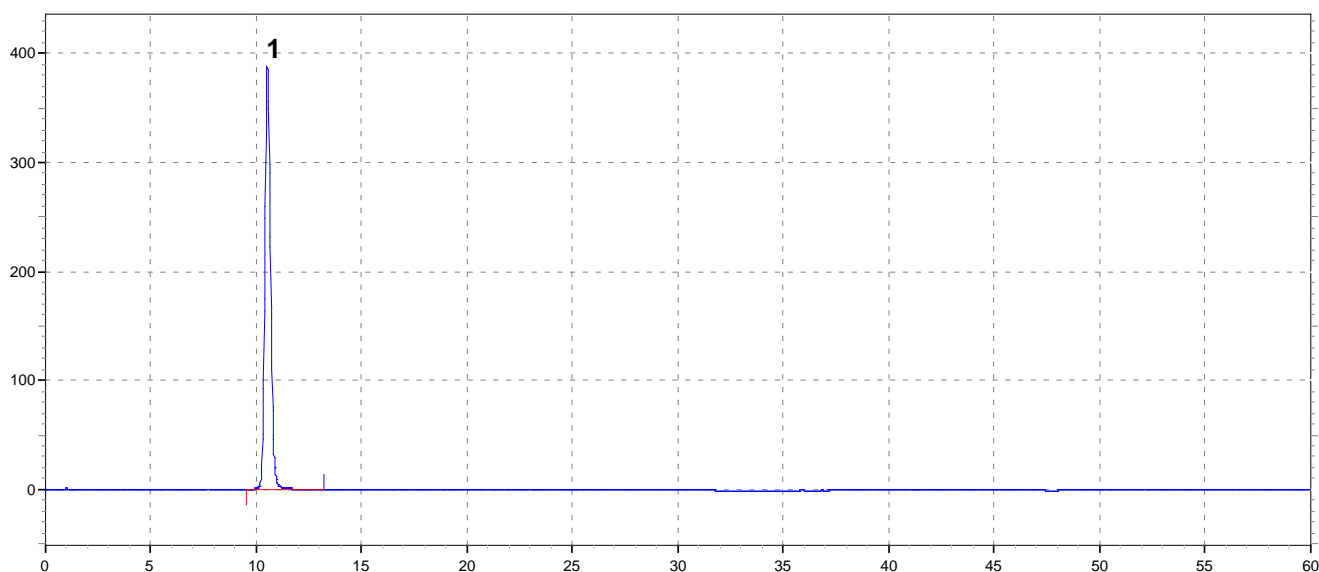




Zolpidem Tablets – BP 2015 Related substances

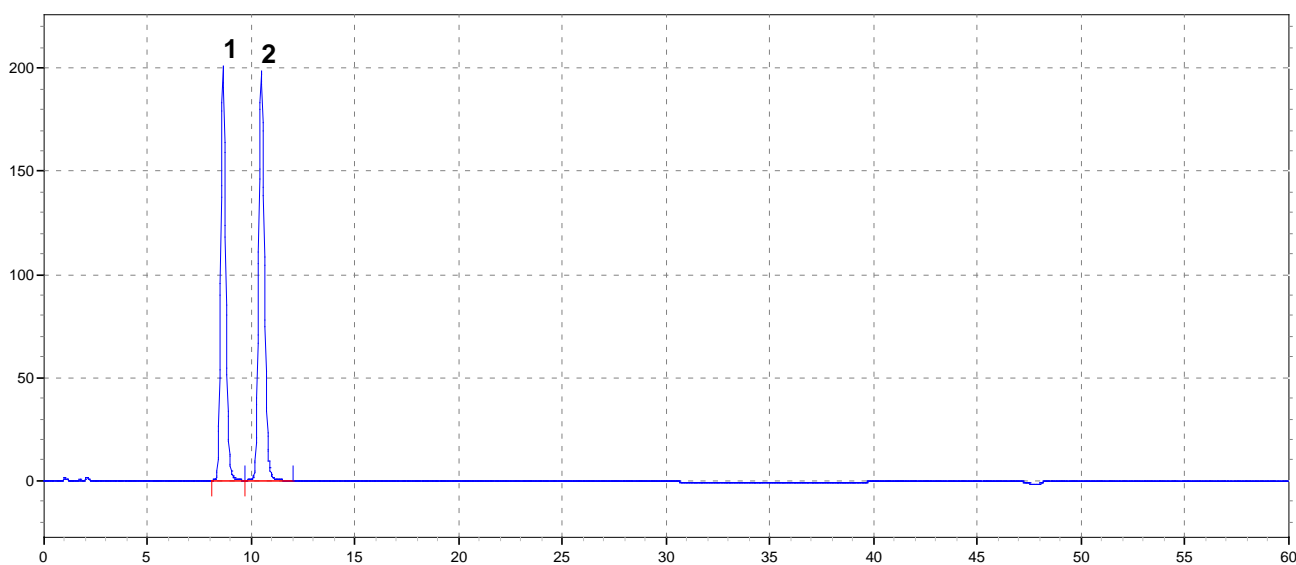
These chromatograms are provided for information only as an aid to analysts and intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for solution (1) in the Related Substances test for Zolpidem Tablets as published in BP 2015.



Peak ID: 1: Zolpidem

Typical chromatogram for solution (3) in the Related Substances test for Zolpidem Tablets as published in BP 2015.



Peak ID: 1: Impurity A; 2: Zolpidem



Chromatographic Conditions

Column : Nova-Pak C18 (150 mm x 3.9 mm, 4 µm)
Method Ref. : Related Substances method for the Zolpidem Tablets monograph from BP 2015
Buffer : 0.56% w/v phosphoric acid adjusted to pH 5.5 with triethylamine.
Mobile Phase A : A mixture of 18 volumes of acetonitrile, 23 volumes of methanol and 59 volumes of buffer.
Mobile Phase B : Acetonitrile.

Gradient :

Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)
0-20	100	0
20-40	100-50	0-50
40-45	50	50
45-46	50-100	50-0
46-60	100	0

Diluent : Mobile phase A
Flow Rate : 1.0 mL/min
Column Temp : 25°C
Injection Volume : 20 µL
Detection : 254 nm