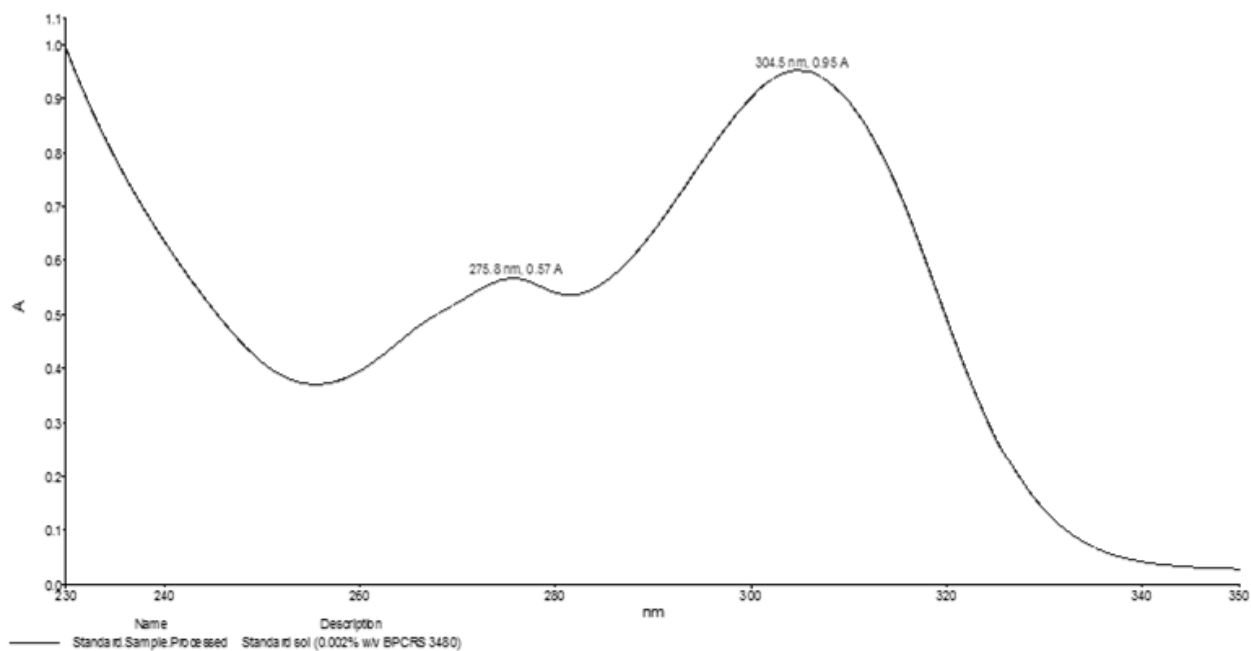




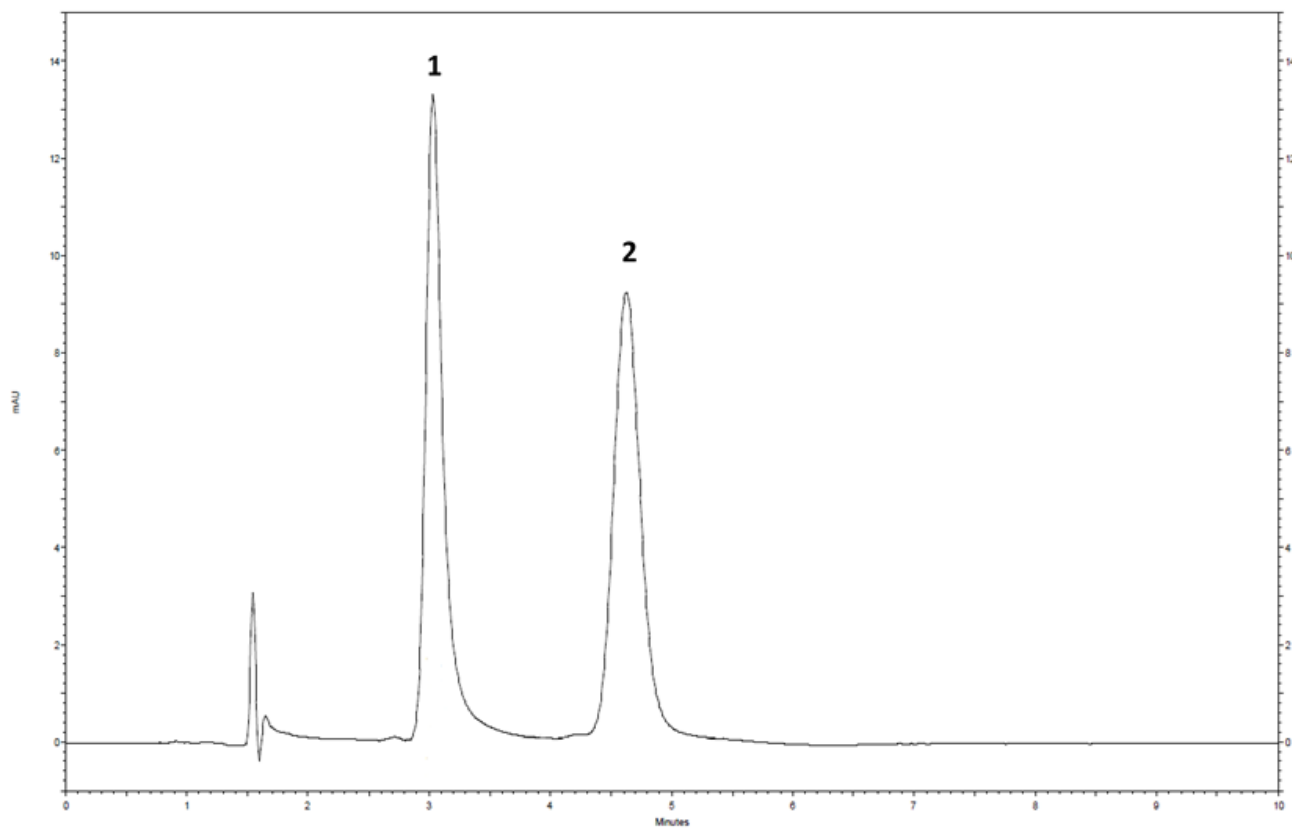
Esomeprazole Gastro-Resistant Tablets – BP 2023

