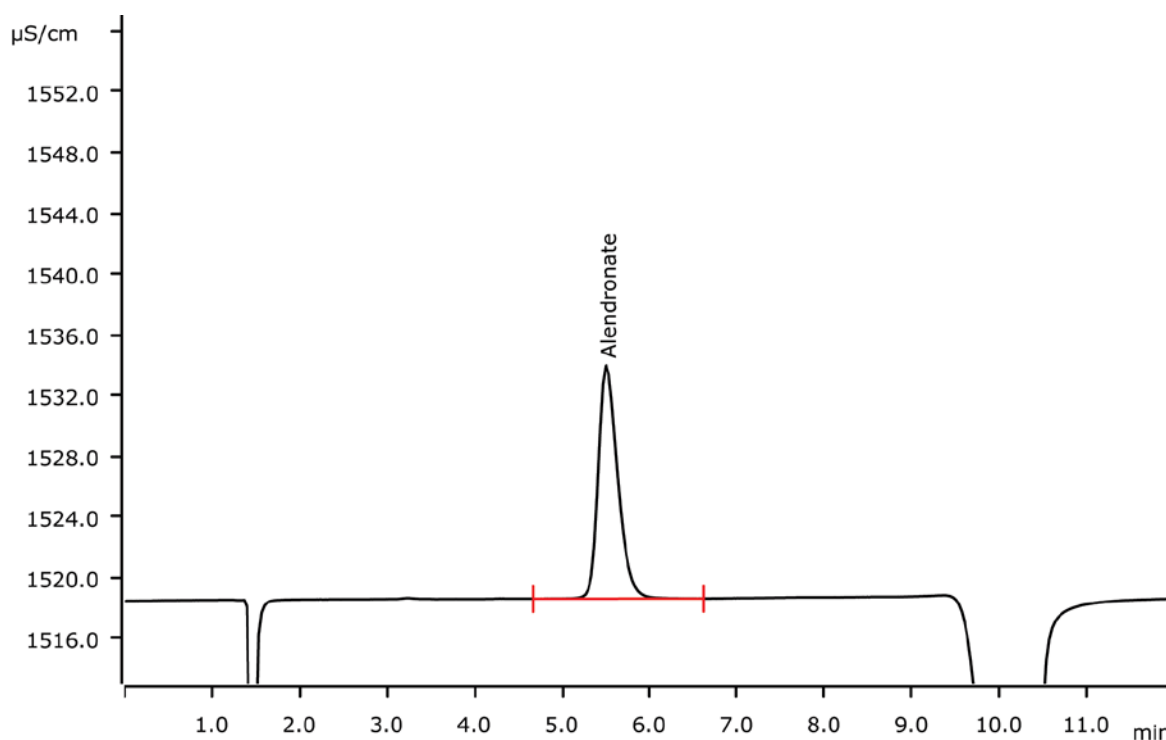


Alendronate in tablets according to the Chinese Pharmacopeia



Alendronate or alendronic acid is a bisphosphonate applied against osteoporosis. It is the main constituent of the tablets and is determined according to the Chinese Pharmacopeia (2015). The bisphosphonate is separated on a Metrosep A Supp 4 - 250/4.0 column before it is quantified with direct conductivity detection.

Results

System suitability / Results	RSD (retention time) [%] n = 6	RSD (area) [%] n = 6	Theor. plates (req. 2000)
Alendronate	0.02	0.39	3000

	Concentration [mg/tablet]	Recovery [%]
Sample tablets 1	10.6	106.3
Sample tablets 2	10.8	107.8

Sample

Alendronate tablets

Sample preparation

According to the Chinese Pharmacopeia

Columns

Metrosep A Supp 4 - 250/4.0	6.1006.430
Metrosep A Supp 4/5 Guard/4.0	6.1005.500

Solutions

Eluent	6.0 mmol/L oxalic acid
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Analysis

Direct conductivity detection

Instrumentation

930 Compact IC Flex Oven/Deg	2.930.2160
IC Conductivity Detector	2.850.9010
858 Professional Sample Processor	2.858.0020

Parameters

Flow rate	1.0 mL/min
Injection volume	20 μ L
P _{max}	12 MPa
Recording time	12 min
Column temperature	30 °C

