



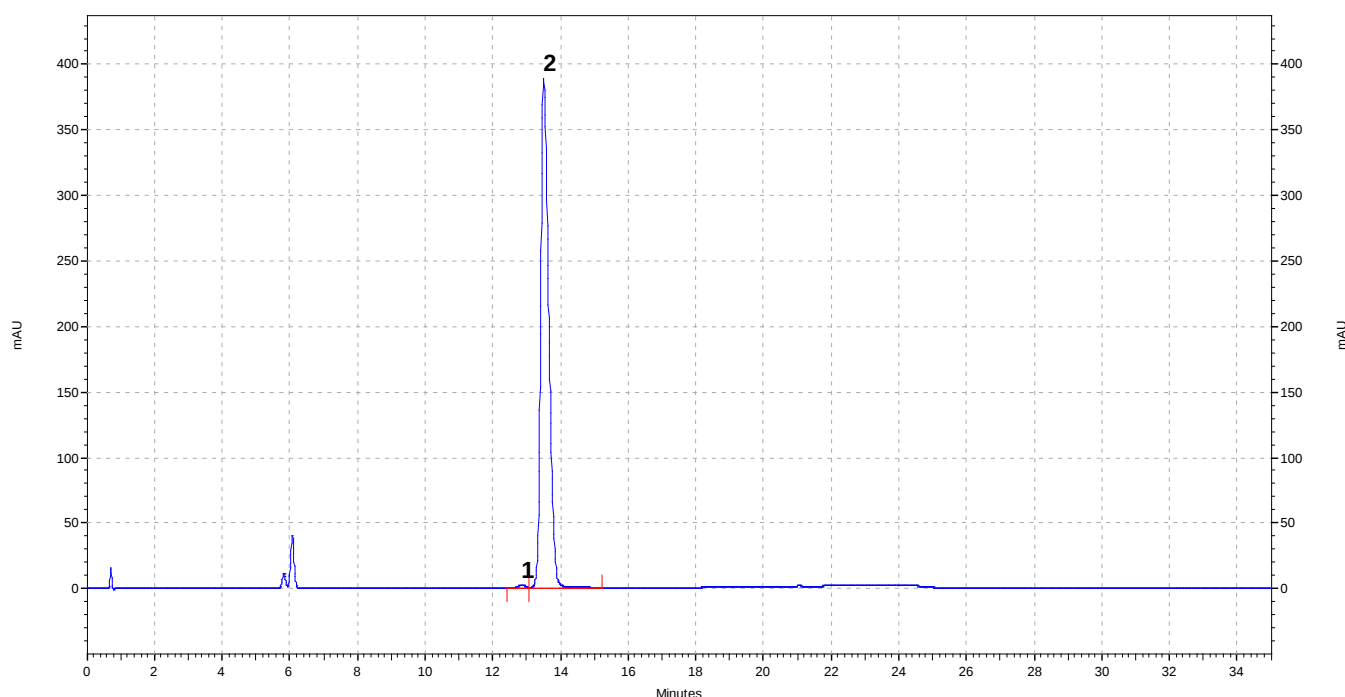
Montelukast Chewable Tablets – BP 2015

Montelukast Granules – BP 2015

Montelukast Tablets – BP 2015

This chromatogram is provided for information only as an aid to analysts and intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (3) in the Related Substances test and Assay for Montelukast Chewable Tablets, Montelukast Granules and Montelukast Tablets as published in BP 2015.



Peak ID: 1: Impurity G; 2: Montelukast

Column * : Phenomenex Luna Phenyl Hexyl (100 mm x 4.6 mm, 3 μ m)
Method Ref. : Related substances method for the Montelukast Tablets monograph from BP 2015
Mobile Phase A : A 0.2% solution of trifluoroacetic acid in water.
Mobile Phase B : A mixture of 2 volumes of acetonitrile and 3 volumes of methanol.

Gradient *

Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)
0	48	52
5	45	55
12	45	55
22	25	75
23	25	75
25	48	52
35	48	52

Diluent : A mixture of 1 volume of water and 3 volumes of methanol.
Flow Rate : 1.5 mL/min
Column Temp : 50°C
Injection Volume : 15 μ L
Detection : 255 nm

* Note: Neither a guard column or a 5 minute isocratic hold were used as specified in the monograph.