

TEST CERTIFICATE

S-A-LE 1299



DORSHORST 2
7217PH HARFSEN
NETHERLANDS

INSTRUMENT: HPLC - VWD
ID NR.: 1299
MODEL: AGILENT SERIES 1100/1200
CAL. DATE: AUGUST 31, 2020

HPLC - VWD

NR. 1299: AGILENT SERIES 1100/1200

GENERAL

In this report the performance of the Agilent Series 1100 and 1200 HPLC modules combined to one system was investigated. The system consisted of a degasser, binary pump, autosampler, thermostatted column compartment, variable wavelength (VW) detector and a PC with Chemstation software.

Table 1: System specifications

	Agilent Series	Module	Serial	Number own system
Degasser	1100	G1322A	JP73023655	1284
Binary pump SL	1200	G1312B	DE63056189	1073
Autosampler ALS	1100	G1329A	DE14909176	1285
Column oven	1200	G1316B	DE60556119	1070
VW detector	1200	G1314B	DE71362174	1299

The system performance was tested in practice to check the operational performance of instrument modules. For this a test application to Gallic Acid by HPLC-VWD has been developed and will be used (PQ tests).

SYSTEM PERFORMANCE (PQ TESTS)

The performance characteristics linearity and repeatability were determined using a standard Gallic acid test method. The main details of the method, the solutions and the criteria are presented underneath:

METHOD

The following liquid chromatographic conditions were used:

- HPLC column : X select HSS T3, 3.5 μ m particles, 4.6*100 mm column
- Mobile phase A : 95% MilliQ water/ 5% Methanol/ 0.1% TFA (v/v/v)
- Mobile phase B : 80% Methanol/ 20% MilliQ water/ 0.1% TFA (v/v/v)
- Flow : 1,0 ml/min
- Injection volume : 20 μ l
- Detector : VWD, wavelength 271 nm
- Column temperature : Ambient
- Quantification : External calibration, based on response factors
- Gradient :

T0 min	-	100%	A	-	0%	B
T7 min	-	100%	A	-	0%	B
T13 min	-	70%	A	-	30%	B
T13,5 min	-	0%	A	-	100%	B
T16,5 min	-	0%	A	-	100%	B
T16,6 min	-	100%	A	-	0%	B

SOLUTIONS

Calibration standards were prepared using a stock solution containing 1000 ppm Gallic acid in methanol. The stock solution was diluted with a reconstitution solvent that contained 78% MilliQ water, 20% methanol and 2% formic acid (v/v/v) to reach the desired range of standard solutions. The calibration standards contained Gallic acid in the range of 0,36 to 25,0 mg/L.

CRITERIA

The acceptance criterion for the correlation coefficient is 0,999. The acceptance criterion for the relative standard deviation is 5,0%.

LINEARITY

The linearity was determined by measuring 5 calibration standard solutions in the range of 0,36 to 25,0 mg/L. The five point calibration curve of Gallic acid standard solutions in MilliQ water was recorded at 271 nm and is presented in Table 2 and Figure 1 below. The correlation coefficient of 1 comply with the specified acceptance criterion of $r > 0,999$.

Table 22: Results of the five point calibration curve

Concentration (mg/L)	Area (mAU)
0,36	21,2
1,5	87,8
3,0	174,3
6,0	368,7
25,0	1560,5

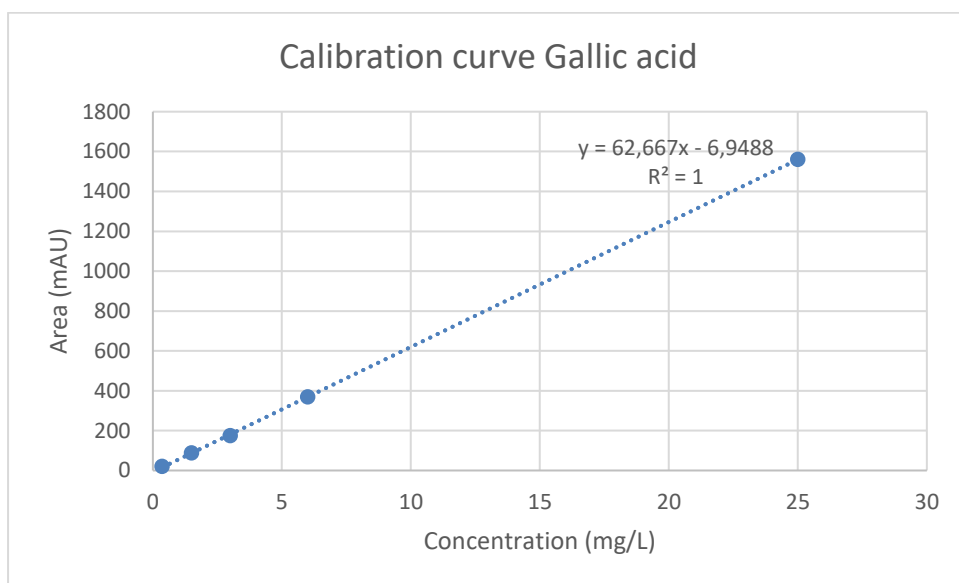


Figure 1: Graph of the five point calibration curve

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REPEATABILITY

Repeatability was determined for the mid calibration standard with a concentration of 3,0 mg/L Gallic acid and is presented in Table 3 below. The relative standard deviation (2,1%) is within the acceptance criterion of 5,0% and therefore acceptable.

Table 3: Repeatability of the mid cal. standard

Number	Area (mAU)
3.1	173,7
3.2	168,2
3.3	169,0
3.4	169,1
3.5	168,7
3.6	168,0
Average	169,45
RSD (%)	2,1%

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CONCLUSION

The system meets all the stated criteria, it is therefore in a good state and ready for use.

AUTHORISATION: 31-08-2020



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