

IC Application Note No. U-36

Title: Assay determination of Ranitidine HCI according to USP

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

Sample:Ranitidine hydrochlorideSample Preparation:112 mg dissolved in eluent

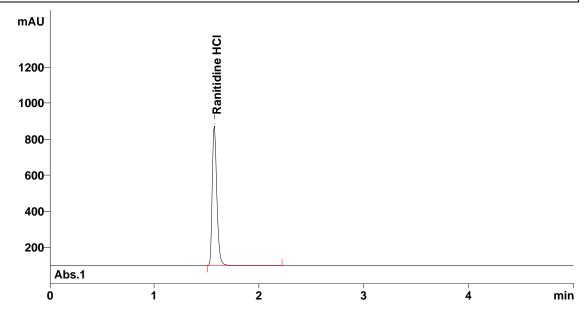
Column: 6.1008.100 Prontosil 120-5-C18 AQ 150

Wavelength: 322 nm

Eluent: Methanol / 0.1 mol/L aqueous ammonium acetate (85:15)

Flow: 2.0 mL/min

Injection Volume: 10 μL



Chromatogram:	Ranitidine HCI mg/mL
	0.106

Results:

Test factors	Value	Limit	Result
Theoretical plates	6770	More than 700	PASS
Tailing factor	1.378	Less than 2.0	PASS
RSD (%, n = 6)	0.22	Less than 2.0	PASS