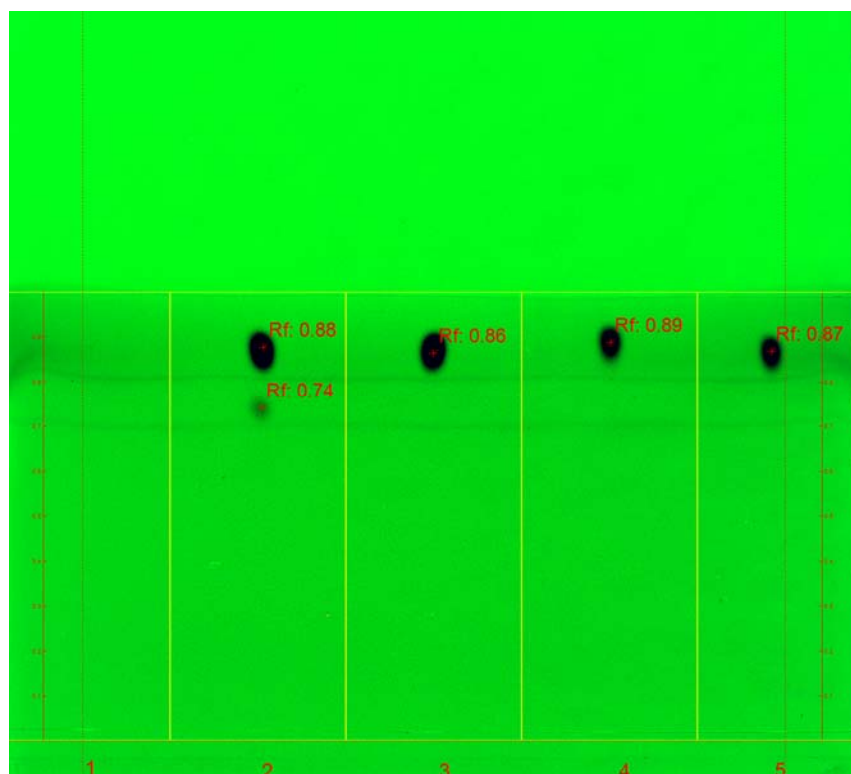




Itraconazole Oral Solution – BP 2019

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 Itraconazole Oral Solution by Thin Layer Chromatography as published in BP 2019.

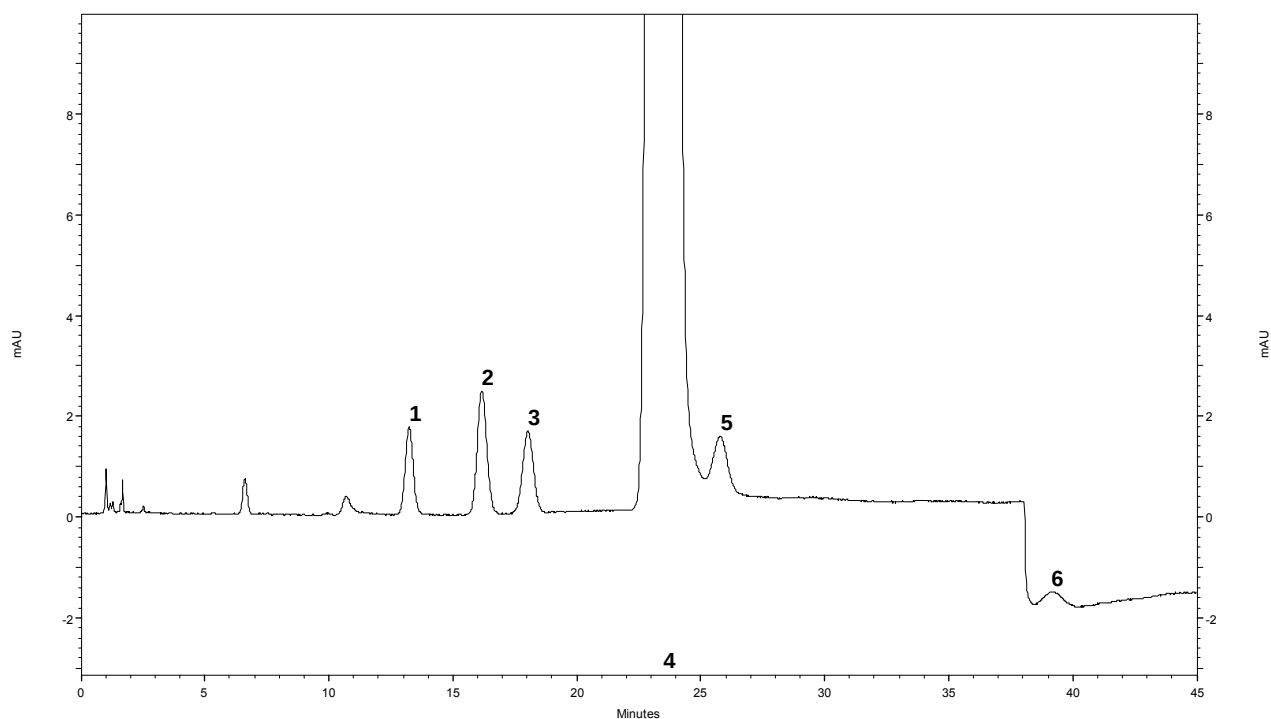


- | | |
|-------|--|
| 1 | Blank |
| 2 | System suitability test 0.2 % w/v itraconazole and 0.2 % w/v fluconazole |
| 3 | 0.2 % w/v itraconazole standard solution |
| 4 - 5 | 0.2 % w/v itraconazole oral solution sample solutions |

