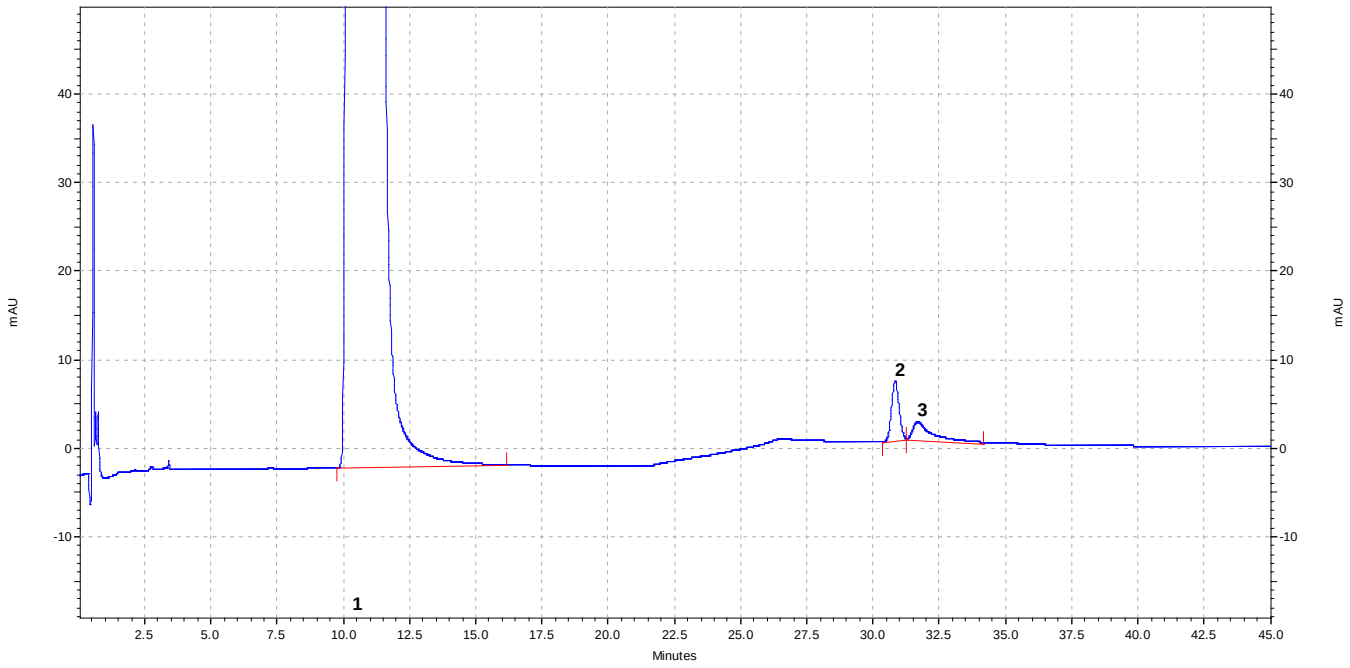
Carvedilol Tablets – BP 2016

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

Typical chromatogram for solution (4) in the Related substances test for Carvedilol Tablets as published in BP 2016.



