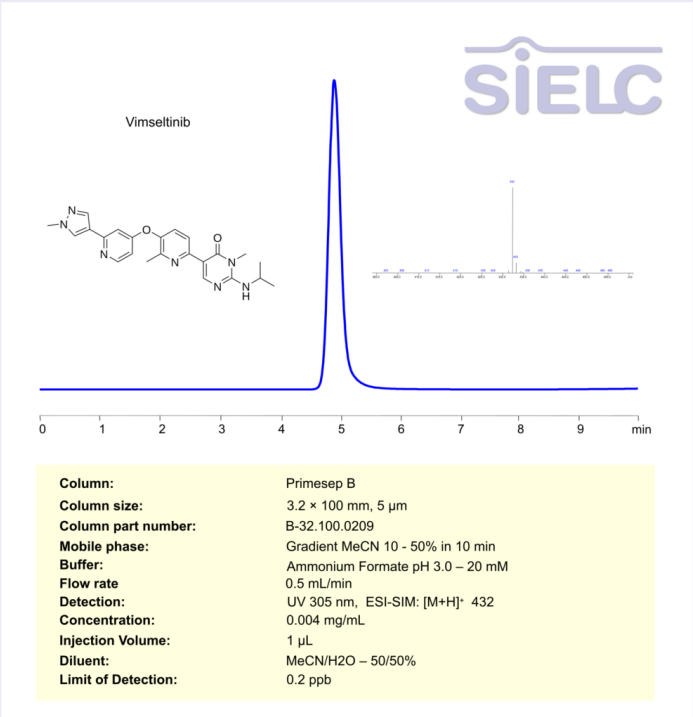
HPLC-MS Method for the Analysis of Vimseltinib on Primesep B Column



Column:	Primesep B
Column size:	3.2 × 100 mm, 5 µm
Column part number:	B-32.100.0209
Mobile phase:	Gradient MeCN 10 - 50% in 10 min
Buffer:	Ammonium Formate pH 3.0 – 20 mM
Flow rate	0.5 mL/min
Detection:	UV 305 nm, ESI-SIM: $[M+H]^+$ 432
Concentration:	0.004 mg/mL
Injection Volume:	1 µL
Diluent:	MeCN/H2O – 50/50%
Limit of Detection:	0.2 ppb

Vimseltinib, sold under the brand name Romvimza, is an oral tyrosine kinase inhibitor designed to treat symptomatic tenosynovial giant cell tumor (TGCT), a rare and locally aggressive tumor that affects the joints. It specifically targets and inhibits the colony-stimulating factor 1 receptor (CSF1R), a key factor in the development and survival of macrophages, thus helping to reduce inflammation and tumor growth. In February 2025, the U.S. Food and Drug Administration (FDA) granted full approval for Vimseltinib following the successful results of the Phase 3 MOTION trial.

Vimseltinib can be retained and analyzed using the Primesep B stationary phase column. The analysis utilizes an gradientc method with a simple mobile phase consisting of water, acetonitrile (MeCN), and Ammonium formate. Detection is performed using UV at 305 nm. Mass spectrometric detection was carried out in ESI-SIM mode, monitoring the ions [M+H]+ at m/z 432

*LOD was determined for this combination of instrument, method, and analyte, and it can vary from one laboratory to another even when the same general type of analysis is being performed.

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Method Parameters

Column	Primesep B, 3.2 x 100 mm, 5 µm, 100 Å, dual ended
Mobile Phase	Gradient MeCN – 10-50%, 10 mn
Buffer	Ammonium Formate pH 3.0 – 20 mM
Flow Rate	0.5 mL/min
Detection	UV 305 nm, ESI-SIM: [M+H]+ 432
Limit of Detection	0.2 ppb

Quelle: https://sielc.com/hplc-ms-method-for-analysis-vimseltinib