



Orodispersible Olanzapine Tablets – BP 2016

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

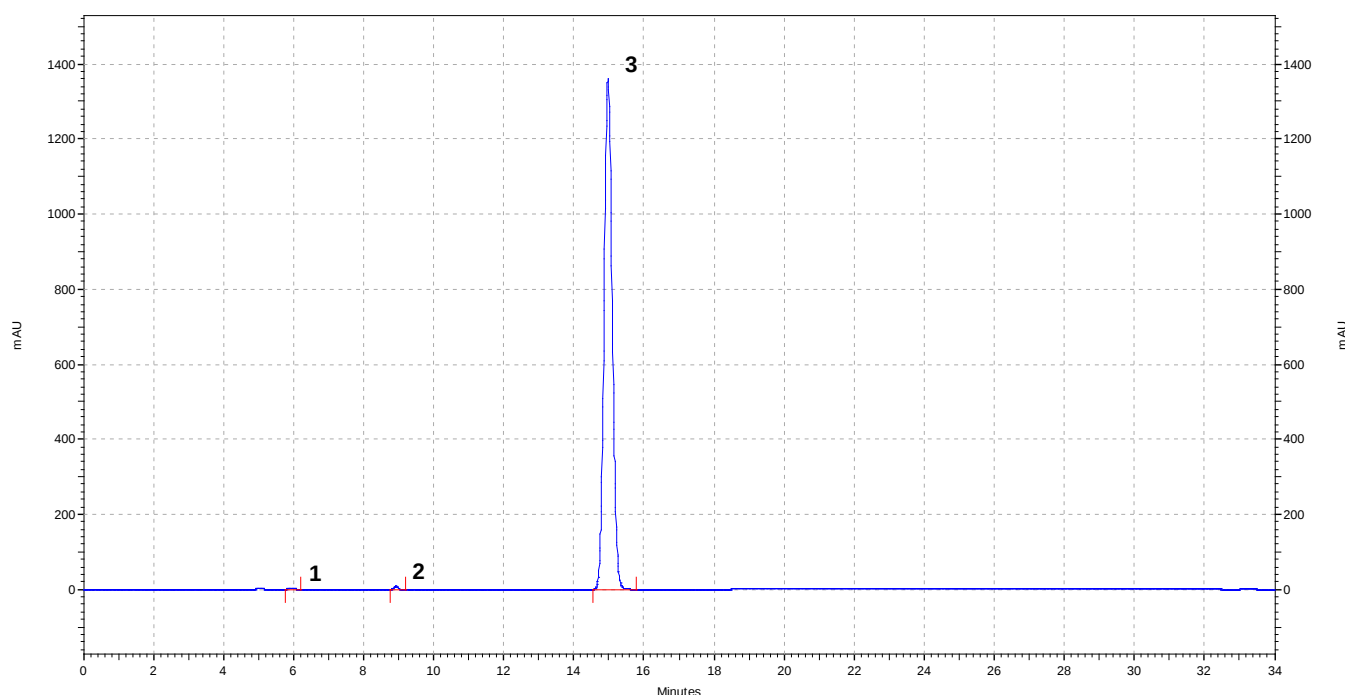
The chromatograms below were recorded using the following conditions:

Column : Inertsil ODS-3 (25 cm x 4.6 mm, 5µm)
Method Ref. : Related Substances method, Orodispersible Olanzapine Tablets from BP 2016
Buffer : 0.345% w/v sodium dihydrogen phosphate monohydrate adjusted to pH 6.8 with dilute sodium hydroxide.
Mobile Phase A : A mixture of 45 volumes of equal volumes of acetonitrile and methanol and 55 volumes of buffer.
Mobile Phase B : A mixture of 75 volumes of equal volumes of acetonitrile and methanol and 25 volumes of buffer.