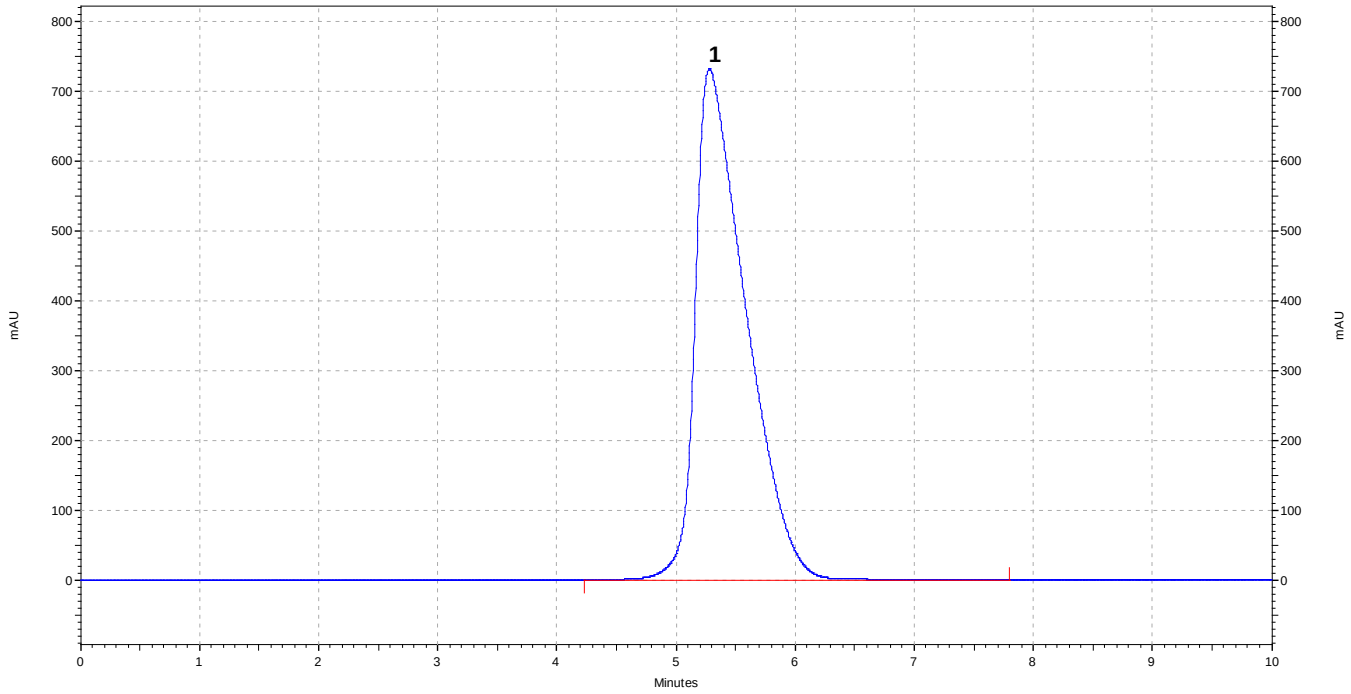
Peak ID: 1: Carvedilol; 2: Impurity A; 3: Impurity D

Column : Hypersil MOS-1 (50 mm x 4.6 mm, 3µm)
Method Ref. : Related Substances method for the Carvedilol Tablets monograph from BP 2016
Buffer : 0.7g potassium dihydrogen phosphate dissolved in 500 mL water and 10 mL triethylamine, adjusted to pH 3.0 with phosphoric acid.
Mobile Phase A : A mixture of 1.04g sodium dodecyl sulfate in 150 mL buffer solution and 720 mL acetonitrile. Sufficient water added to produce 2000 mL.
Mobile Phase B : A mixture of 1.04g sodium dodecyl sulfate in 150 mL buffer solution and 900 mL acetonitrile. Sufficient water added to produce 2000 mL.
Gradient :

Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)
0-20	100	0
20-25	100-0	0-100
25-45	0	100
45-46	0-100	100-0
46-60	100	0

Diluent : A mixture of 10 volumes of 1M hydrochloric acid and 90 volumes of methanol.
Flow Rate : 1.0 mL/min
Column Temp : 40°C
Injection Volume : 25 µL
Detection : 240 nm

Typical chromatogram for solution (1) in the Assay for Carvedilol Tablets as published in BP 2016.



Peak ID: 1: Carvedilol

Column	: Nucleosil 100-C18 (125 mm x 4.6 mm, 10µm)
Method Ref.	: Assay method for the Carvedilol Tablets monograph from BP 2016
Buffer	: 0.1M phosphoric acid adjusted to pH 2.0 with 0.1M potassium dihydrogen phosphate.
Mobile Phase	: A mixture of 50 volumes of methanol and 50 volumes of buffer.
Diluent	: Mobile phase
Flow Rate	: 1.5 mL/min
Column Temp	: 25°C
Injection Volume	: 160 µL
Detection	: 285 nm