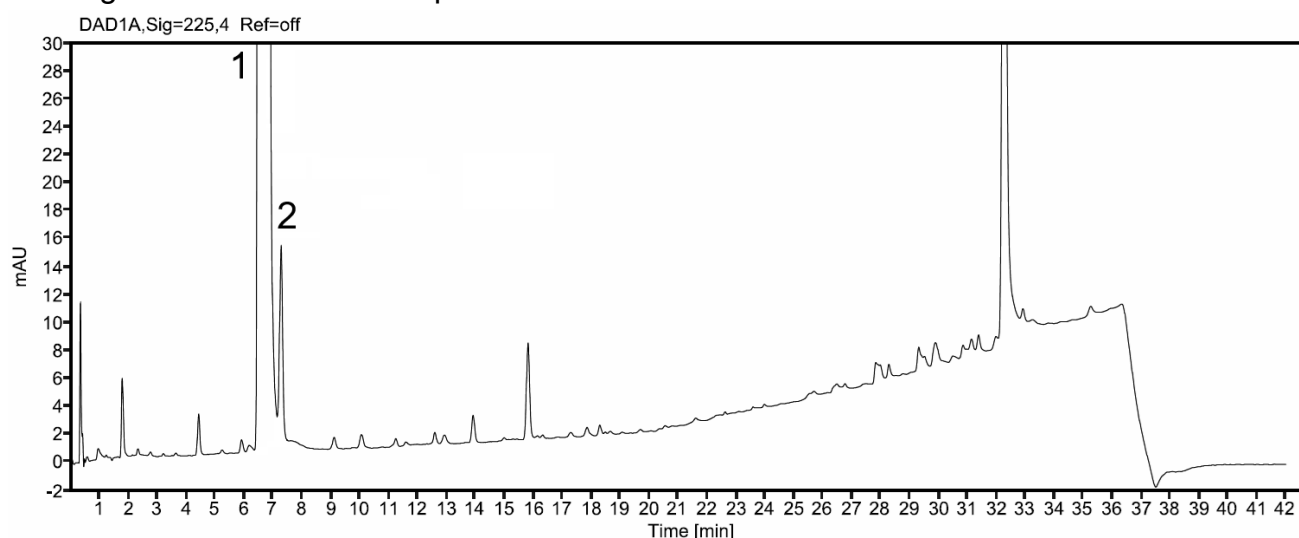




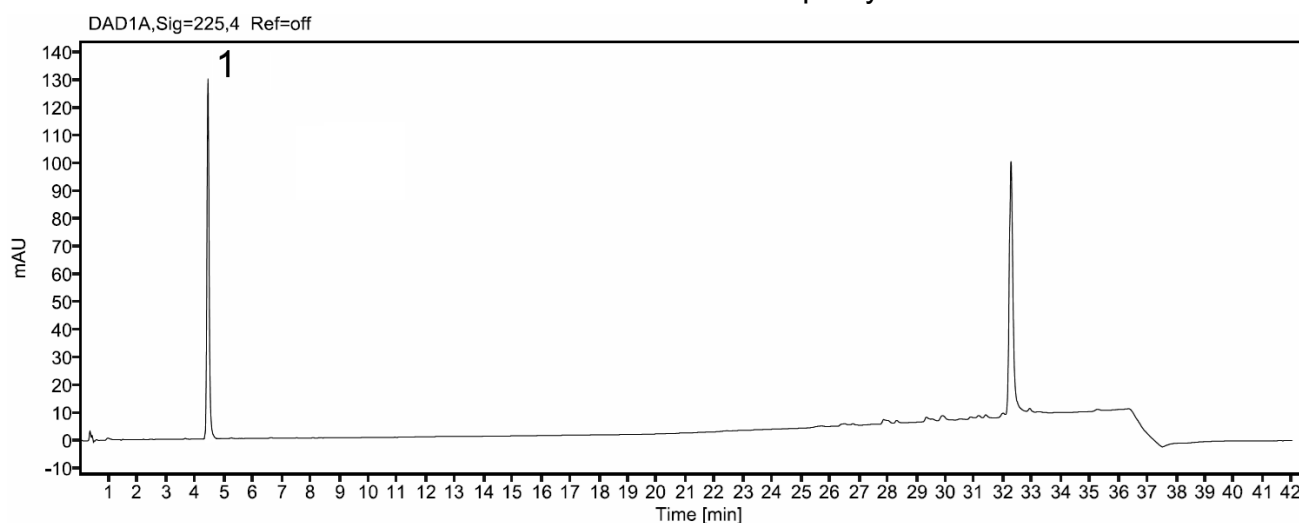
Melatonin Prolonged-release Tablets – BP 2027

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) from the Related Substances test for Melatonin Prolonged-release Tablets as published in BP 2027.



