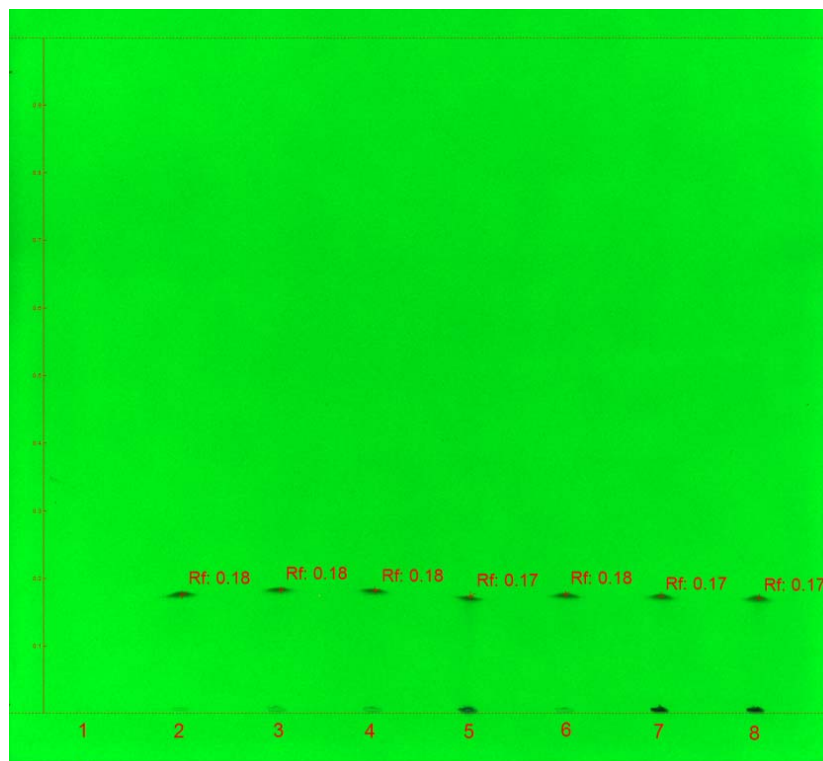


Prolonged-Release Tolterodine Capsules – BP 2019

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 Prolonged-Release Tolterodine Capsules by Thin Layer Chromatography as published in BP 2019.

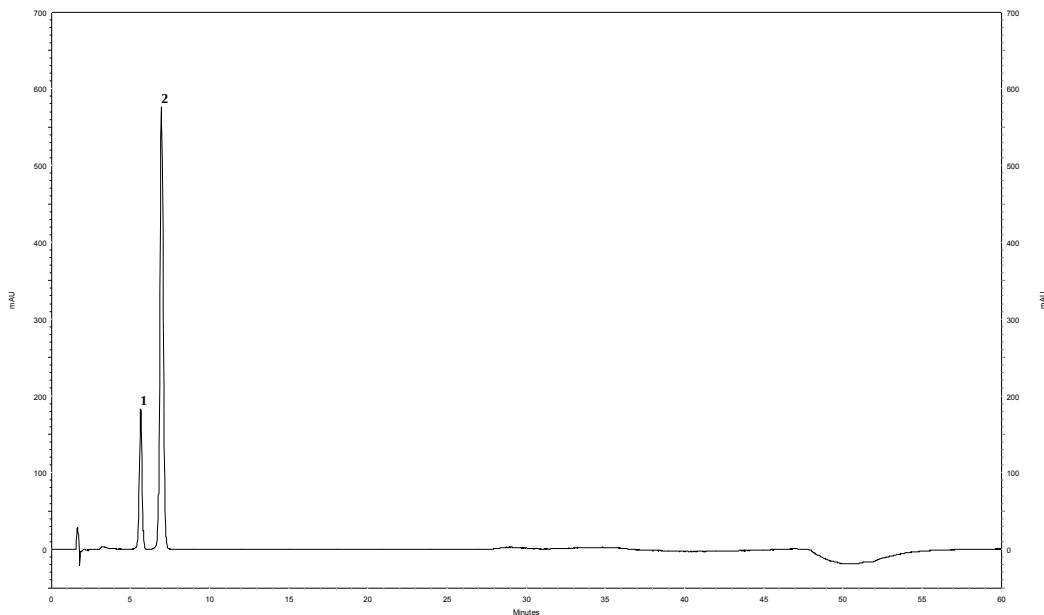


- 1 Blank
- 2 0.25 % w/v tolterodine tartrate standard solution
- 3 - 8 0.25 % w/v sample solution preparations

TLC plate	Merck TLC silica gel 60 F ₂₅₄ Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	Triethylamine : ethyl acetate : pentane (2:30:70 v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 10 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	150 mm
Development time	40 minutes
Drying time	15 minutes in air
Visualisation	Developed plate was visualised under UV light (254 nm)



Typical chromatogram for solution (3) in the Related Substances test for Prolonged-Release Tolterodine Capsules as published in BP 2019.



