

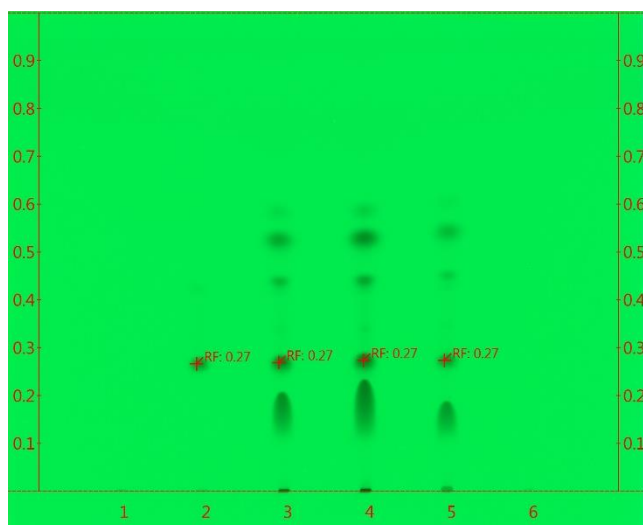


Nifedipine Oral Suspension – BP 2021

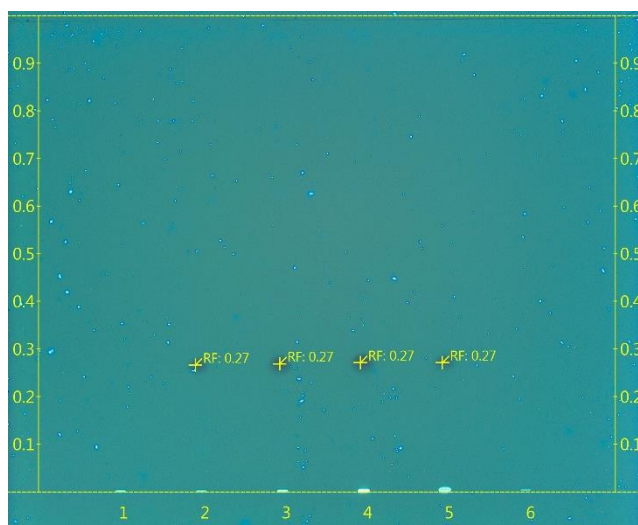
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for the Identification test for Nifedipine Oral Suspension by Thin Layer Chromatography as published in BP 2021.

254 nm:



366 nm:

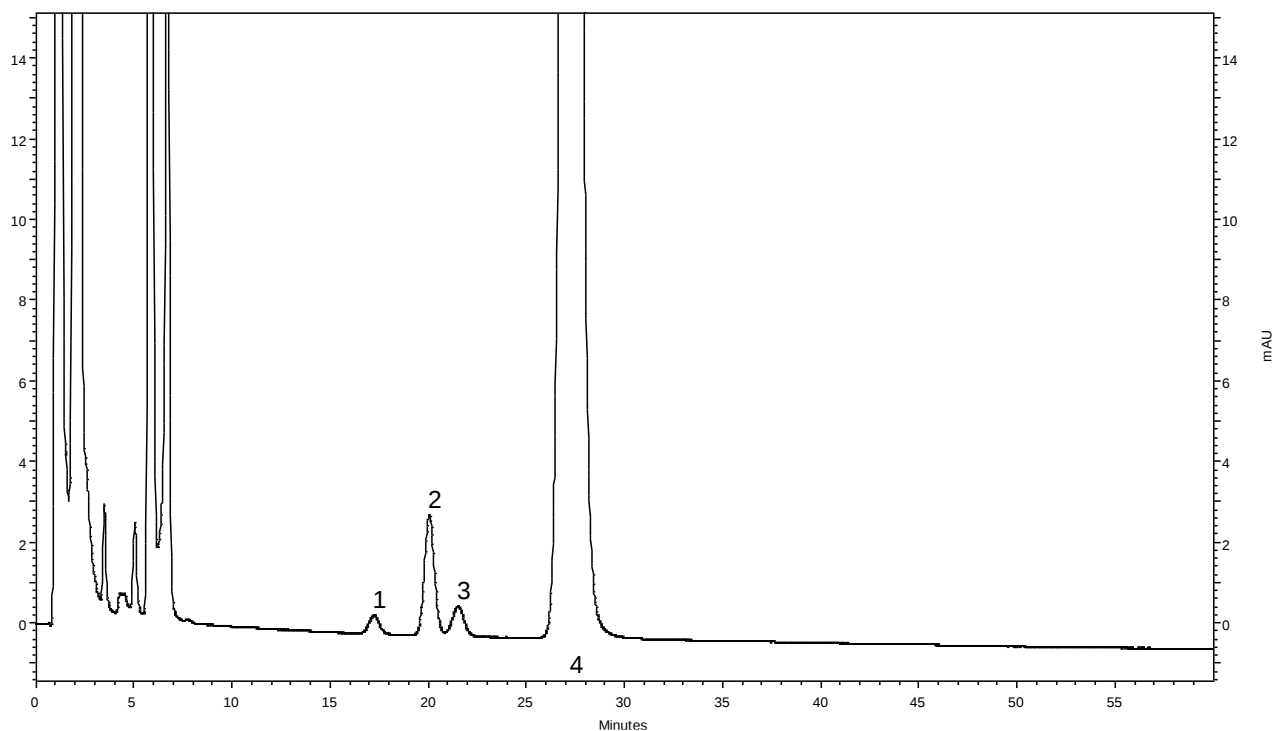


- | | |
|-------|-------------------------------------|
| 1 & 6 | Blank |
| 2 | 0.02 % w/v nifedipine |
| 3 | System suitability solution |
| 4-5 | Oral suspension 0.02 % w/v solution |

