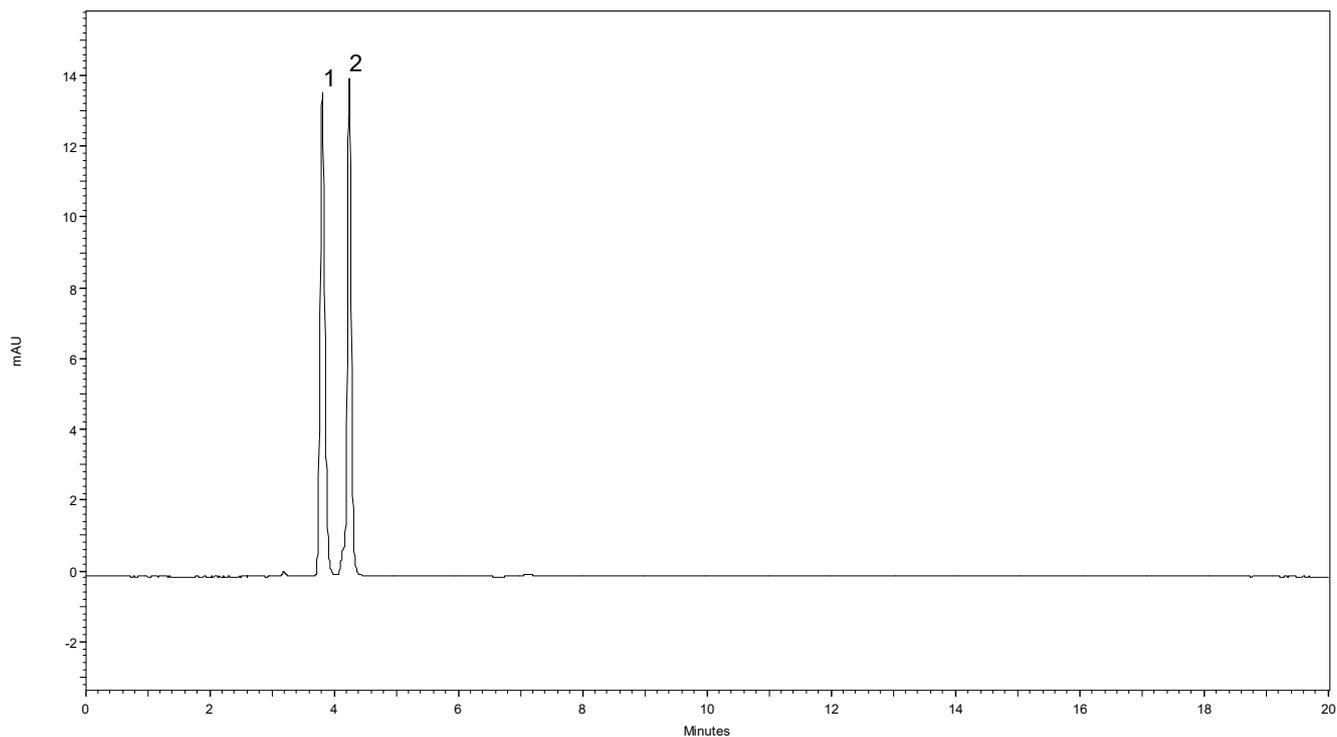




## Nicorandil Tablets – BP 2021

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.

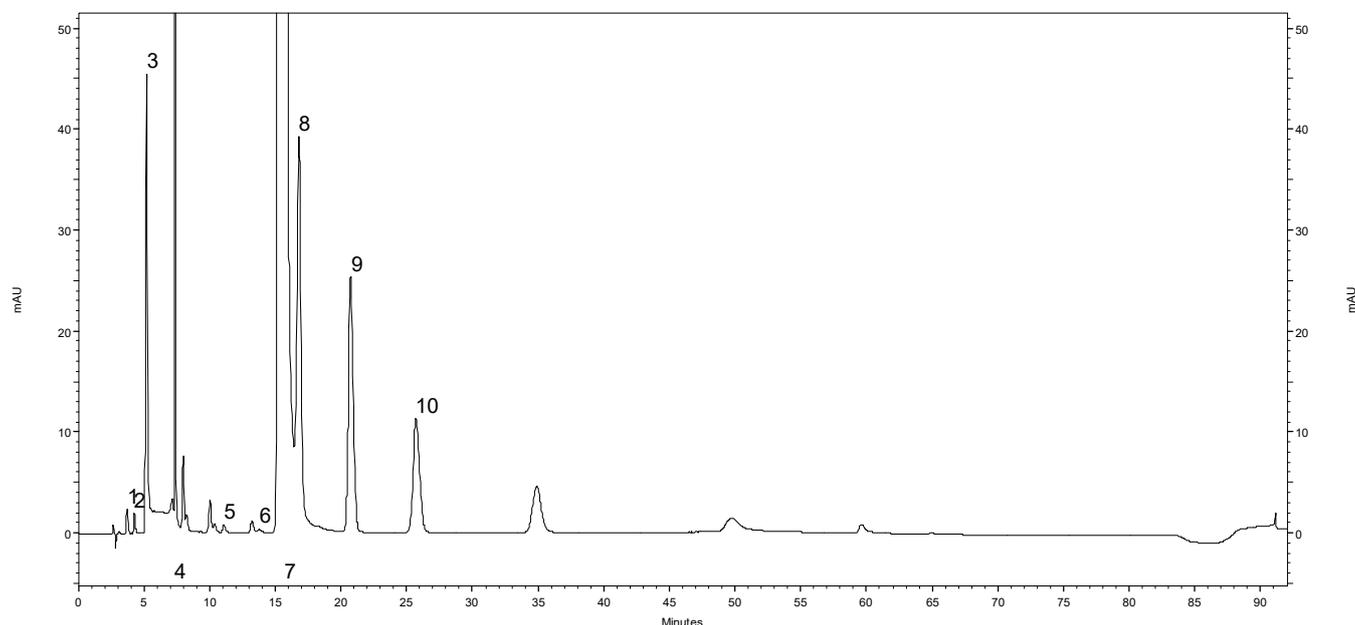
Typical chromatogram for solution (3) in the Related Substances test for Nicorandil Tablets as published in BP 2021.