Peak ID: 1: Impurity E; 2: Tolterodine tartrate

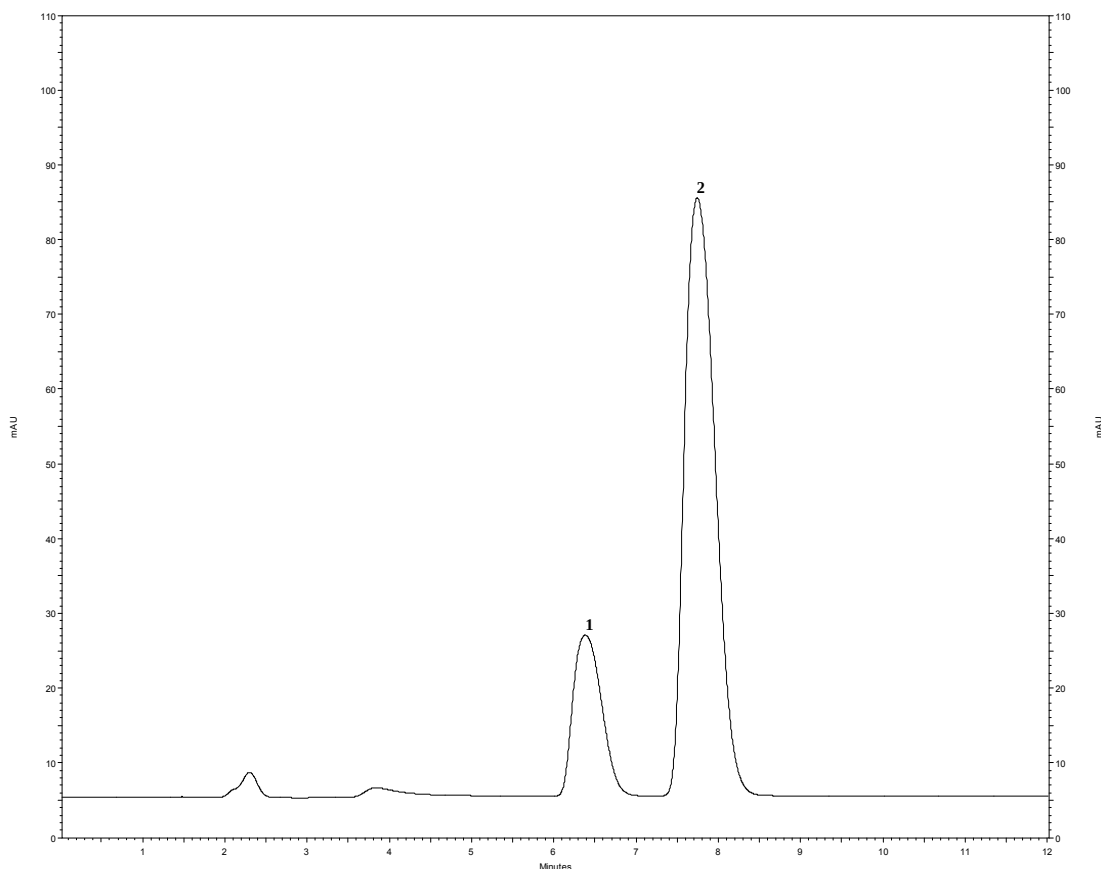
Column : Thermo Hypersil BDS C18 (250 mm x 4.6 mm, 5 μ m)
Buffer : 0.288 % w/v of ammonium dihydrogen orthophosphate
Mobile Phase A : Triethylamine: buffer (5:450, v/v) adjusted to pH 5.9 with 50 % v/v orthophosphoric acid and mixed with 550 volumes of methanol
Mobile Phase B : Methanol
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-25	100	0
25-45	100-80	0-20
45-46	80	20
46-50	80-100	20-0
50-60	100	0

Diluent : Methanol
Flow Rate : 1.5 mL/min
Column Temp : 25°C
Injection Volume : 20 μ L
Detection : UV, 220 nm



Typical chromatogram for solution (3) in the Assay test for Prolonged-Release Tolterodine Capsules as published in BP 2019.



Peak ID: 1: Impurity E; 2: Tolterodine Tartrate

Column	: Thermo, Hypersil BDS C18 (250 mm x 4.6 mm, 5 μ m)
Buffer	: 0.288 % w/v of ammonium dihydrogen orthophosphate
Mobile Phase	: Triethylamine: buffer (5:450, v/v) adjusted to pH 5.9 with 50 % v/v orthophosphoric acid and mixed with 550 volumes of methanol
Diluent	: Methanol
Flow Rate	: 1.5 mL/min
Column Temp	: 25°C
Injection Volume	: 10 μ L
Detection	: UV, 220 nm