Gradient	:	<table><tr><th>Time (min)</th><th>Mobile Phase A (% v/v)</th><th>Mobile Phase B (% v/v)</th></tr><tr><td>0-2</td><td>100</td><td>0</td></tr><tr><td>2-7</td><td>100-60</td><td>0-40</td></tr><tr><td>7-13</td><td>60</td><td>40</td></tr><tr><td>13-17</td><td>60-0</td><td>40-100</td></tr><tr><td>17-30</td><td>0</td><td>100</td></tr><tr><td>30-31</td><td>0-100</td><td>100-0</td></tr><tr><td>31-34</td><td>100</td><td>0</td></tr></table>	Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)	0-2	100	0	2-7	100-60	0-40	7-13	60	40	13-17	60-0	40-100	17-30	0	100	30-31	0-100	100-0	31-34	100	0
Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)																								
0-2	100	0																								
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13-17	60-0	40-100																								
17-30	0	100																								
30-31	0-100	100-0																								
31-34	100	0																								

Diluent : A mixture of 4 volumes of acetonitrile and 6 volumes of water.
Flow Rate : 1.5 mL/min
Column Temp : 25°C
Injection Volume : 50 µL
Detection : 250 nm

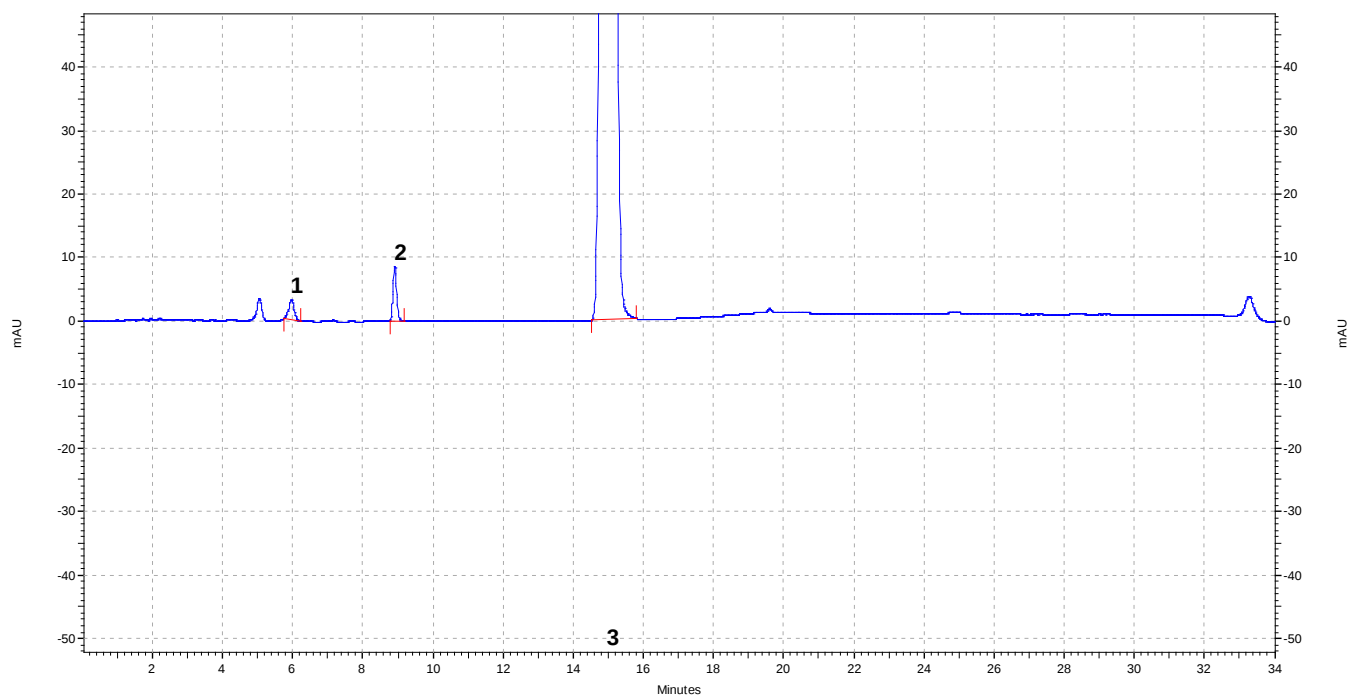
Typical chromatogram for solution (3) in the Related Substances test for Orodispersible Olanzapine Tablets as published in BP 2016.



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



Typical chromatogram for solution (3) in the Related Substances test for Orodispersible Olanzapine Tablets as published in BP 2016 (zoom of peaks of interest).



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