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 solution (2) in the Identification test for Esomeprazole Gastro-Resistant Tablets as published in BP 2023.



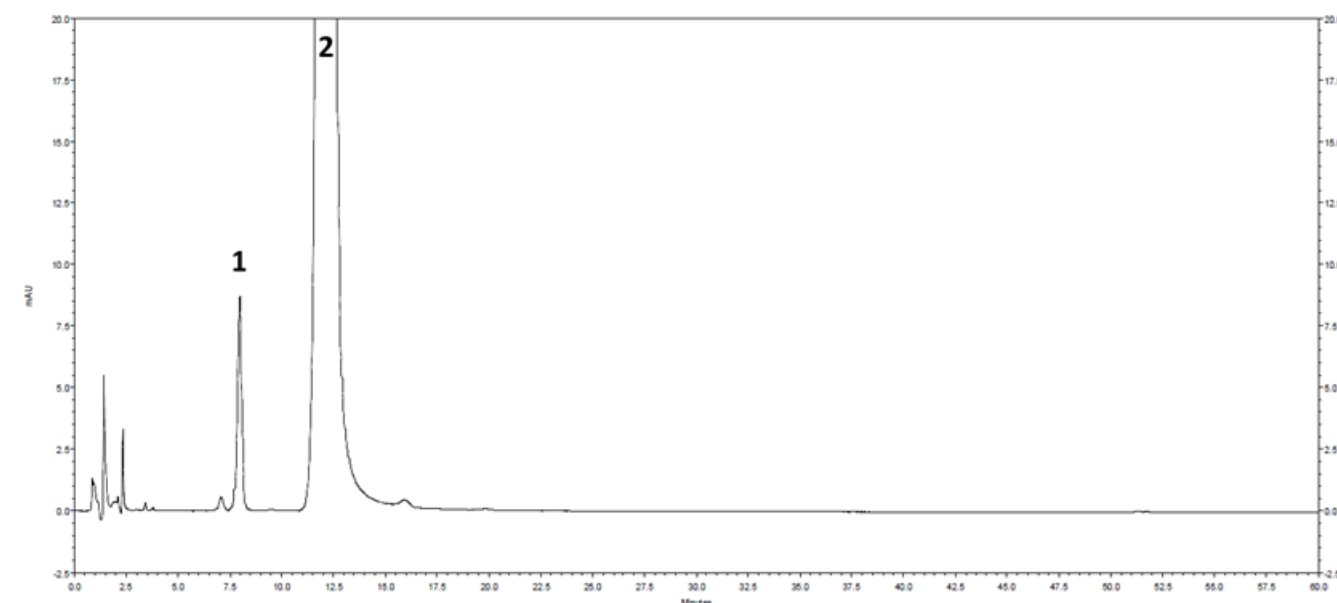
Typical chromatogram for solution (2) in the Identification test for Esomeprazole Gastro-Resistant Tablets as published in BP 2023.



