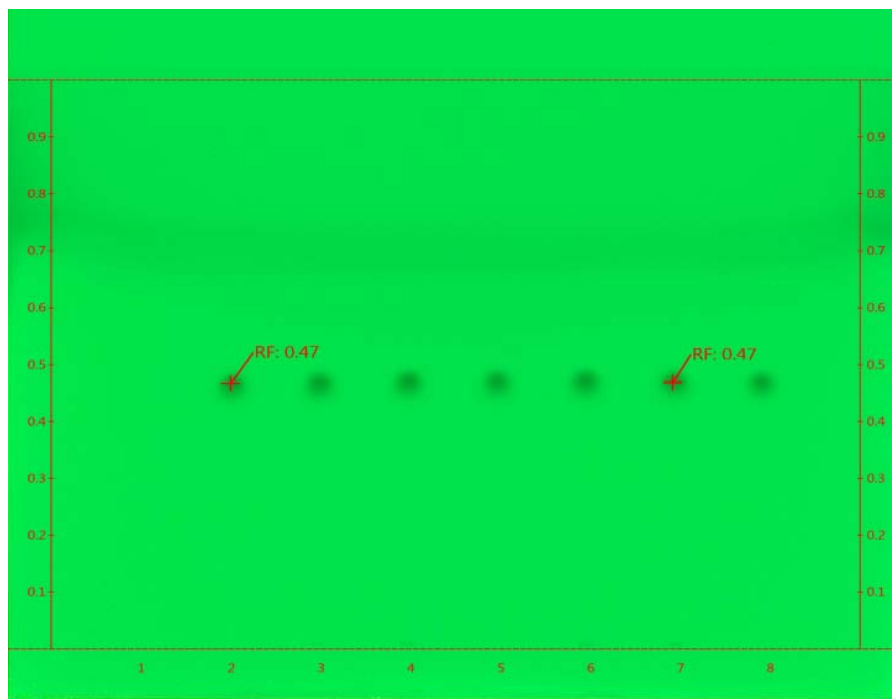




Letrozole Tablets – BP 2020

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 Letrozole Tablets by Thin Layer Chromatography as published in BP 2020.

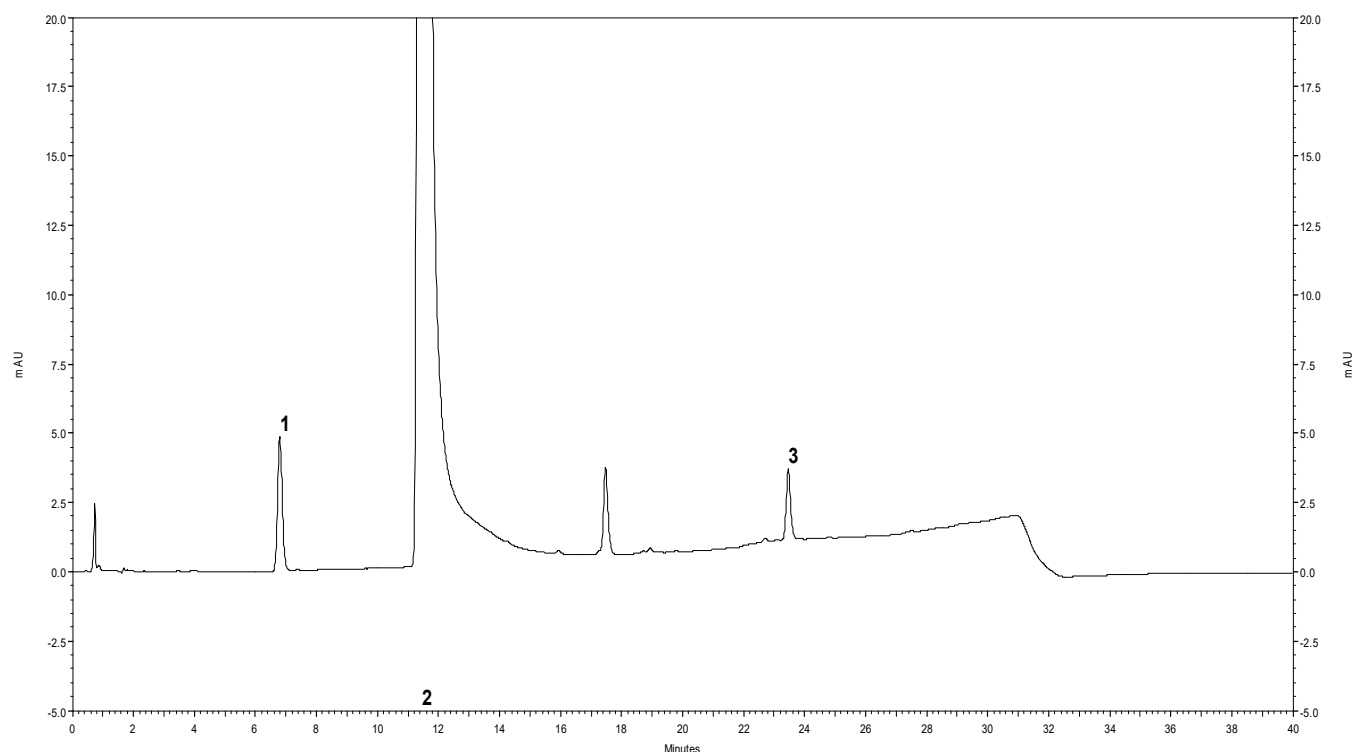


- | | |
|---------|---------------------------------------|
| 1 | Blank |
| 2,5,8 | 0.2 % w/v letrozole standard solution |
| 3,4,6,7 | 0.2 % w/v tablets sample solution |

TLC plate	Merck TLC silica gel 60 F ₂₅₄ Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	Methanol: ethyl acetate (1: 9 v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 5 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	150 mm
Development time	35 minutes
Drying time	15 minutes in air
Derivatisation	N/A
Visualisation	Developed plate was visualised under UV light (254 nm)



Typical chromatogram for solution (3) in the Related Substances test for Letrozole Tablets as published in BP 2020.



