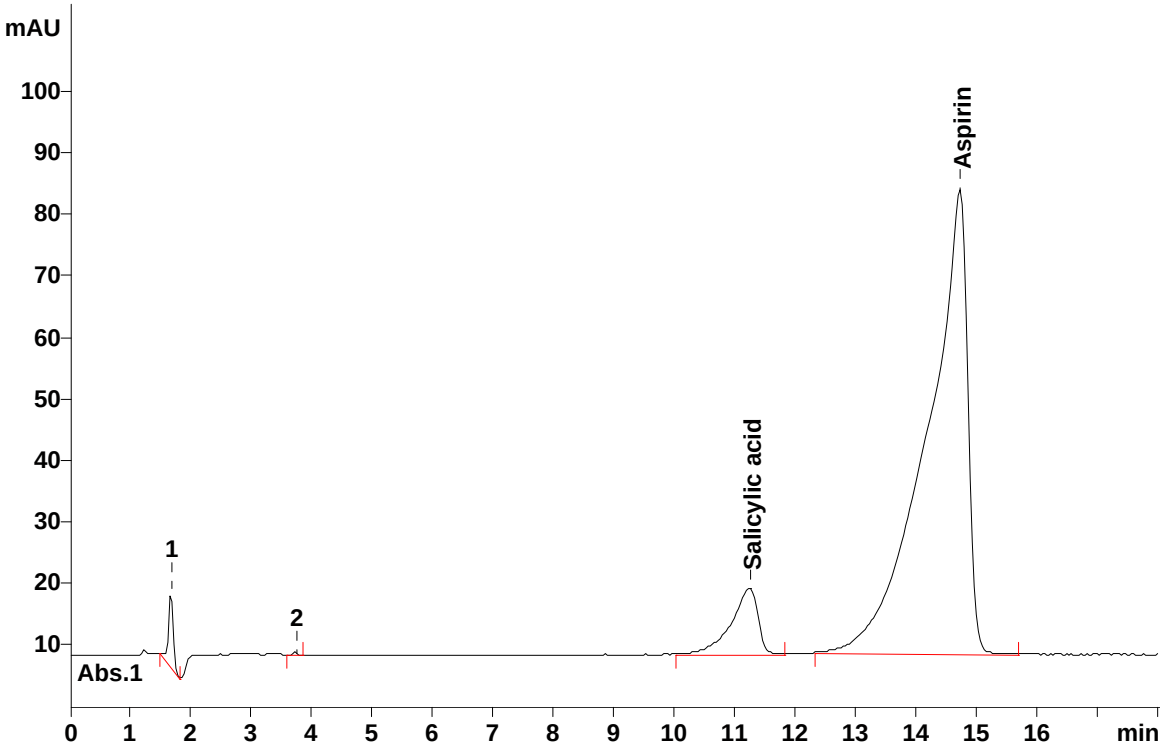
IC Application Note No. U-28

Title:	**Salicylic acid impurity in aspirin tablets according to the USP method**

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

Sample:	Aspirin (acetylsalicylic acid) standards
Sample Preparation:	Aspirin and salicylic acid are dissolved in acetonitrile / formic acid (99:1)

Column:	6.1008.100 Prontosil 120-5-C18 AQ 150
Wavelength:	280 nm
Eluent:	2 g/L sodium 1-heptanesulfonate in water / acetonitrile (85:15), pH = 3.4 with glacial acetic acid
Flow:	2.0 mL/min
Injection Volume:	10 µL



Chromatogram:	Salicylic acid mg/mL	Aspirin (acetylsalicylic acid) mg/mL
	0.3	**1.0**

Results:

Test factors	Value	Limit	Result
Tailing factor	0.78	Less than 2	PASS
RSD Aspirin	1.5%	Less than 2.0%	PASS
RSD salicylic acid	1.3%	Less than 4.0%	PASS
Resolution	4.3	More than 2	PASS