Peak ID: 1: (R)-Omeprazole. 2: Esomeprazole

Column	Chiralpak AGP (100 mm x 4.0 mm, 5.0 µm)
Method Ref.	Identification for the Esomeprazole Gastro-Resistant Capsules monograph from BP 2023
Mobile Phase	Acetonitrile : buffer (13:87, v/v)
Buffer	A solution containing 0.0025M disodium hydrogen orthophosphate dodecahydrate and 0.005M sodium dihydrogen orthophosphate dihydrate
Diluent	Solution A
Flow rate	0.6 mL/min
Column Temp	25 °C
Injection Volume	20 µL
Detection	302 nm

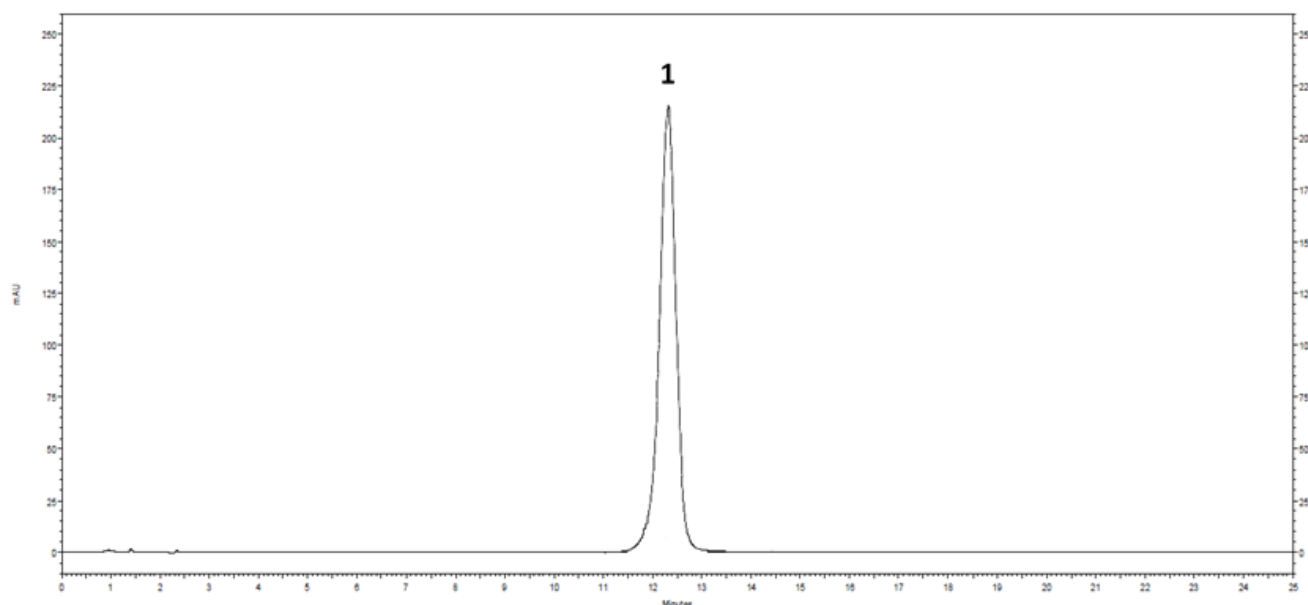
Typical chromatogram for solution (3) in the Related substances test for Esomeprazole Gastro-Resistant Tablets as published in BP 2023.



Peak ID: 1: Impurity D. 2: Omeprazole

Column	Nucleosil C8 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related substances for the Esomeprazole Gastro-Resistant Capsules monograph from BP 2023
Mobile Phase	Acetonitrile : buffer (27:73, v/v)
Buffer	0.14% w/v disodium hydrogen orthophosphate dodecahydrate adjusted to pH 7.6 with orthophosphoric acid
Diluent	Ethanol : solution A : water (3.6:18.4:78, v/v/v)
Flow rate	1.0 mL/min
Column Temp	25 °C
Injection Volume	40 µL
Detection	280 nm

Typical chromatogram for solution (2) in the Assay test for Esomeprazole Gastro-Resistant Tablets as published in BP 2023.



Peak ID: 1: Omeprazole

Column	Nucleosil C8 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related substances for the Esomeprazole Gastro-Resistant Capsules monograph from BP 2023
Mobile Phase	Acetonitrile : buffer (27:73, v/v)
Buffer	0.14% w/v disodium hydrogen orthophosphate dodecahydrate adjusted to pH 7.6 with orthophosphoric acid
Diluent	Solution A
Flow rate	1.0 mL/min
Column Temp	25 °C
Injection Volume	40 µL
Detection	302 nm