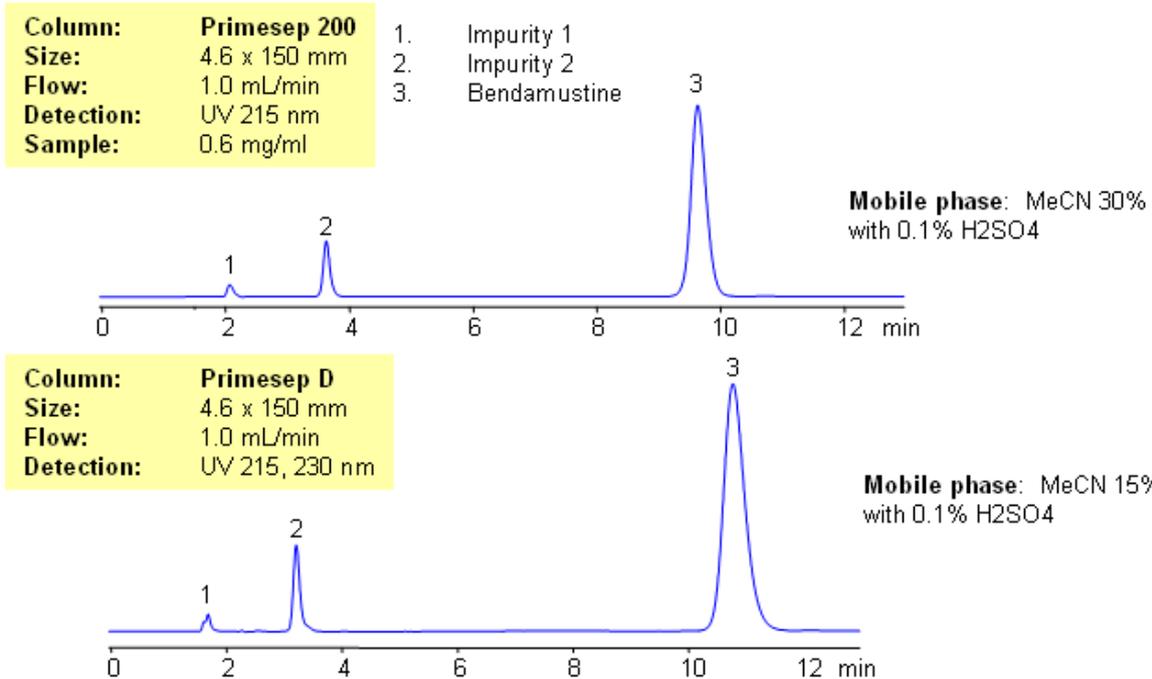


HPLC Analysis of Bendamustine and Related Impurities



Application Notes: Bendamustine is a hydrophobic and basic drug, classified as nitrogen mustard. Two approaches were used to separate bendamustine from related impurities. In one approach, a Primesep 200 HPLC column was used in reversed-phase cation-exchange mode. Primesep D column was also used in reversed-phase cation-exclusion mode. Both methods are alternative to each other. Both can be used to quantify bendamustine in various sample matrices (drug composition, blood, plasma, urine, etc.). Sample preparation is required in the case of biofluids using the Primesep 200 column. Primesep D can be used for direct analysis of bendamustine in blood, plasma and urine. Proteins in the biofluids repel from stationary phase. Sulfuric acid in the mobile phase can be replaced with ammonium formate or acetate for LC/MS and with TFA for ELSD/CAD.

Application Columns: Primesep 200, Primesep D Application compounds: bendamustine and related impurities Detection technique: UV, LC/MS, ELSD/CAD

Method Parameters

| | |
|---------------------|---------------------------------------|
| Column | Primesep D, 4.6x150 mm, 5 µm, 100 Å |
| Mobile Phase | MeCN – 15% |
| Buffer | H ₂ SO ₄ – 0.1% |
| Flow Rate | 1.0 mL/min |
| Detection | UV, 230 nm |

Quelle: <https://sielc.com/HPLC%20Analysis%20of%20Bendamustine%20and%20Related%20Impurities>