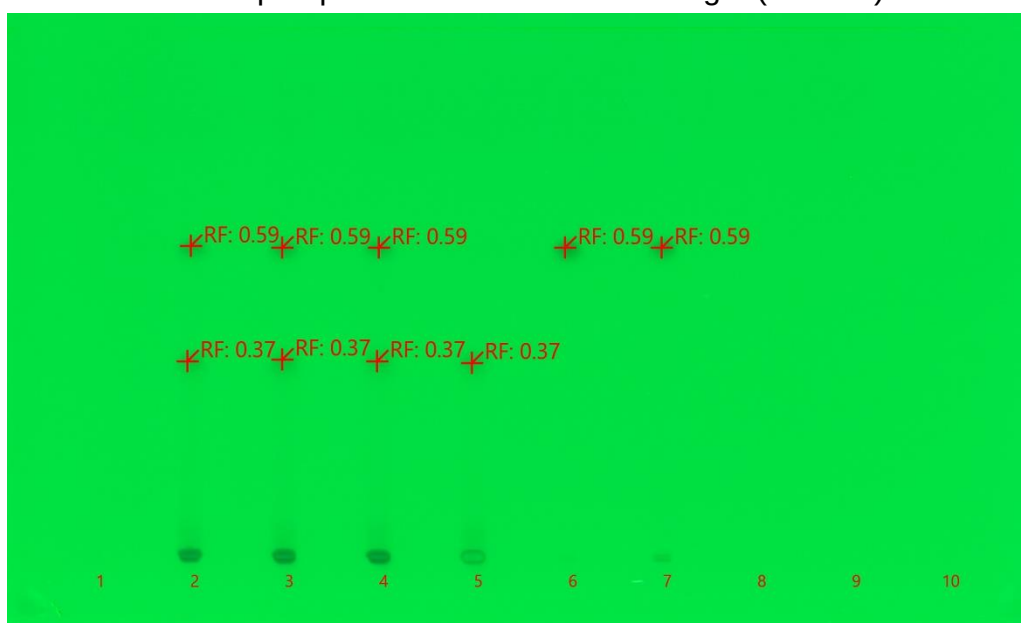


Flecainide Oral Solution – BP 2024

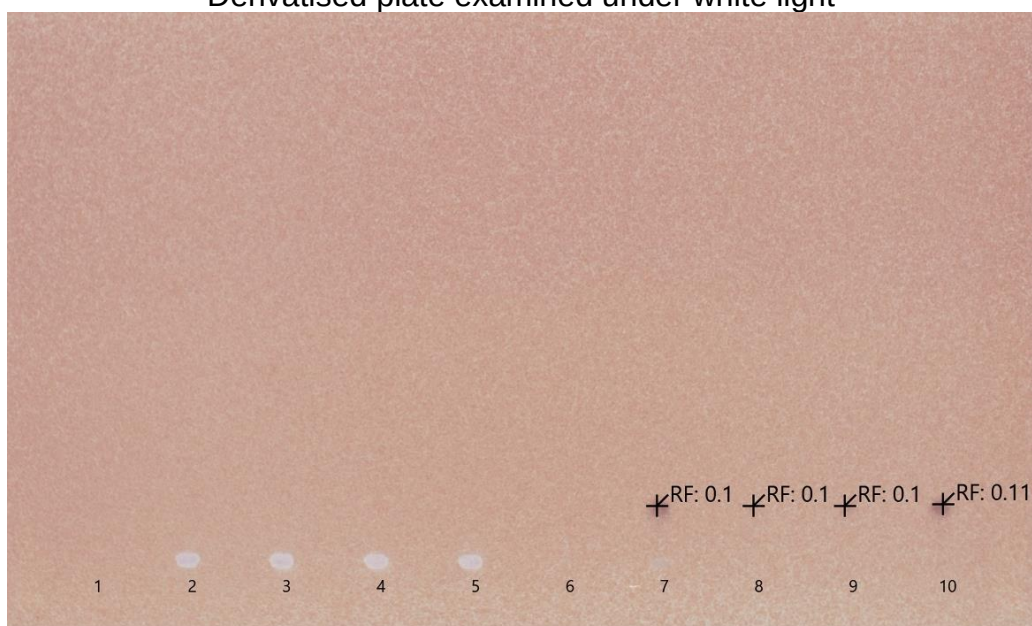
These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Typical chromatogram for the (Piperidin-2-yl)methanamine test for Flecainide Oral Solution by Thin Layer Chromatography as published in BP 2024.

Developed plate examined under UV light (254 nm)



