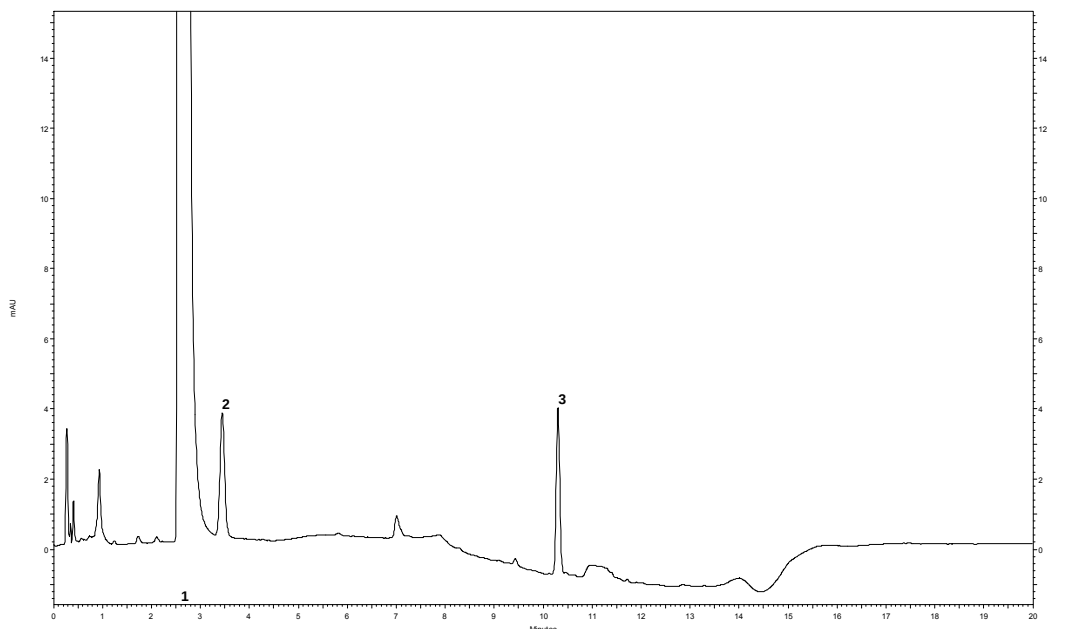




Phenylephrine Eye Drops – BP 2018

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

Typical chromatogram for solution (3) in the Related Substances test for Phenylephrine Eye Drops as published in BP 2018.



Peak ID: 1: Phenylephrine; 2: Impurity C; 3: Impurity E

Column : Agilent, Zorbax Eclipse Plus C18 (50 mm × 4.6 mm, 1.8 µm)
Method Ref. : Related substances method from the Phenylephrine Hydrochloride Ph. Eur. monograph from BP 2016
Mobile Phase A : Acetonitrile: buffer pH 2.8 (10: 90, v/v)
Mobile Phase B : Buffer pH 2.8: acetonitrile (10: 90, v/v)
Buffer pH 2.8 : 3.25 g of sodium octanesulfonate monohydrate was dissolved in 1000 mL of water by stirring for 30 min and the pH was adjusted to 2.8 with dilute phosphoric acid.
Gradient :

Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)
0-3	93	7
3-13	93-70	7-30
13-14	70-93	30-7
14-20	93	7

Diluent : Solvent mixture (Mobile Phase B: Mobile Phase A (20: 80, v/v))
Flow Rate : 1.5 mL/min
Column Temp : 45°C
Injection Volume : 10 µL
Detection : UV, 215 nm