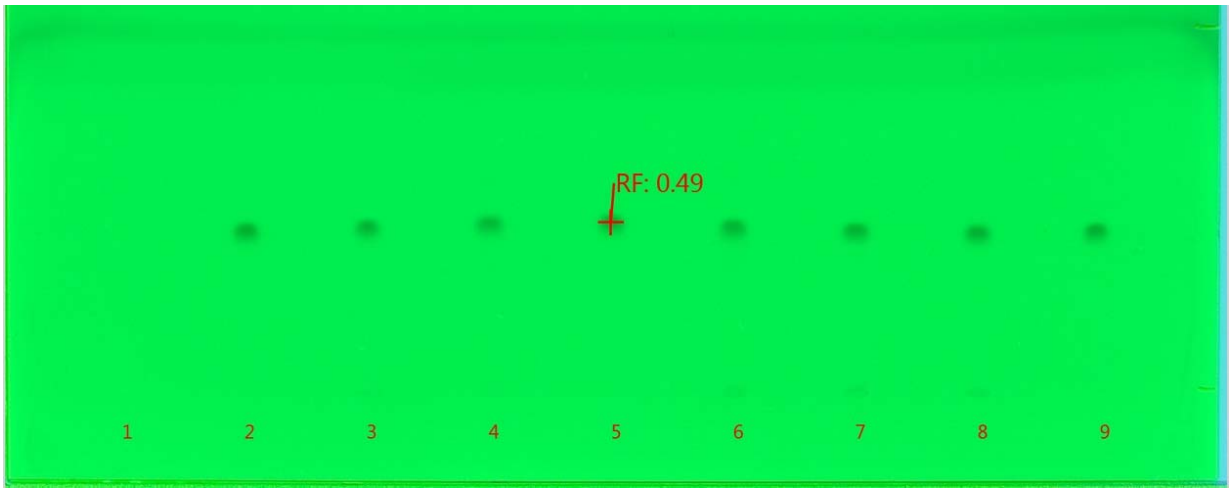
Ritonavir Oral Solution – BP 2020

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.

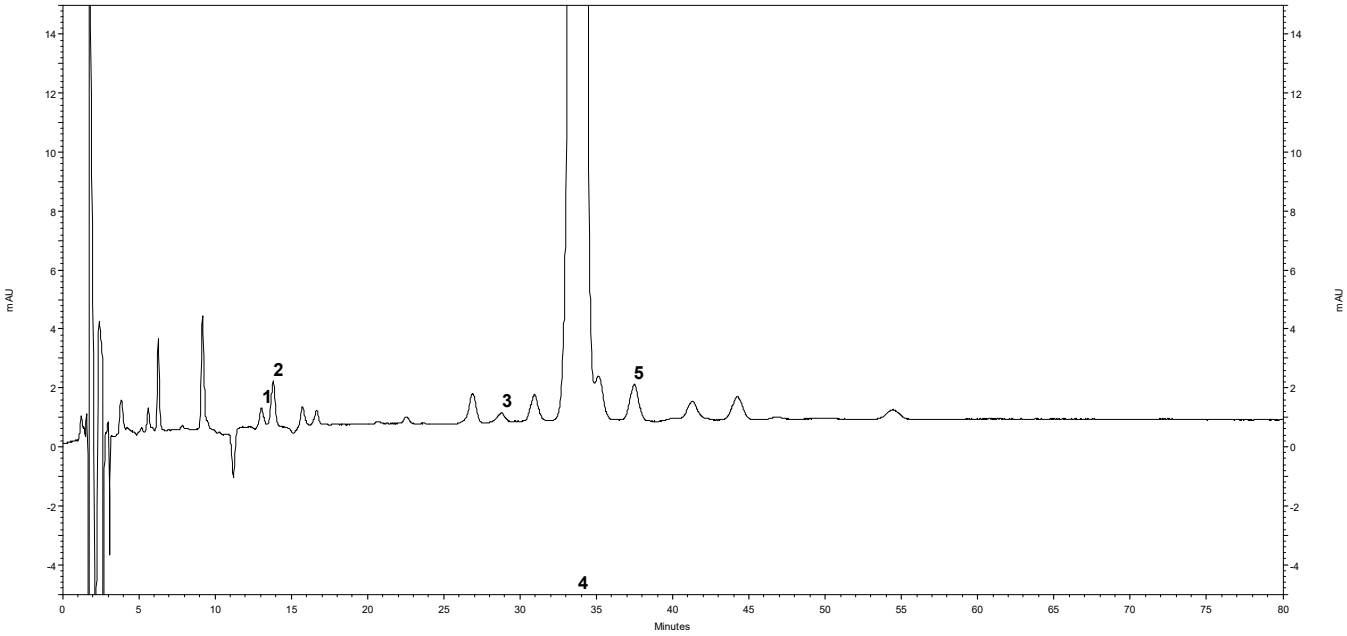
Typical chromatogram for the Identification test for Ritonavir Oral Solution by Thin Layer Chromatography as published in BP 2020.



1	Blank
2	0.2 % w/v ritonavir standard
3 - 4	0.2 % w/v tablet sample solution (run on the same plate)
5	0.2 % w/v ritonavir standard
6 - 8	0.2 % w/v oral solution sample solution
9	0.2 % w/v ritonavir standard

TLC plate	Merck TLC silica gel 60 F_{254} Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	Acetonitrile : water (50:50, v/v)
Mobile Phase	Glacial acetic acid : n-heptane : ethyl acetate (5:6:18, v/v/v)
Mobile Phase volume	116 mL
Band application	3 mm band size with a spotting volume of 2 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	60 mm
Development time	10 minutes
Drying time	5 minutes in air
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm)

Typical chromatogram for solution (4) in the Related Substances test for Ritonavir Oral Solution as published in BP 2020.



