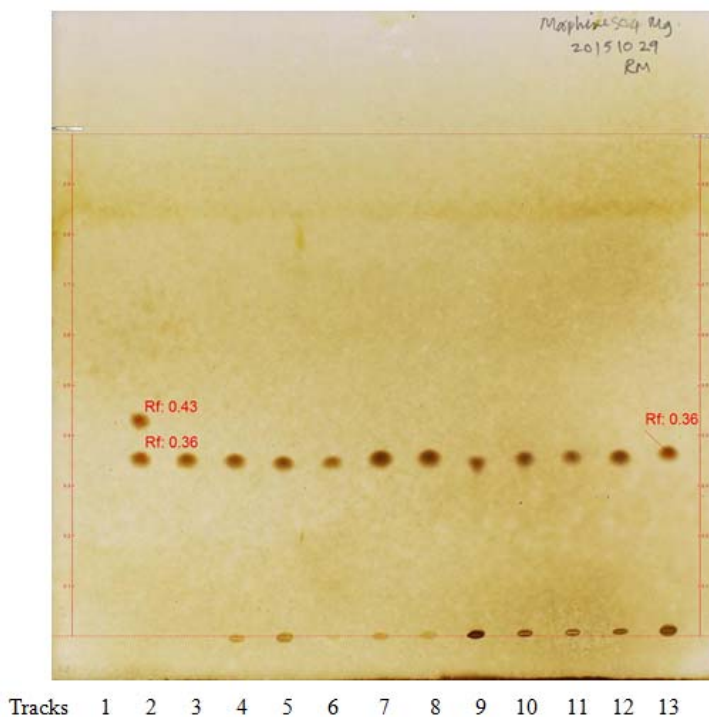




Morphine Prolonged Release Tablets – BP 2018

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 Morphine Prolonged-release Tablets by Thin Layer Chromatography as published in BP 2018.

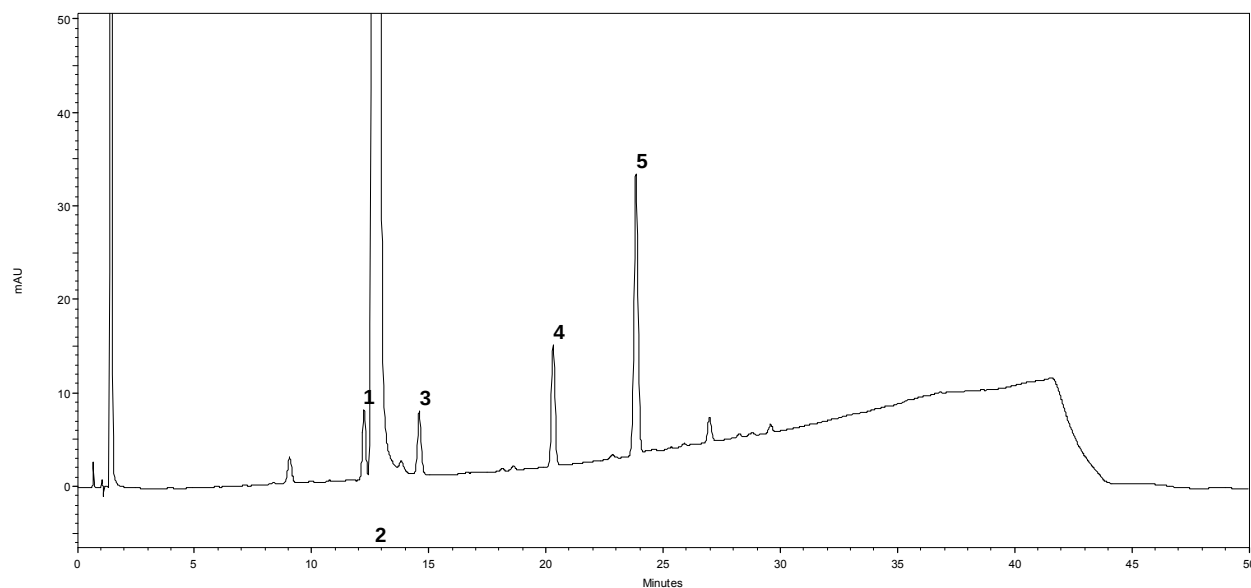


- | | |
|---------|---|
| 1 | Blank |
| 2 | System suitability test 0.05 % w/v morphine sulfate & codeine phosphate |
| 3 | 0.05 % w/v morphine sulfate |
| 4 - 11 | Prolonged release tablets 0.05 % w/v solution |
| 12 - 13 | Tablets 0.05 % w/v (also ran on the same plate) |