Peak ID: 1: Impurity A; 2: Letrozole; 3: Impurity B

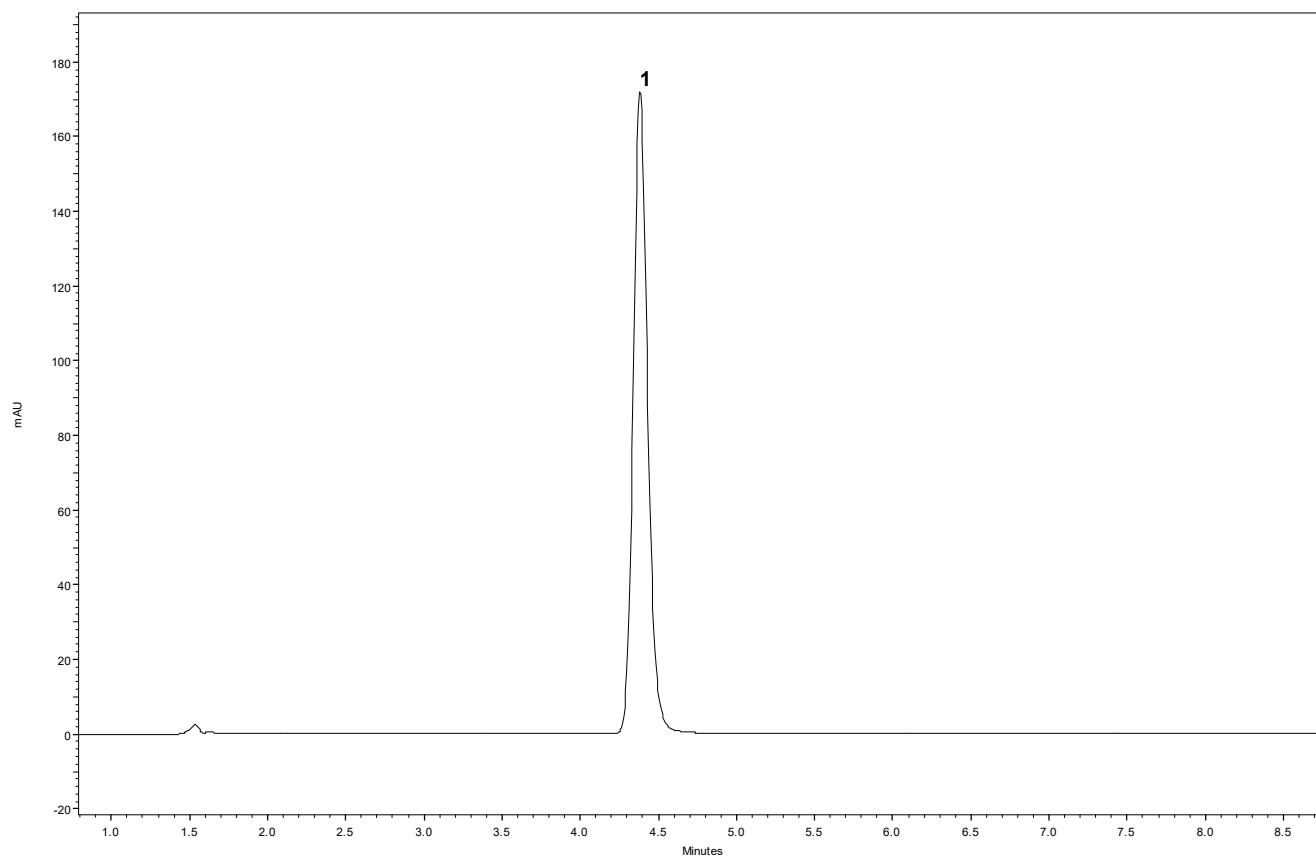
Column : Supelco, Nucleosil 100-5 C18 (125 mm x 4.6 mm, 5 µm)
Method Ref. : Related Substances for the Letrozole Tablets monograph from BP 2020
Mobile Phase A : Water
Mobile Phase B : Acetonitrile
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-4	70	30
4-29	70-30	30-70
29-30	30-70	70-30
30-40	70	30

Diluent : Acetonitrile: water (30: 70, v/v)
Flow rate : 1.0 mL/min
Column Temp : 25 °C
Injection Volume : 20 µL
Detection : 230 nm



Typical chromatogram for solution (2) in the Assay test for Letrozole Tablets as published in BP 2020.



Peak ID: 1: Letrozole

Column	: Supelco, Nucleosil 100-5 C18 (125 mm x 4.6 mm, 5 μ m)
Method Ref.	: Assay for the Letrozole Tablets monograph from BP 2020
Mobile Phase	: Acetonitrile: water (12:13, v/v)
Diluent	: 30 % acetonitrile: mobile phase (1: 24, v/v)
Flow rate	: 1.0 mL/min
Column Temp	: 25 °C
Injection Volume	: 20 μ L
Detection	: 230 nm