Peak ID: 1: Impurity 1 (Nicotinic acid); 2: Impurity B (Nicorandil amide)



Typical chromatogram for solution (4) in the Related Substances test for Nicorandil Tablets as published in BP 2021.



Peak ID: 1: Impurity 1 (Nicotinic acid); 2: Impurity B (Nicorandil amide); 3: Impurity 2 (2-aminoethyl-nicotinate nitrate); 4: Impurity D (2-(3-pyridyl) 2-oxazoline); 5: Impurity 3 (methyl nicotinate); 6: **N-(2-hydroxyethyl)isonicotinamide nitric ester**; 7: Nicorandil; 8: Nicorandil dimer; 9: Nicorandil trimer; 10: Nicorandil tetramer

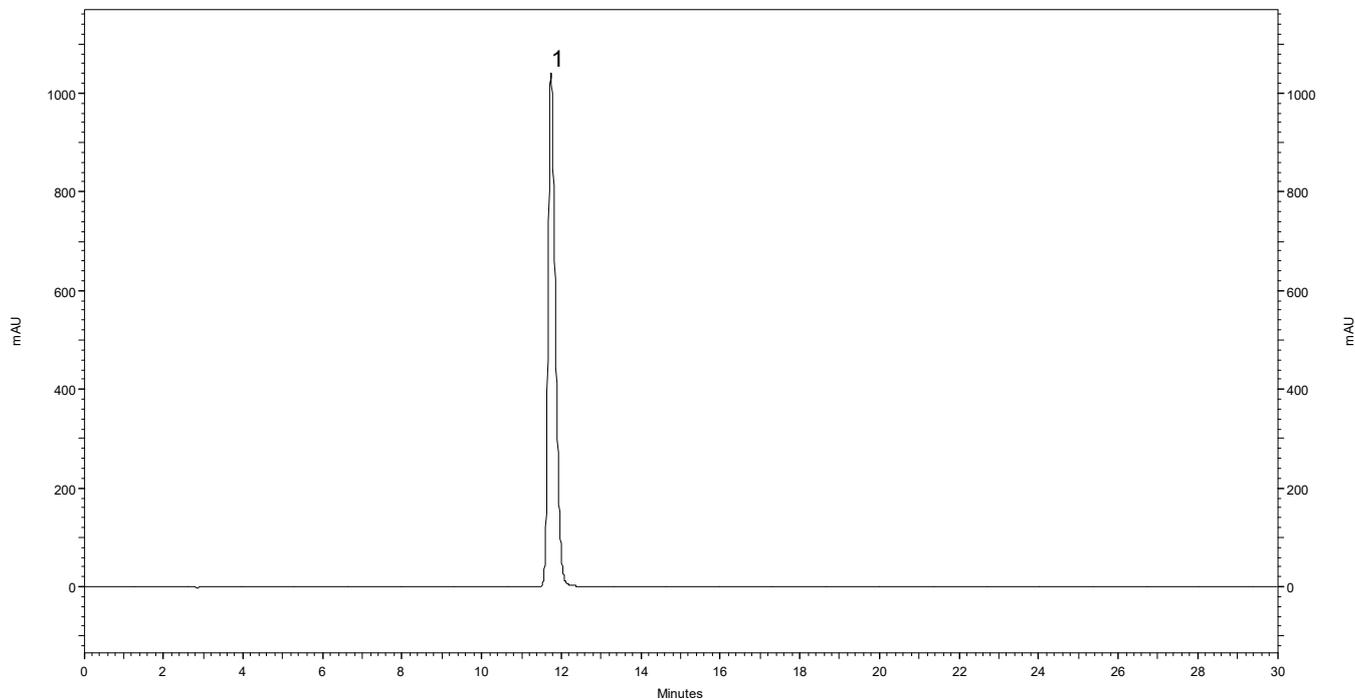
Column : YMC, Pack ODS-AQ (250 mm x 4.6 mm, 5 µm)  
Method Ref. : Related substances for the Nicorandil Tablets monograph from BP 2021  
Mobile Phase A : Trifluoroacetic acid: triethylamine: tetrahydrofuran: methanol: water (1.5: 2: 10: 25: 965, v/v/v/v/v)  
Mobile Phase B: : Methanol  
Diluent : Methanol: water (7: 93, v/v)  
Flow rate : 1.0 mL/min  
Column Temp : 25 °C  
Injection Volume : 40 µL  
Detection : 254 nm

Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-45	100	0
45-80	100-75	0-25
80-82	75-100	25-0
82-92	100	0



Typical chromatogram for solution (2) in the Assay test for Nicorandil Tablets as published in BP 2021.



Peak ID: 1: Nicorandil

Column : YMC, Pack ODS-AQ (250 mm x 4.6 mm, 5 µm)  
Method Ref. : Assay for the Nicorandil Tablets monograph from BP 2021  
Mobile Phase : Trifluoroacetic acid : triethylamine : tetrahydrofuran: methanol : water  
(1.5: 2: 10: 25: 965, v/v/v/v/v)  
Diluent : Methanol: water (7: 93, v/v)  
Flow rate : 1.0 mL/min  
Column Temp : 25 °C  
Injection Volume : 40 µL  
Detection : 254 nm