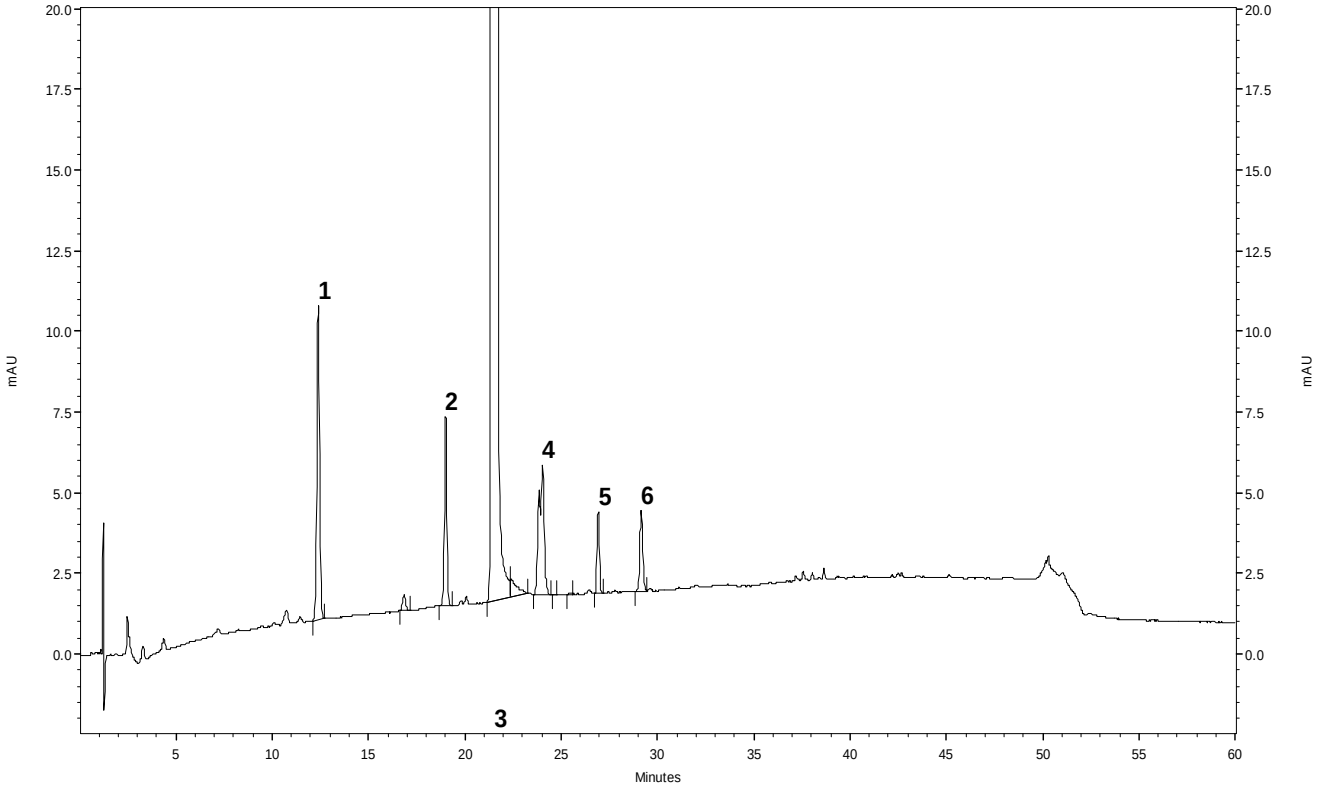
Pantoprazole Injection – BP 2018

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 Pantoprazole for Injection as published in BP 2018.



