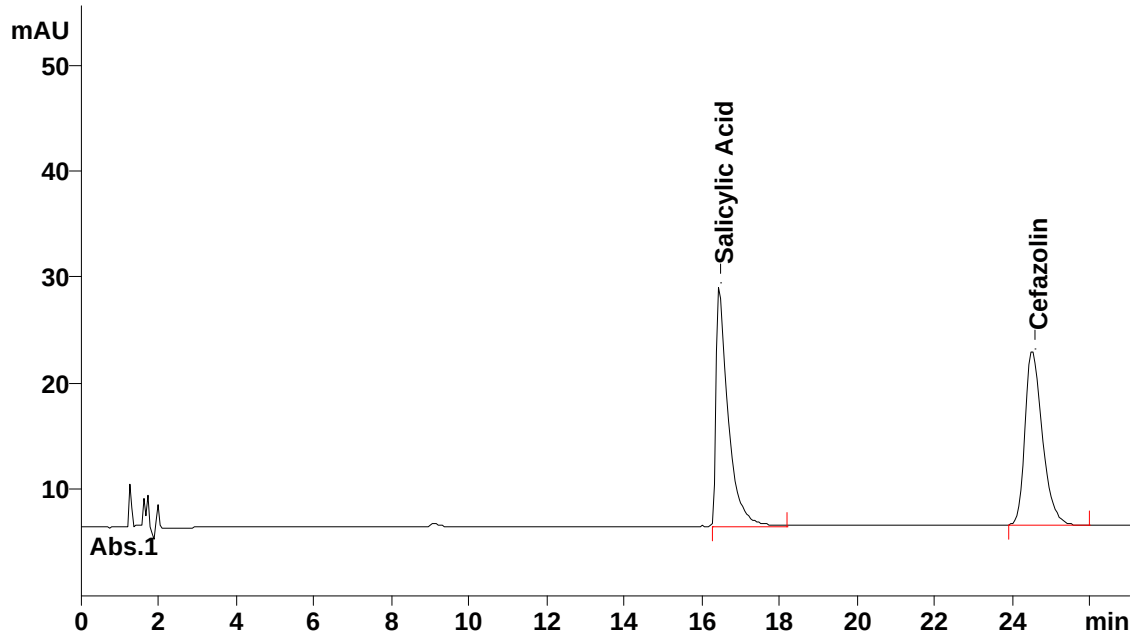
IC Application Note No. U-27

Title:	**System suitability test for Cefazolin according to USP**

***Summary*:**	Determination of Cefazolin according to USP 28-NF 23 (second supplement) using RP chromatography with UV detection.

Sample:	Cefazolin
Sample Preparation:	approx. 1 mg/mL in phosphate buffer pH = 7.0. Dilute 0.75 mL of this solution to 10 mL after addition of internal standard

Column:	6.1008.100 Prontosil 120-5-C18 AQ 150
Wavelength:	254 nm
Buffer pH = 3.6	0.900 g/L disodium hydrogen phosphate 1.298 g/L citric acid monohydrate
Eluent:	Buffer pH = 3.6 (according to USP) / acetonitrile (9:1)
Flow:	2.0 mL/min
Injection Volume:	10 µL



Chromatogram:	Salicylic acid (internal standard)	Cefazolin mg/mL
	n.q.	**0.075**

Results:

Test factors	Value	Limit	Result
Tailing factor	1.5	Less than 1.5	PASS
Theo. plates	13120	More than 1500	PASS
Resolution	10.3	More than 2	PASS
RSD(n=6)	1.4 %	Less than 2.0 %	PASS
Rel. retention time Cefazolin	1	About 1	PASS
Rel. retention time salicylic acid	0.68	About 0.7	PASS

Sample assay:

Run	Cefazolin (mg/ml)
Sample 1-3	**0.075**
Sample 2-3	**0.076**
Sample 3-3	**0.076**
Average	**0.0756**
Purity	**98.51%**