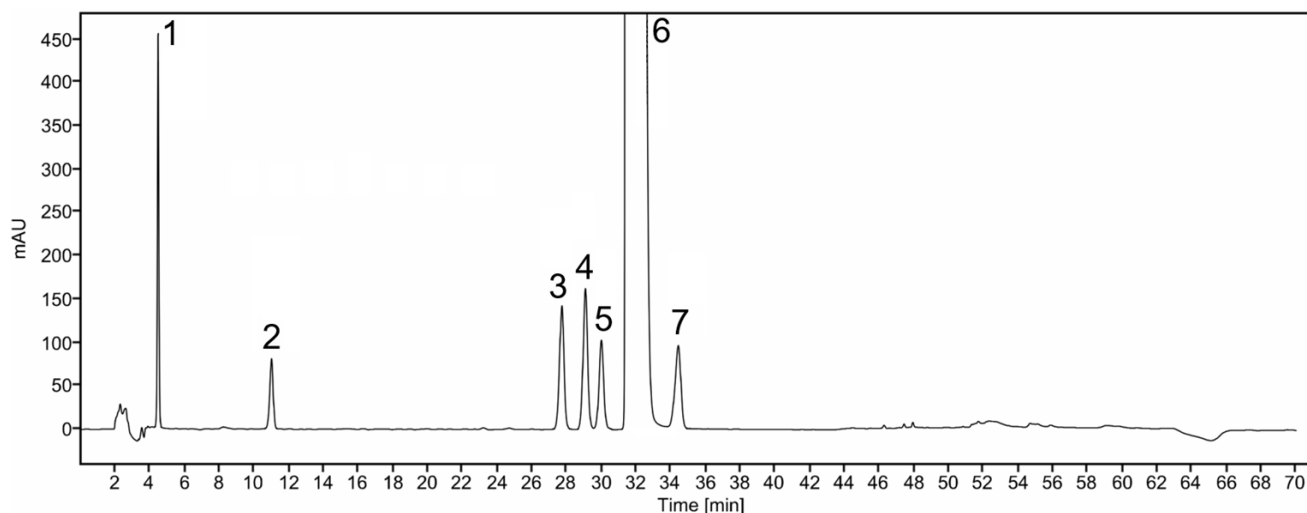




Aripiprazole Orodispersible Tablets – BP 2026

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 chromatogram for solution (3) from the Related Substances test for Aripiprazole Orodispersible Tablets as published in BP 2026.

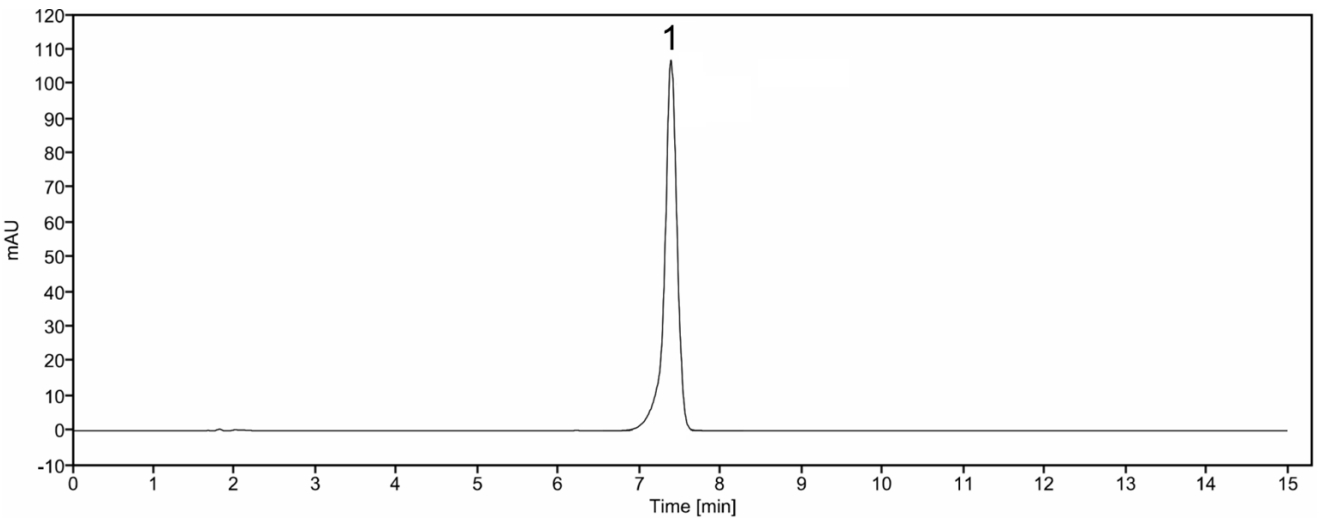


Peak ID: 1: Impurity A. 2: Impurity B. 3: Impurity E. 4: Impurity 2. 5: Impurity 1. 6: Aripiprazole. 7: Impurity F.

Column	Luna C18 (2) (250 mm x 4.6 mm, 5 µm)
Method Ref.	Related Substances for the Aripiprazole Orodispersible Tablets monograph from BP 2026
Mobile Phase A	0.111% w/v potassium dihydrogen orthophosphate and 0.12% w/v sodium pentanesulfonate, pH adjusted to 3.0 with 10% orthophosphoric acid
Mobile Phase B	Acetonitrile
Solution B	Equal volumes of acetonitrile and methanol
Solution C	0.111% w/v potassium dihydrogen orthophosphate, previously adjusted to pH 3.0 with 10% v/v orthophosphoric acid

Diluent	Solution B: 0.1M hydrochloric acid: methanol: solution C (40:1.5:6:2.5, v/v/v/v)			
Flow rate	1.0 mL/min			
Column Temp	25°C			
Injection Volume	20 µL			
Detection	215 nm			
Gradient				
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Flow rate (mL/min)	Comment
0 – 10	72 → 70	28 → 30	1.0	linear gradient
10 – 40	70 → 60	30 → 40	1.0	linear gradient
40 – 50	60 → 37	40 → 63	1.0	linear gradient
50 – 60	37	63	1.0	isocratic
60 – 61	37 → 72	63 → 28	1.0	linear gradient
61 - 70	72	28	1.0	re-equilibration

Typical chromatogram for solution (2) from the Assay test for Aripiprazole Orodispersible Tablets as published in BP 2026.



Peak ID: 1: Aripiprazole

Column	ACE C8 (250 mm x 4.6 mm, 5 µm)
Method Ref.	Assay for the Aripiprazole Orodispersible Tablets monograph from BP 2026
Buffer	0.01M potassium dihydrogen orthophosphate and 0.001% v/v of triethylamine, adjusted to pH 4.0 with dilute orthophosphoric acid
Mobile Phase	Acetonitrile: buffer (38:62, v/v)
Solution A	2 volumes of 0.1M hydrochloric acid and 3 volumes of acetonitrile
Diluent	Solution A
Flow rate	1.5 mL/min
Column Temp	25°C
Injection Volume	5 µL
Detection	220 nm