	214,678	215,944
STD Gradient_3	-0,110	3,057	109,494	214,482	215,770

Calculated Steps [%]

	STD A-B	LON	STD C-D	C-D (1.0 ml/mi	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*** ***UV_VIS_1***	***Ripple Step mAU*** ***UV_VIS_1***	***Ripple Step 99 mAU*** ***UV_VIS_1***	***Ripple Step 1 mAU*** ***UV_VIS_1***	***Ripple Step 50 mAU*** ***UV_VIS_1***
Solvent change	n.a.	n.a.	n.a.	n.a.	n.a.
STD Gradient_1	0,090	0,168	0,071	0,157	0,131
STD Gradient_2	0,088	0,095	0,070	0,131	0,084
STD Gradient_3	0,094	0,075	0,067	0,079	0,124

Determination of Pump Unit for Dionex DGPs

Sequence name:	PQ_STD_GRAD
Right end of the sequence	GRAD
Pump's model number:	LPG-3400RS
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:	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	**2,000**	(= 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.
	n.a.	n.a.	n.a.	n.a.	n.a.
Used %B	**0,000**	**1,000**	**50,000**	**99,000**	**100,000**

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.
	n.a.	n.a.	n.a.	n.a.	n.a.
Used %B	**0,000**	**1,000**	**99,000**	**0,000**	**0,000**

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.
	n.a.	n.a.	n.a.	n.a.	n.a.
	0,0	0,0	0,0	0,0	0,0
Used %D	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**

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
Used %D	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**

Observed Values for Pumps with Mixing Kit 1 or 2:

Si m UV	Signal Start 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	Signal Step 100 mAU UV_VIS_1	Signal Step End mAU UV_VIS_1
n.a	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0	3,207	109,949	-0,111	n.a.	n.a.	n.a.
0	3,101	109,752	-0,131	n.a.	n.a.	n.a.
0	2,978	109,496	-0,239	n.a.	n.a.	n.a.

with Micro Mixing Kit:

Ri m UV	Ripple Step 1 mAU UV_VIS_1	Ripple Step 50 mAU UV_VIS_1	Ripple Step 99 mAU UV_VIS_1
n.a	n.a.	n.a.	n.a.
n.a	0,090	0,168	0,071
n.a	0,088	0,095	0,070
n.a	0,094	0,075	0,067

le Name) - STD Gradient A-B

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

le Name) - LON Gradient A-B

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

le Name) - STD Gradient C-D

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

ɔle 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:

Signal Sta 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	Signal Step 100 mAU UV_VIS_1	Signal End mAU UV_VIS_1
n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0,059	3,466	109,936	215,004	216,248	-0,111
0,053	3,206	109,743	214,678	215,944	-0,139
-0,110	3,057	109,494	214,482	215,770	-0,256

Linear Driftcorrection: Y = m*X + t ***Drift corrected Signal values: Y(corr) = Y(obs) - m*X - t***

Slope m mAU / min m = (Y2-Y1)/(X2-X1)	***Offset t mAU t = Y1-m*X1***	***Signal Step S 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!
-0,007499782	0,06682306	0,000	3,429	109,929	215,027
-0,008446109	0,061605985	0,000	3,178	109,749	214,718
-0,006420933	-0,103933589	0,000	3,187	109,650	214,663

Calculated Steps [%]

Signal Step 100 mAU UV_VIS_1	Signal Step S % UV_VIS_1	Signal Step 1 % UV_VIS_1	Signal Step 50 % UV_VIS_1	Signal Step 99 % UV_VIS_1	Signal Step 100 % UV_VIS_1
#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!	#VALEUR!
216,293	0,000	1,585	50,824	99,414	100,000
216,009	0,000	1,471	50,808	99,402	100,000
215,970	0,000	1,476	50,771	99,395	100,000

Thermo Fisher
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Performance Qualification

• *Precision of the Stand. Gradient*

• *Instruments and Fluidics*

Instrument Name	*Model*	*Supplier's Name*	*Serial Number*
Pump	**LPG-3400RS**	**Thermo Scientific**	**8043253**
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-avr-15
Next Qualification:	2020-oct

