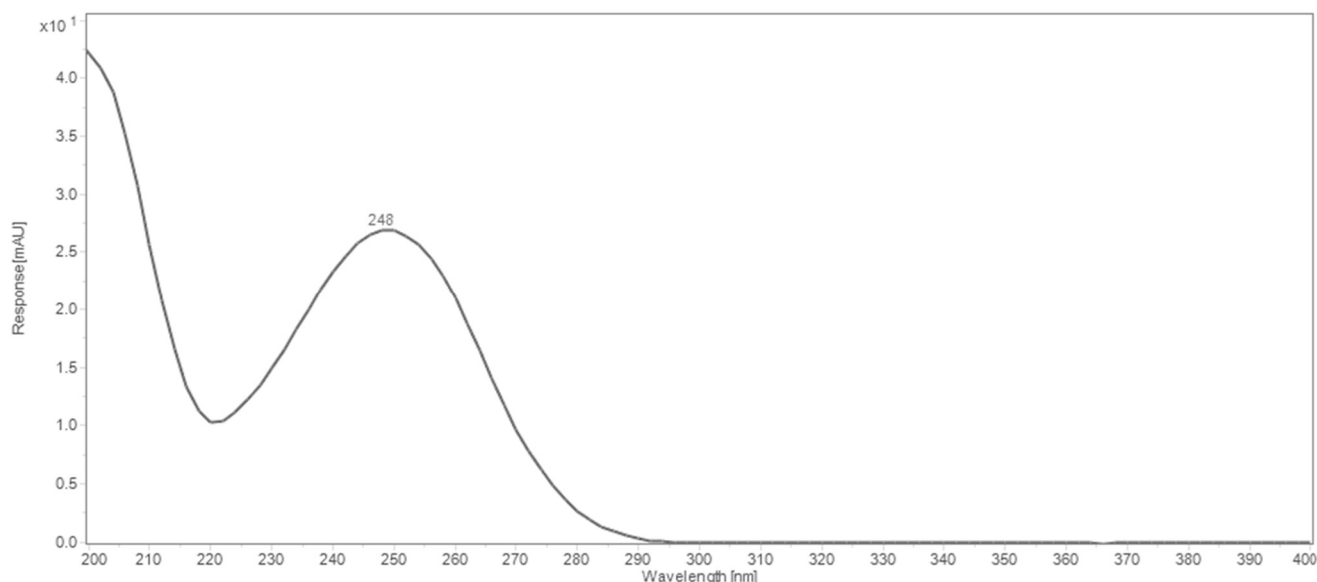




Mirabegron Prolonged-release Tablets – BP 2026

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.

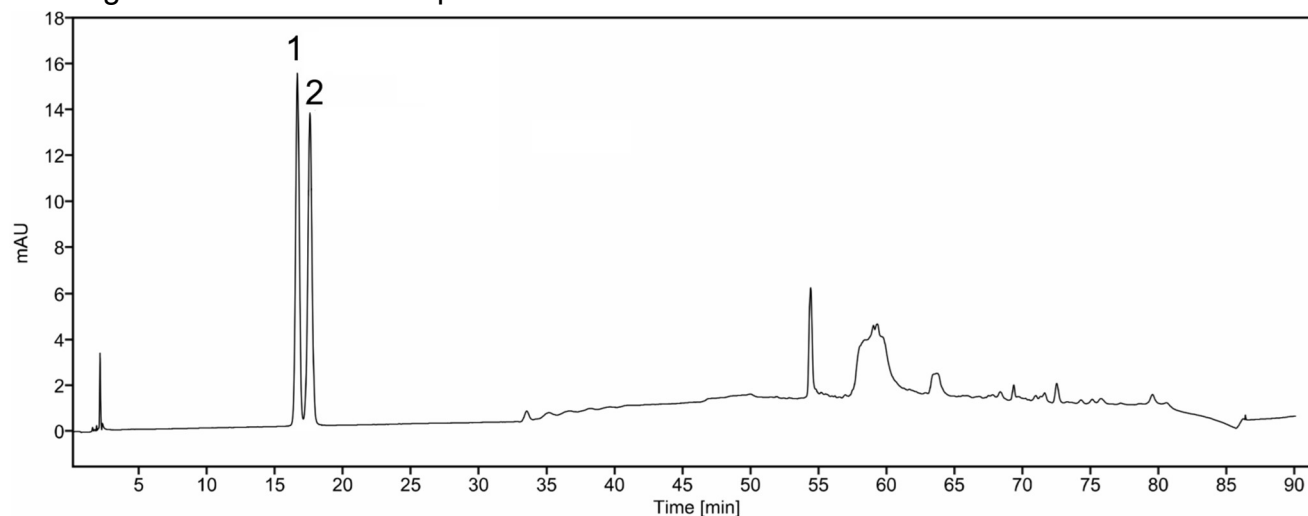
Typical spectrum for the Identification test for Mirabegron Prolonged-release Tablets as published in BP 2026.



