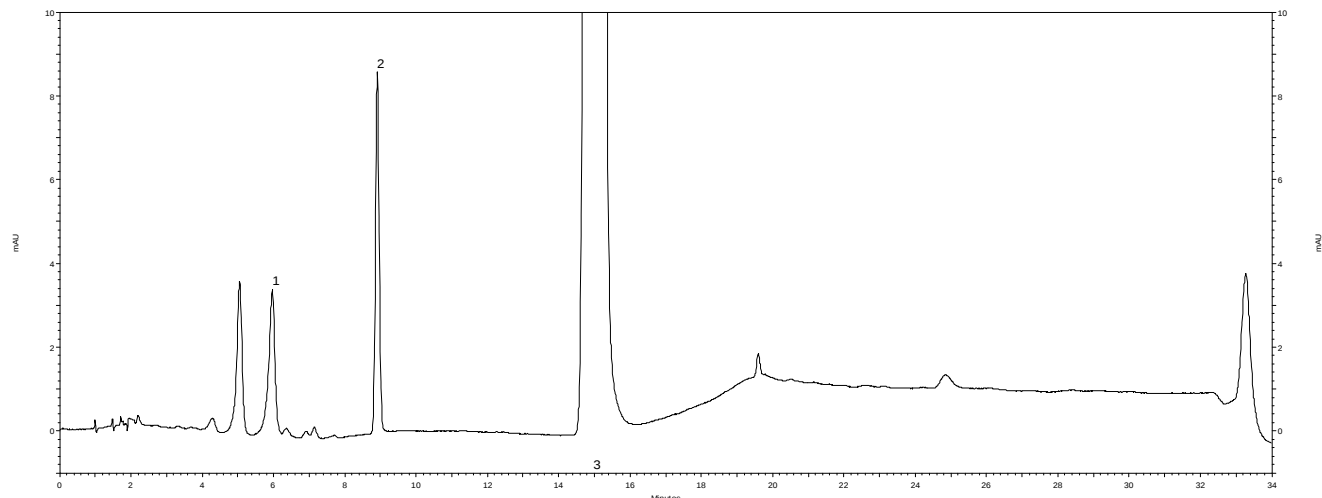




Orodispersible Olanzapine Tablets – BP 2018

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (4) in the Related Substances test for Orodispersible Olanzapine Tablets as published in BP 2018.



Peak ID: 1: Impurity D; 2: Impurity B; 3: Olanzapine

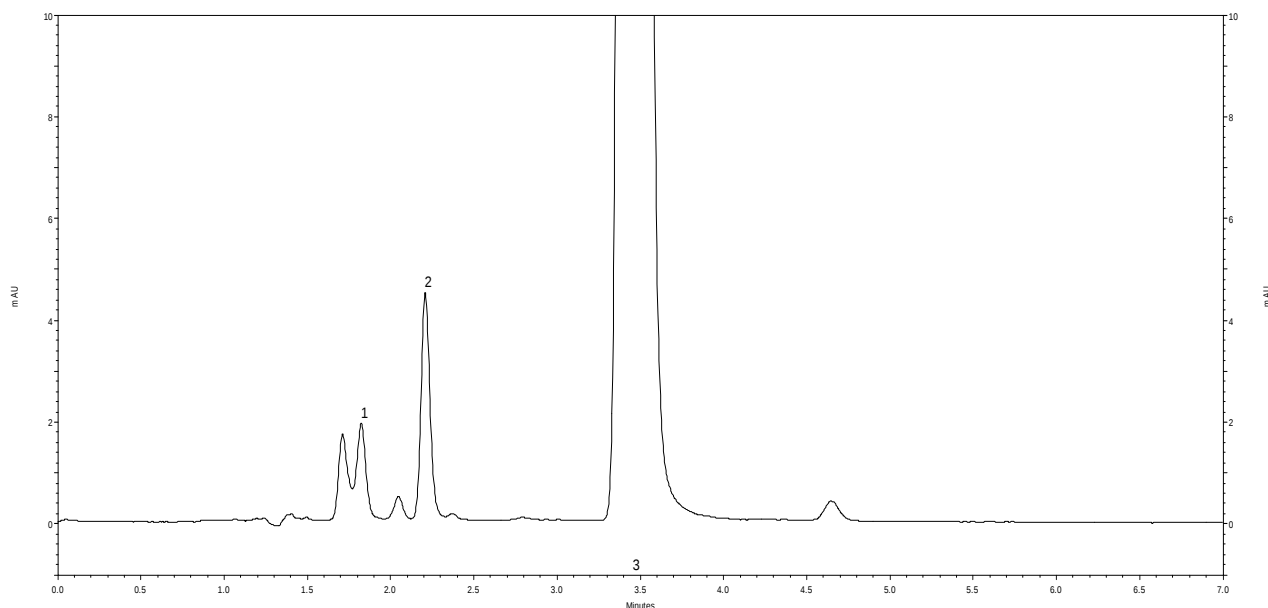
Column : Phenomenex, Inertsil ODS-3 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Related substances for the Orodispersible Olanzapine Tablets monograph from BP 2018
Mobile Phase A : 45 volumes of a mixture of equal volumes of acetonitrile and methanol and 55 volumes of a 0.345 % w/v buffer solution of sodium dihydrogen phosphate monohydrate adjusted to pH 6.8 with dilute sodium hydroxide
Mobile phase B : 75 volumes of a mixture of equal volumes of acetonitrile and methanol and 25 volumes of the buffer solution
Gradient:

Time (minutes)	% Mobile Phase A	% Mobile Phase B
0	100	0
2	100	0
7	60	40
13	60	40
17	0	100
30	0	100
31	100	0
34	100	0

Diluent : Acetonitrile: Water (40: 60, v/v)
Flow Rate : 1.5 mL/min
Column Temp : 25°C
Injection Volume : 50 µL
Detection : UV, 250 nm



Typical chromatogram for solution (3) in the Assay test for Orodispersible Olanzapine Tablets as published in BP 2018.



Peak ID: 1: Impurity D; 2: Impurity B; 3: Olanzapine

Column	: Phenomenex, Inertsil ODS-3 (250 mm x 4.6 mm, 5 µm)
Method Ref.	: Related substances for the Orodispersible Olanzapine Tablets monograph from BP 2018
Mobile Phase	: 25 volumes of a 0.0345 % w/v buffer solution of sodium dihydrogen phosphate monohydrate adjusted to pH 6.8 with dilute sodium hydroxide and 75 volumes of a mixture of equal volumes of acetonitrile and methanol
Diluent	: Acetonitrile: Water (40: 60, v/v)
Flow Rate	: 2.0 mL/min
Column Temp	: 25°C
Injection Volume	: 10 µL
Detection	: UV, 250 nm