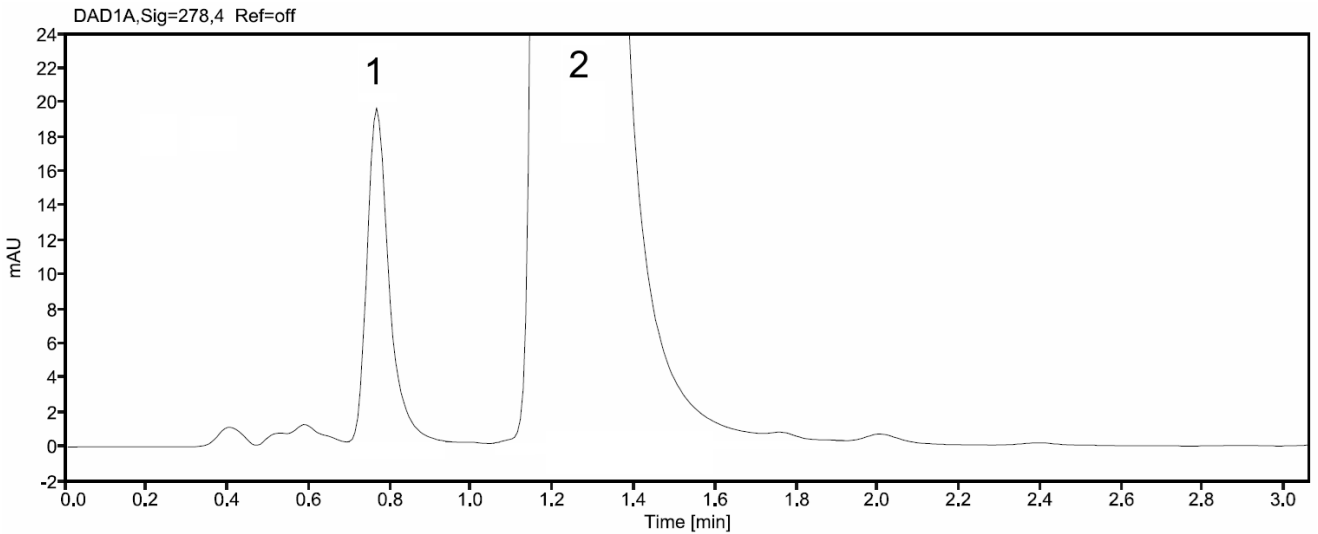
Peak ID: 1: Melatonin. 2: Impurity D.



Peak ID: 1: AFMK.

Column	Eclipse Plus C18 (50 mm x 4.6 mm, 1.8 μm)		
Method Ref.	Related Substances for the Melatonin Prolonged-release Tablets monograph from BP 2027		
Buffer	2.45 g/L potassium dihydrogen orthophosphate adjusted to pH 3.0 with 85% orthophosphoric acid		
Mobile Phase A	Acetonitrile: buffer (80:20, v/v)		
Mobile Phase B	Buffer		
Diluent	Acetonitrile: water (20:80, v/v)		
Flow rate	1.5 mL/min		
Column Temp	25°C		
Injection Volume	10 μL		
Detection	225 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 20	12.5 → 37.5	87.5 → 62.5	linear gradient
20 – 36	37.5 → 87.5	62.5 → 12.5	linear gradient
36 – 39	87.5 → 12.5	12.5 → 87.5	linear gradient
39 – 42	12.5	87.5	re-equilibration

Typical chromatogram for solution (3) from the Assay test for Melatonin Prolonged-release Tablets as published in BP 2027.



Peak ID: 1: AFMK. 2: Melatonin.

Column	XBridge C18 (50 mm x 3.0 mm, 2.5 µm)
Method Ref.	Assay for the Melatonin Prolonged-release Tablets monograph from BP 2027
Buffer	0.5 g/L potassium dihydrogen orthophosphate adjusted to pH 3.5 with orthophosphoric acid
Mobile Phase	Acetonitrile: buffer (25:75, v/v)
Diluent	Mobile phase
Flow rate	0.6 mL/min
Column Temp	25°C
Injection Volume	10 µL
Detection	278 nm