Column	ACE C18 (150 mm x 4.6 mm, 3.0 µm)
Method Ref.	Identification for the Mirabegron Prolonged-release Tablets monograph from BP 2026
Buffer	0.3% w/v sodium hydroxide and 0.87% v/v perchloric acid adjusted to pH 2.0 with 1M sodium hydroxide
Mobile Phase	Acetonitrile R1: buffer (1:4, v/v)
Diluent (Solution A)	Acetonitrile R1: buffer (1:1, v/v)
Flow rate	1.0 mL/min
Column Temp	40°C

Injection Volume	10 µL
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Typical chromatogram for solution (3) from the Related Substances test for Mirabegron Prolonged-release Tablets as published in BP 2026.

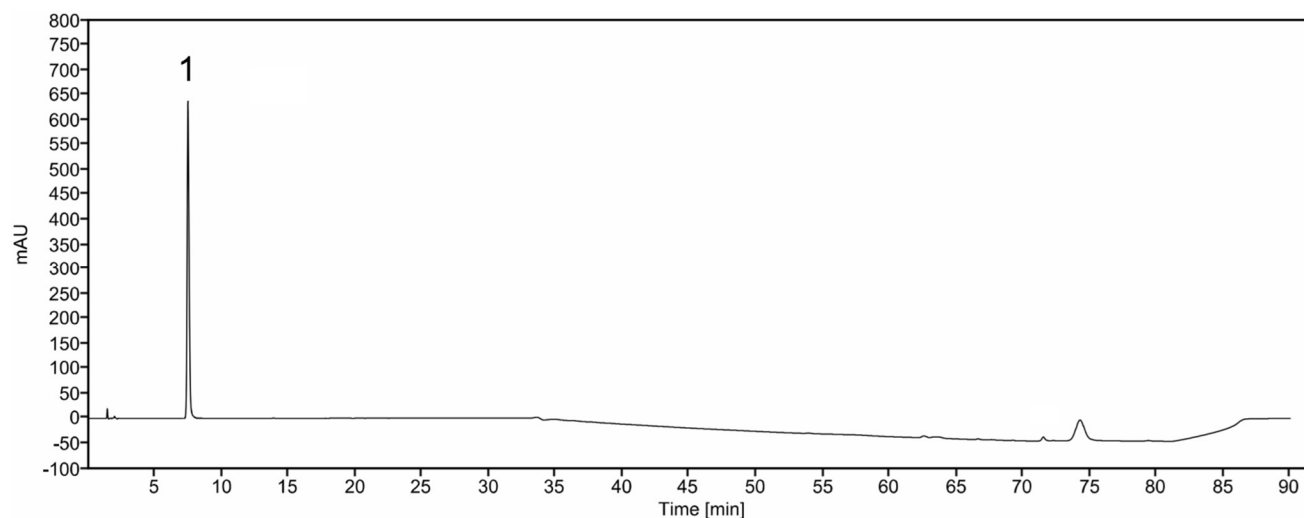


Peak ID: 1: Mirabegron. 2: 2',4'-dihydroxyacetophenone.

Column	XBridge BEH C18 (150 mm x 4.6 mm, 3.5 μm)		
Method Ref.	Related Substances for the Mirabegron Prolonged-release Tablets monograph from BP 2026		
Mobile Phase A	50 volumes of tetrahydrofuran, 100 volumes of acetonitrile R1 and 850 volumes of 0.7% w/v sodium perchlorate, adjusted to pH 1.0 with perchloric acid		
Mobile Phase B	Acetonitrile R1		
Diluent	Mobile phase A		
Flow rate	1.0 mL/min		
Column Temp	15°C		
Injection Volume	20 μL		
Detection	250 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 30	100	0	isocratic
30 – 66	100 → 50	0 → 50	linear gradient

66 – 78	50	50	isocratic
78 – 83	50 → 100	50 → 0	linear gradient
83 – 90	100	0	re-equilibration

Typical chromatogram for solution (4) from the Related Substances test for Mirabegron Prolonged-release Tablets as published in BP 2026.