TLC plate	Merck TLC silica gel 60 F ₂₅₄ Plate, 20 cm × 20 cm
Diluent	Dichloromethane
Mobile Phase	0.015 % w/v of ammonium acetate and 0.0003 % v/v of glacial acetic acid in water : 1,4-dioxane : methanol (20:40:40, v/v/v)
Sample application	5 µL
Development	100 mm
Development time	55 minutes
Drying	Dry in air
Visualisation	Developed plates examined under UV light (254 nm)



Typical chromatogram for solution (3) in the Related Substances test for Itraconazole Oral Solution as published in BP 2019.

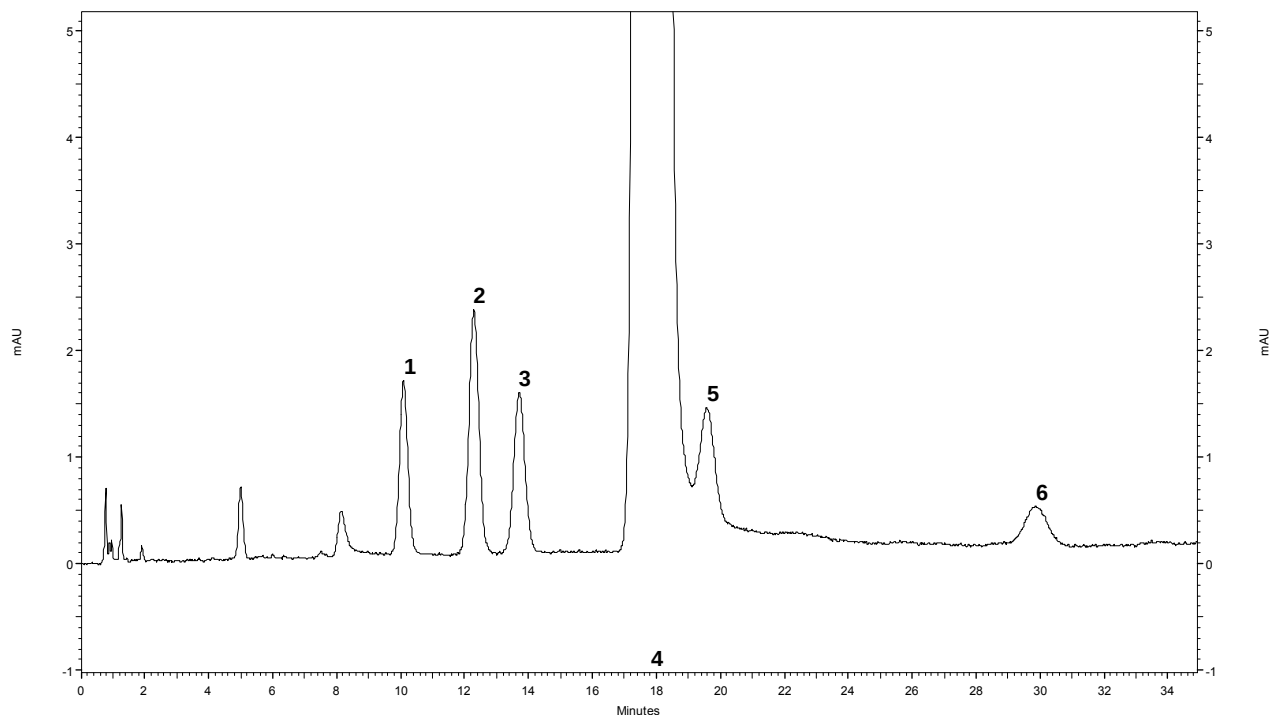


Peak ID: 1: Impurity B; 2: Impurity C + D; 3: Impurity E; 4: Itraconazole; 5: Impurity F; 6: Impurity G

Column	: Phenomenex Prodigy ODS (2) (150 mm × 4.6 mm, 5 µm)
Mobile Phase	: 48 volumes of acetonitrile and 52 volumes of 0.01M potassium dihydrogen orthophosphate previously adjusted to pH 3.0 with orthophosphoric acid
Diluent	: 0.1 volumes of hydrochloric acid and 50 volumes of mobile phase (solution A)
Flow Rate	: 1.5 mL/min
Column Temp	: 40°C
Injection Volume	: 15 µL
Detection	: UV, 254 nm



Typical chromatogram for solution (3) in the Assay test for Itraconazole Oral Solution as published in BP 2019.



Peak ID: 1: Impurity B; 2: Impurity C + D; 3: Impurity E; 4: Itraconazole; 5: Impurity F; 6: Impurity G

Column	: Phenomenex Prodigy ODS (2) (150 mm × 4.6 mm, 5 µm)
Mobile Phase	: 48 volumes of acetonitrile and 52 volumes of 0.01M potassium dihydrogen orthophosphate previously adjusted to pH 3.0 with orthophosphoric acid
Diluent	: 0.1 volumes of hydrochloric acid and 50 volumes of mobile phase (solution A)
Flow Rate	: 2.0 mL/min
Column Temp	: 40°C
Injection Volume	: 15 µL
Detection	: UV, 254 nm