

IC Application Note No. U-35

| Title: | Chromatographic purity determination of |
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| | Thiamine hydrochloride according to USP |

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

Sample: Thiamine hydrochloride

Sample Preparation: Tablets dissolved according to USP procedure

Column: 6.1008.100 Prontosil 120-5-C18 AQ 150

Wavelength: 254 nm

Solution A: 5 mmol/L sodium 1-octanesulfonate in diluted glacial

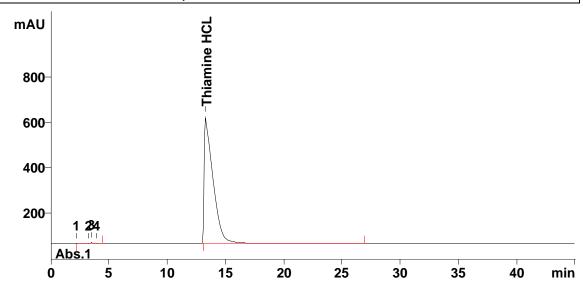
acetic acid (1:100)

Solution B: Methanol / acetonitrile (3:2)

Eluent: Solution A / solution B (60:40)

Flow: 0.75 mL/min

Injection Volume: 10 μL



| Chromatogram: | Thiamine HCI area% |
|---------------|--------------------|
| | 99.8 |

Results:

| Test factors | Value | Limit | Result |
|--------------------------|---------|-----------------|--------|
| Response of Thiamine HCI | 99.77 % | More than 99.0% | PASS |