TLC plate	Merck TLC silica gel 60 F ₂₅₄ Plate, 20 cm × 20 cm
Plate preconditioning	N/A
Diluent	Dichloromethane: methanol (50: 50, v/v)
Mobile Phase	Ethyl acetate: cyclohexane (40: 60, v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 20 µL
Chamber saturation	N/A
Development	150 mm
Development time	88 minutes
Drying time	10 minutes in air
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm) and 366 nm



Typical chromatogram for solution (4) in the test for Impurities A and B, for Nifedipine Oral Suspension as published in BP 2021.

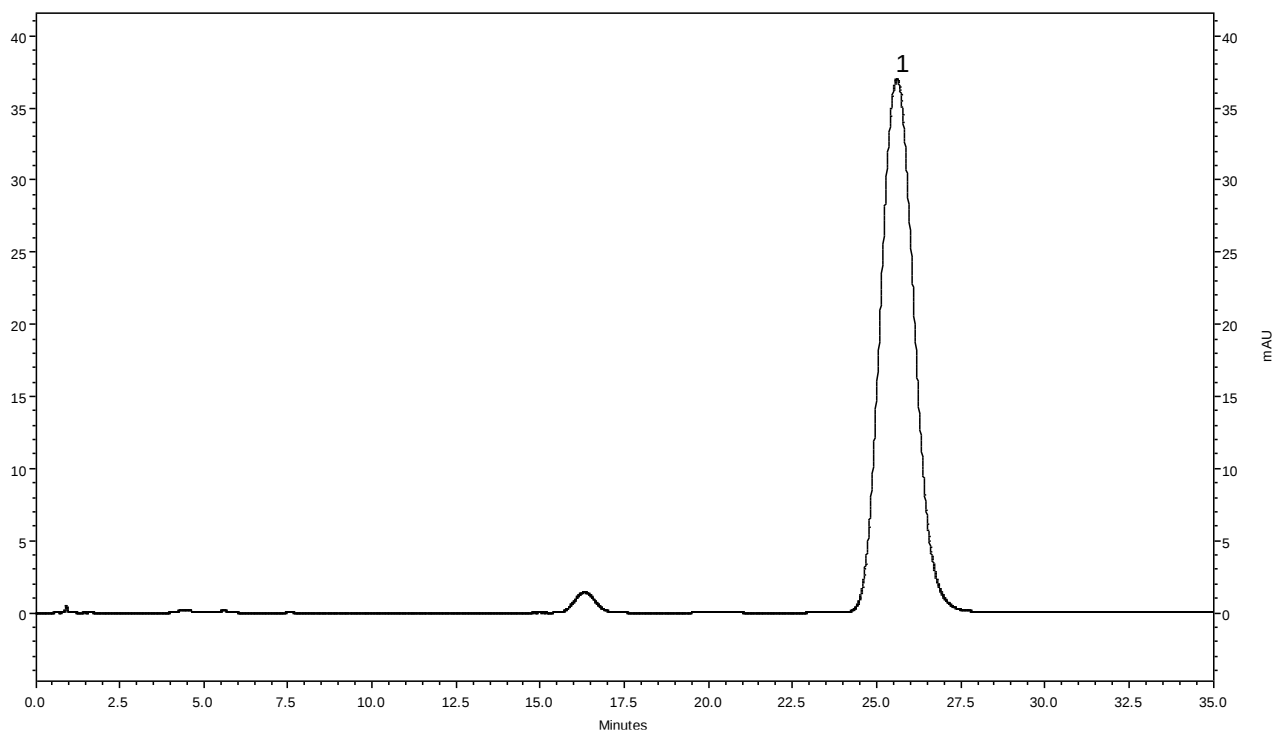


Peak ID: 1: Impurity A; 2: Propyl paraben; 3: Impurity B; 3: Nifedipine

Column	: C18 LiChrospher RP (150 mm x 4.6 mm, 5 µm)
Method Ref.	: Related Substances for the Nifedipine Oral Suspension monograph from BP 2021
Mobile Phase	: Acetonitrile: methanol: water (9: 36: 55, v/v/v)
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 25 °C
Injection Volume	: 20 µL
Detection	: 235 nm



Typical chromatogram for solution (2) in the Assay test for Nifedipine Oral Suspension as published in BP 2021.



Peak ID: 1: Nifedipine

Column	: C18 LiChrospher RP (150 mm x 4.6 mm, 5 µm)
Method Ref.	: Assay for the Nifedipine Oral Suspension monograph from BP 2021
Mobile Phase	: Acetonitrile: methanol: water (9: 36: 55, v/v/v)
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 25 °C
Injection Volume	: 20 µL
Detection	: 235 nm