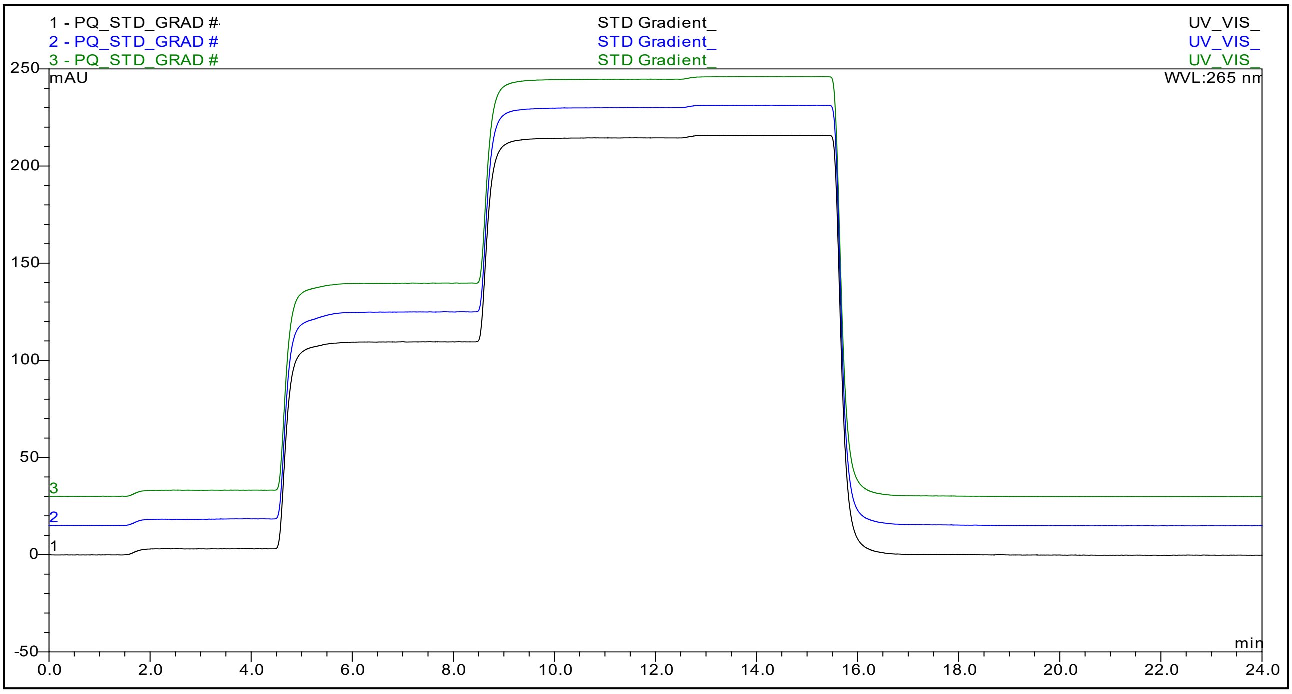
• *Limits and Test Results*

	Limit	*Observed max. SD*	*Result of all Steps*
Gradient Precision	<= 0,500 %	0,065 %	**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}

• *Overlay of three Gradients*



• *Data of three Gradients*

Expected Value [%]	***Calculated Value Gradient_1 [%]***	***Calculated Value Gradient_2 [%]***	***Calculated Value Gradient_3 [%]***	***Critical SD [%]***	***Calculated SD [%]***	***Result***
0,00	0,00	0,00	0,00	0,50	0,000	ok
1,00	1,59	1,47	1,48	0,50	0,065	ok
50,00	50,82	50,81	50,77	0,50	0,027	ok
99,00	99,41	99,40	99,39	0,50	0,010	ok
100,00	100,00	100,00	100,00	0,50	0,000	ok

Pump's model number: LPG-3400RS
Pump's model variant: LPG
Pump unit:

Determination Page Title

Gradient type: • Precision of the Stand. Gradient
Solvent C-D (if used)
Pump unit (DGPs only)
All: • Precision of the Stand. Gradient