TLC plate	Merck TLC silica gel 60 Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	1:1 mixture of ethanol (96 %) and water
Mobile Phase	13.5 M Ammonia : acetone : ethanol (70 % v/v) : toluene (2.5:32.5:35:35 v/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	35 minutes
Drying time	10 minutes in air
Derivatisation	Sprayed with Potassium Iodobismuthate (R2 Soln.).
Visualisation	Derivatised plates examined under white light



Typical chromatogram for solution (4) in the Related Substances test for Morphine Prolonged-release Tablets as published in BP 2018.



Peak ID: 1: Impurity F; 2: Morphine sulfate; 3: Impurity E; 4: Impurity C; 5: Impurity B.

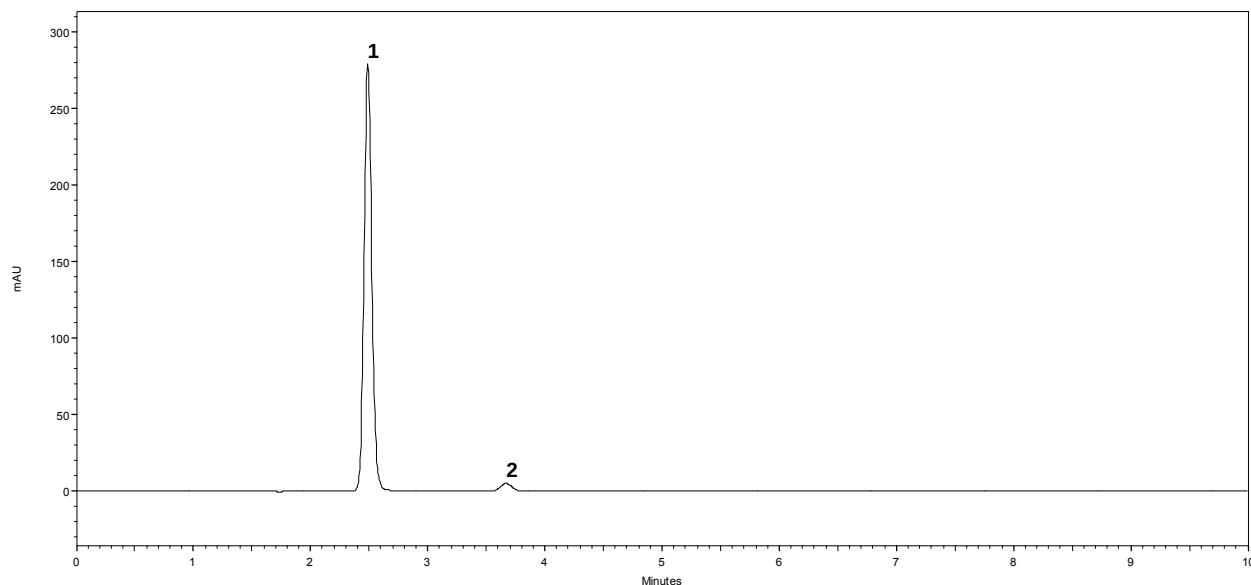
Column : Waters Symmetry C18 (150 mm × 4.6 mm, 5 µm)
Mobile Phase A : 0.101 % w/v sodium heptanesulfonate adjusted to pH 2.6 with 50 % v/v orthophosphoric acid.
Mobile phase B : Methanol
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-2	85	15
2-35	85-50	15-50
35-40	50	50
40-42	50-85	50-15
42-50	85	15

Diluent : 1 % v/v acetic acid
Flow Rate : 1.5 mL/min
Column Temp : 35°C
Injection Volume : 20 µL
Detection : UV, 230 nm



Typical chromatogram for solution (3) in the Assay test for Morphine Prolonged Release Tablets as published in BP 2018.



Peak ID: 1: Morphine sulfate; 2: Pseudomorphine trihydrate

Column	: Phenomenex HyperClone BDS C18 (150 mm X 4.6 mm, 5 µm)
Mobile Phase	: A solution of orthophosphoric acid, acetonitrile and 0.01 M sodium octanesulfonate (0.05 : 30 : 70, v/v/v)
Diluent	: Mobile phase
Flow Rate	: 1.0 mL/min
Column Temp	: 25°C
Injection Volume	: 20 µL
Detection	: UV, 281 nm