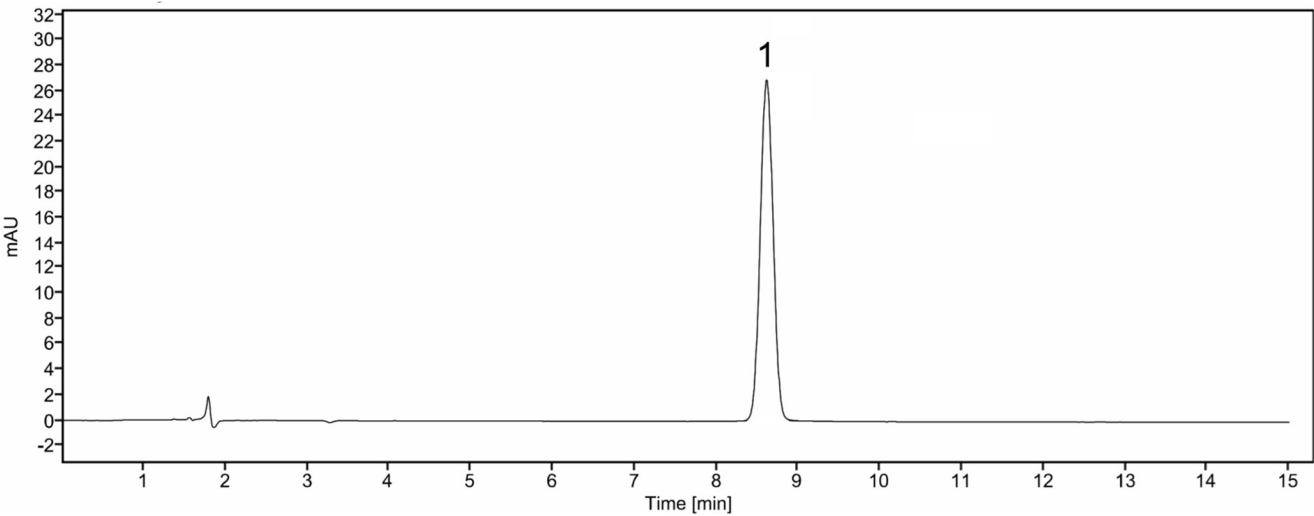


Peak ID: 1: Impurity B.

Column	XBridge BEH C18 (150 mm x 4.6 mm, 3.5 μm)		
Method Ref.	Related Substances for the Mirabegron Prolonged-release Tablets monograph from BP 2026		
Mobile Phase A	50 volumes of tetrahydrofuran, 100 volumes of acetonitrile R1 and 850 volumes of 0.7% w/v sodium perchlorate, adjusted to pH 1.0 with perchloric acid		
Mobile Phase B	Acetonitrile R1		
Diluent	Mobile phase A		
Flow rate	1.0 mL/min		
Column Temp	15°C		
Injection Volume	20 μL		
Detection	210 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 30	100	0	isocratic
30 – 66	100 → 50	0 → 50	linear gradient

66 – 78	50	50	isocratic
78 – 83	50 → 100	50 → 0	linear gradient
83 – 90	100	0	re-equilibration

Typical chromatogram for solution (2) from the Assay test for Mirabegron Prolonged-release Tablets as published in BP 2026.



Peak ID: 1: Mirabegron.

Column	ACE C18 (150 mm x 4.6 mm, 3.0 µm)
Method Ref.	Assay for the Mirabegron Prolonged-release Tablets monograph from BP 2026
Buffer	0.3% w/v sodium hydroxide and 0.87% v/v perchloric acid adjusted to pH 2.0 with 1M sodium hydroxide
Mobile Phase	Acetonitrile R1: buffer (1:4, v/v)
Diluent (Solution A)	Acetonitrile R1: buffer (1:1, v/v)
Flow rate	1.0 mL/min
Column Temp	40°C