Peak ID: 1: Impurity E; 2: Impurity F; 3: Impurity L; 4: Ritonavir; 5: Impurity O

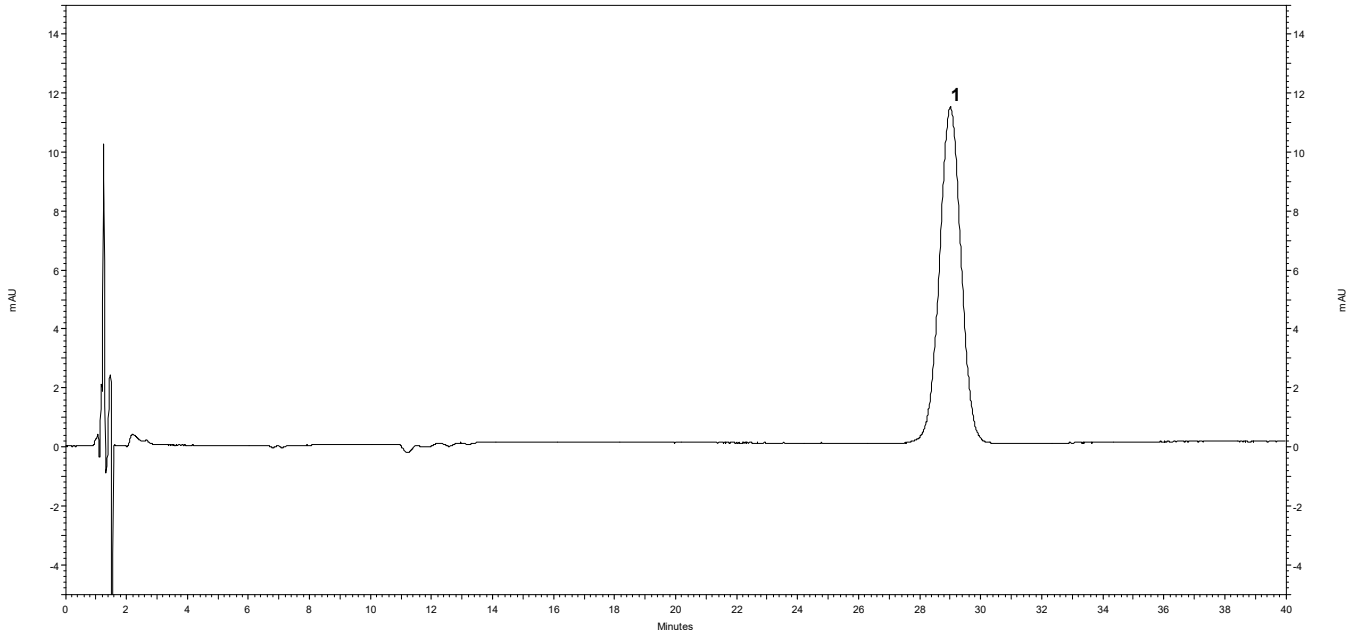
Column	:	YMC Pack C4 (150 mm x 4.6 mm, 3.0 µm)
Method Ref.	:	Related substances for the Ritonavir Oral Solution monograph from BP 2020
Buffer A	:	0.03 M potassium dihydrogen orthophosphate
Buffer B	:	3.8 g/L potassium dihydrogen phosphate and 0.25 g/L dipotassium hydrogen phosphate
Mobile Phase	:	Butanol: tetrahydrofuran (stabiliser free): acetonitrile: buffer B (5:8:18:69, v/v/v/v)
Wash solvent	:	Butanol: tetrahydrofuran (stabiliser free): acetonitrile: buffer A (8:13:30:49, v/v/v/v)

Gradient :

Time (minutes)	Mobile phase (% v/v)	Wash Solvent (% v/v)	Comment
0 – 80	100	0	isocratic
80 - 115	0	100	isocratic
115 - 145	100	0	re-equilibration

Solvent A	:	Acetonitrile : buffer A (50:50, v/v)
Solvent B	:	Buffer A : acetonitrile (35:65 v/v)
Solvent C	:	Butanol : buffer A (8:92 v/v)
Diluent	:	Solvent C
Flow rate	:	1.0 mL/min
Column Temp	:	60 °C
Injection Volume	:	50 µL
Detection	:	UV, 240 nm

Typical chromatogram for solution (2) in the Assay test for Ritonavir Oral Solution as published in BP 2020.



Peak ID: 1: Ritonavir

Column	:	Hypersil BDS C8 (150 x 4.6 mm, 5µm)
Method Ref.	:	Assay for the Ritonavir Oral Solution monograph from BP 2020
Buffer	:	0.03 M potassium dihydrogen orthophosphate
Mobile Phase	:	Methanol : tetrahydrofuran (stabiliser free) : acetonitrile : buffer (10: 10: 17.5: 62.5, v/v/v/v)
Diluent	:	Acetonitrile : buffer (50: 50, v/v)
Flow rate	:	1.5 mL/min
Column Temp	:	40 °C
Injection Volume	:	50 µL
Detection	:	UV, 240 nm