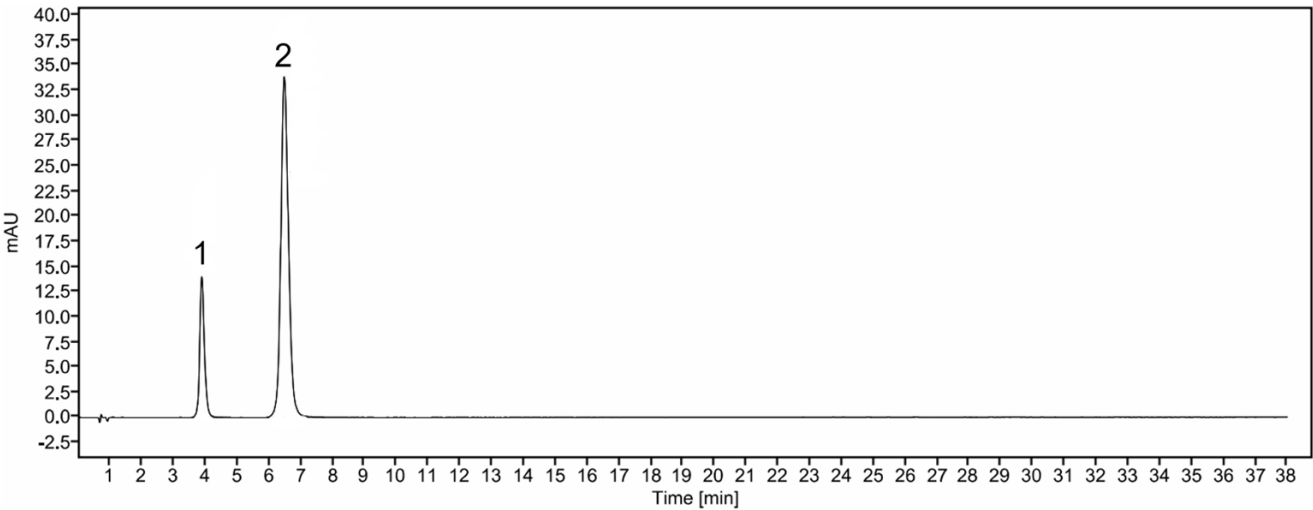
Derivatised plate examined under white light



1	Blank
2-4	Oral solution sample 0.1% w/v solutions
5	Oral solution placebo
6	0.1% w/v of flecainide acetate standard solution
7	0.1% w/v of flecainide acetate standard (10 μ L application volume) and 0.05% w/v of impurity B standard solution (1 μ L application volume)
8	0.005% w/v of impurity B standard solution, 1 μ L application volume
9	0.01% w/v of impurity B standard solution, 1 μ L application volume
10	0.05% w/v of impurity B standard solution, 1 μ L application volume

TLC plate	TLC silica gel 60 F254 precoated plate
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	5 volumes of concentrated ammonia (13.5M) and 95 volumes of acetone
Band application	3 mm band size with a spotting volume of 10 µL
Development	100 mm
Development time	15 minutes
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm) and derivatised plate examined under white light

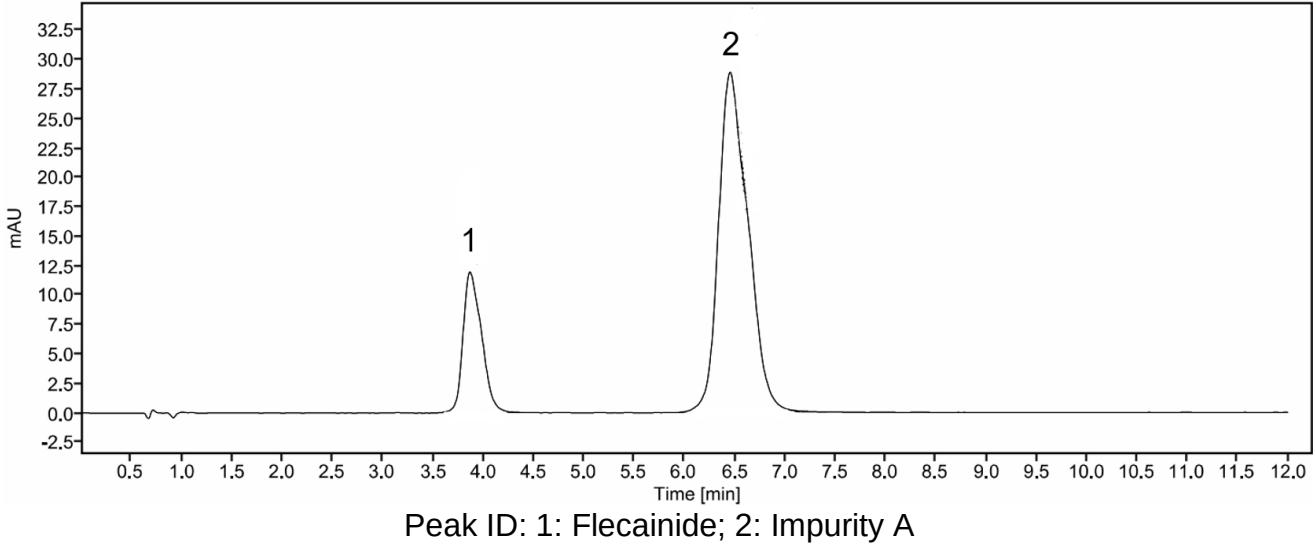
Typical chromatogram for solution (3) in the Related Substances test for Flecainide Oral Solution as published in BP 2024.



Peak ID: 1: Flecainide; 2: Impurity A

Column	Supelco Zorbax, C8 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related substances for the Flecainide Oral Solution monograph from BP 2024
Mobile phase	5 volumes of 1 M tetrabutylammonium hydroxide, 10 volumes of glacial acetic acid, 290 volumes of acetonitrile and 710 volumes of water, the mixture adjusted to pH 5.8 with 18M ammonia
Diluent	Acetonitrile: water (29:71 v/v)
Flow rate	2.0 mL/min
Column Temp	25 °C
Injection Volume	20 µL
Detection	254 nm

Typical chromatogram for solution (3) in the Assay test for Flecainide Oral Solution as published in BP 2024.



Column	Supelco Zorbax, C8 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Assay for the Flecaïnide Oral Solution monograph from BP 2024
Mobile phase	5 volumes of 1 M tetrabutylammonium hydroxide, 10 volumes of glacial acetic acid, 290 volumes of acetonitrile and 710 volumes of water, the mixture adjusted to pH 5.8 with 18M ammonia
Diluent	Acetonitrile: water (29:71 v/v)
Flow rate	2.0 mL/min
Column Temp	25 °C
Injection Volume	20 µL
Detection	254 nm