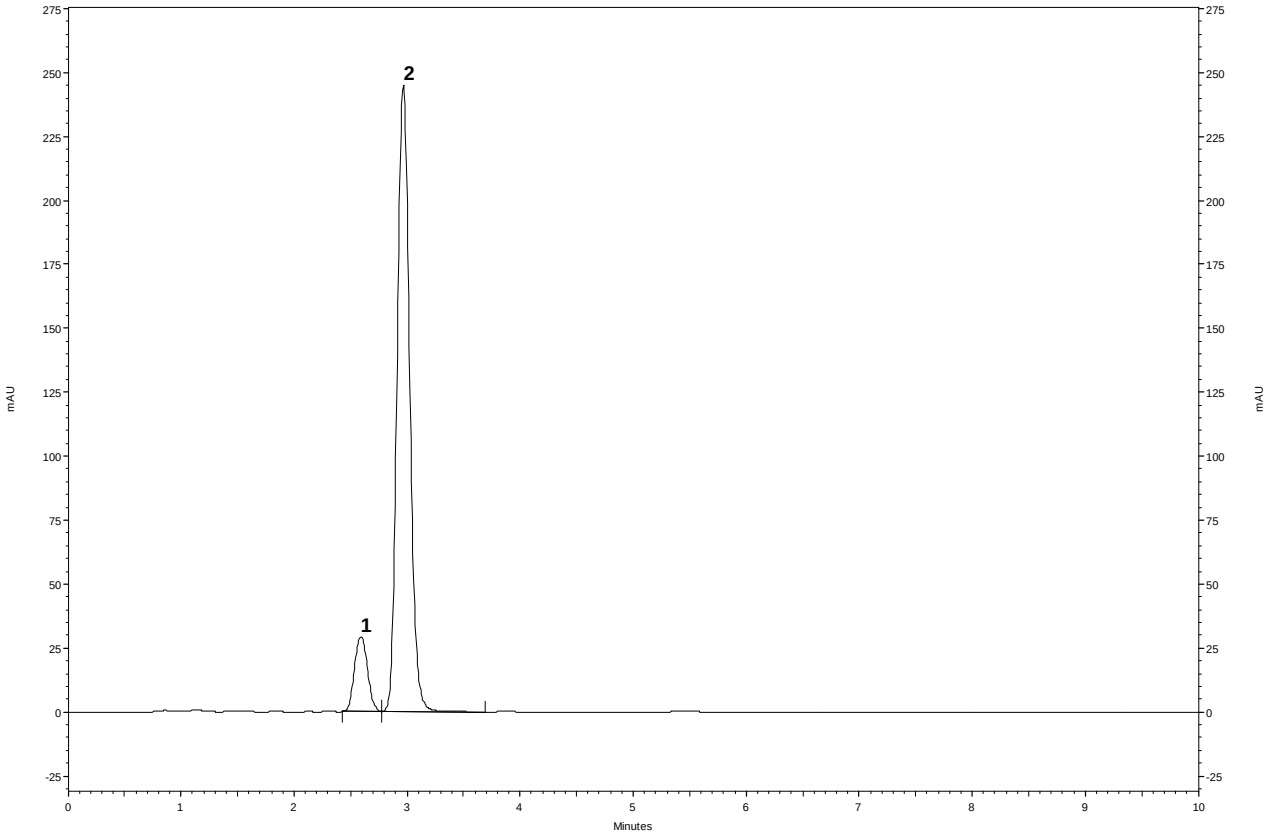
Peak ID: 1: Impurity C; 2: Impurity A; 3: Pantoprazole; 4: Impurities D + F; 5: Impurity E; 6: Impurity B.

Column : Thermo, Hypersil ODS C18 (125 mm x 4.0 mm, 5 µm)
Method Ref. : Related substances for the Pantoprazole for Injection monograph from BP 2018
Mobile Phase A : 0.01 M dipotassium hydrogen phosphate trihydrate, adjusted to pH 7 with 20 % orthophosphoric acid.
Mobile Phase B : 1 volumes water and 99 volumes acetonitrile.
Gradient :

Time (min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)
0-3	90	10
3-33	90-60	10-40
33-48	60-15	40-85
48-50	15-90	85-10
50-60	90	10

Diluent : 50 volumes mobile acetonitrile and 50 volumes of 0.001 M sodium hydroxide.
Flow Rate : 1.0 mL/min
Column Temp : 40°C
Autosampler Temp : 5°C
Injection Volume : 20 µL
Detection : UV, 290 nm

Typical chromatogram for solution (3) in the Assay test for Pantoprazole for Injection as published in BP 2018.



Peak ID: 1: Impurity A; 2: Pantoprazole

Column	: Thermo, Hypersil ODS C18 (125 mm x 4.0 mm, 5 µm)
Method Ref.	: Assay for the Pantoprazole for Injection monograph from BP 2018
Buffer	: 0.01 M dipotassium hydrogen phosphate trihydrate, adjusted to pH 7 with 20 % orthophosphoric acid.
Mobile Phase	: A solution of 35 volumes of a mixture of 1 volume of water and 99 volumes of acetonitrile, and 65 volumes of buffer.
Diluent	: A solution of 50 volumes of acetonitrile and 50 volumes of 0.001 M solution of sodium hydroxide.
Flow Rate	: 1.0 mL/min
Column Temp	: 25°C
Autosampler Temp	: 5°C
Injection Volume	: 20 µL
Detection	: UV, 290 nm