

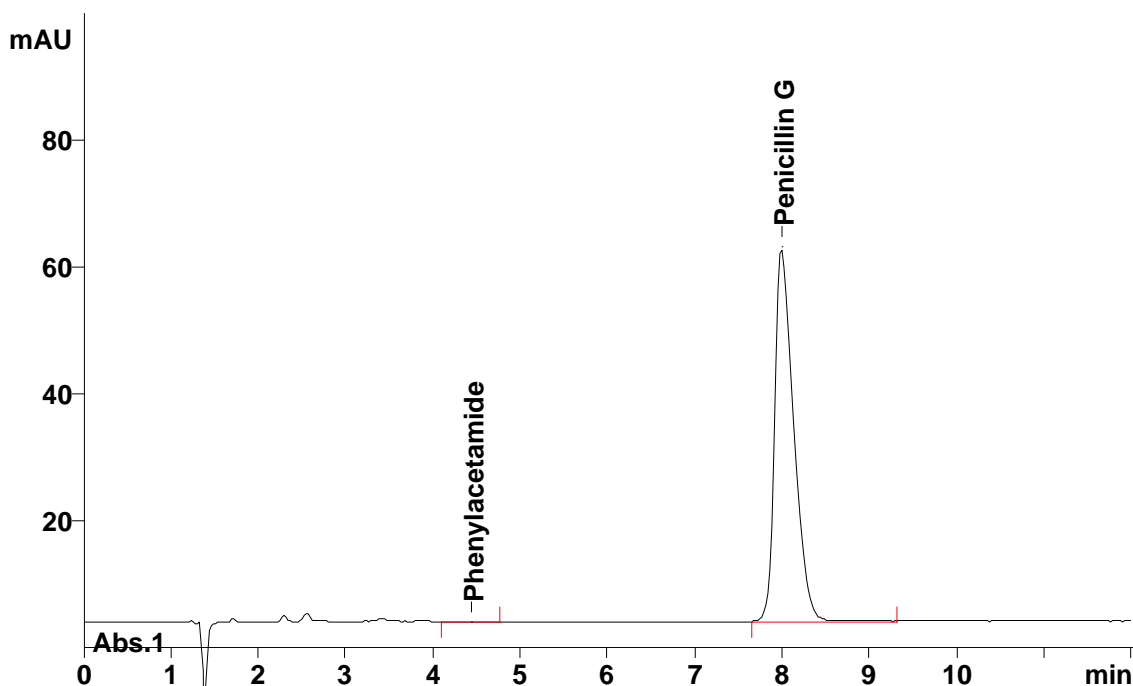
IC Application Note No. U-37

Title: System suitability test for Penicillin G potassium according to USP

Summary: Determination of Penicillin G potassium and 2-phenylacetamide according to USP 28-NF 23 (second supplement) using RP chromatography with UV detection.

Sample: Penicillin G potassium
Sample Preparation: 6.24 mg dissolved in 100 mL ultrapure water

Column: 6.1008.100 Prontosil 120-5-C18 AQ 150
Wavelength: 220 nm
Eluent: 10 mmol/L monobasic potassium phosphate / methanol (60:40)
Flow: 1.0 mL/min
Injection Volume: 10 µL



Chromatogram:	2-phenylacetamide	Penicillin G potassium mg/mL
	Not detected	0.062

Results:

Test factors	Value	Limit	Result
Theoretical plates	4354	More than 1000	PASS
Tailing factor	1.06	Less than 2.2	PASS
RSD (n = 6)	1.2%	Less than 2.0%	PASS
Resolution	11.0	More than 2	PASS

Sample assay:

Run	Concentration (mg/mL)
Sample 1-6	0.062
Sample 1-6	0.061
Sample 1-6	0.061
Sample 1-6	0.062
Sample 1-6	0.061
Sample 1-6	0.062
Average	0.062