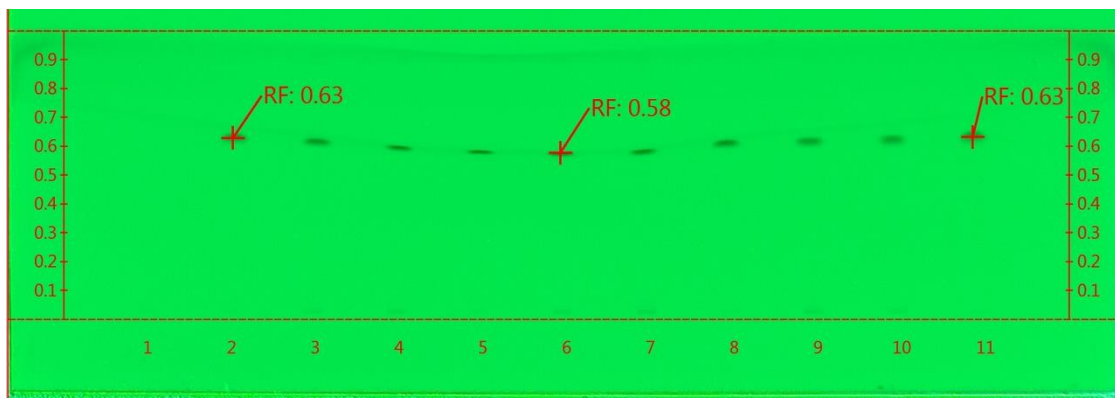




Repaglinide Tablets – BP 2022

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 Repaglinide Tablets by Thin Layer Chromatography as published in BP 2022.



1 Blank

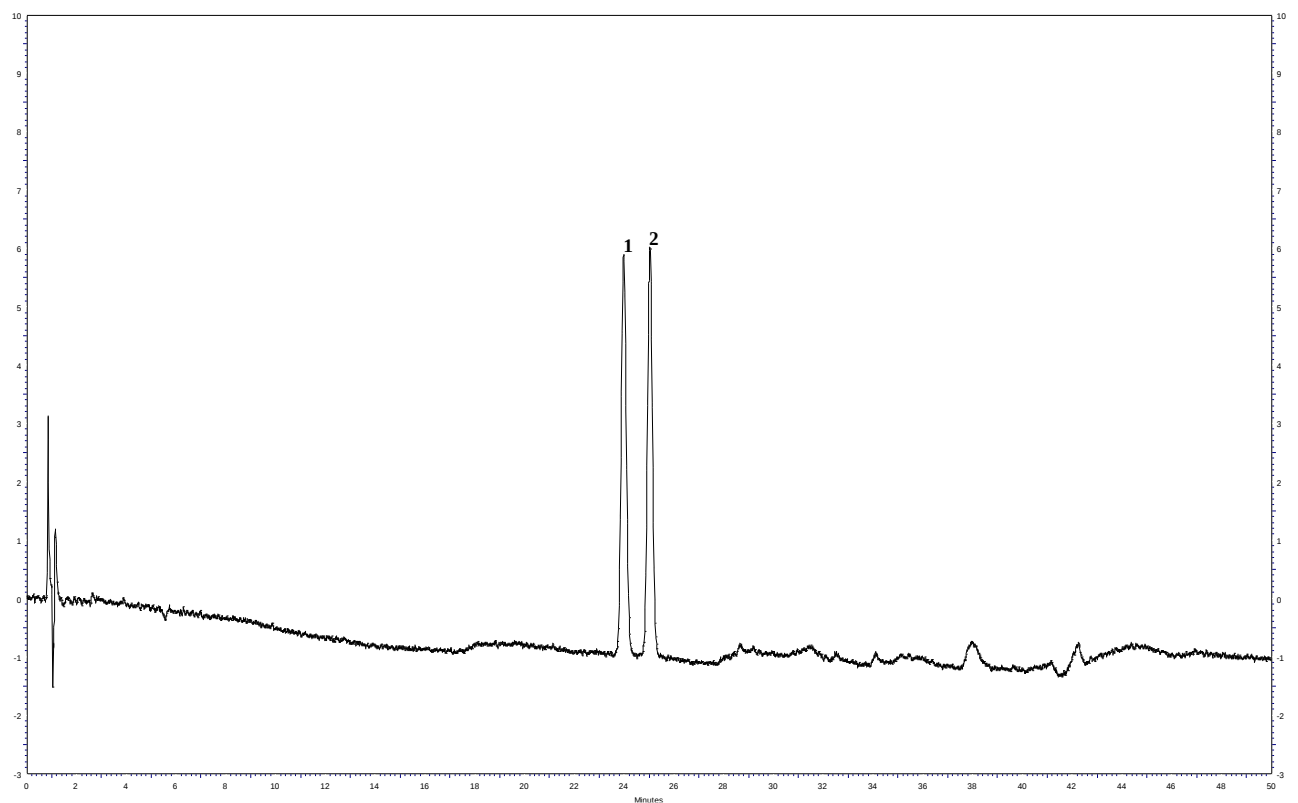
2,5,8,11 0.01 % w/v of repaglinide standard solution

3-4;6-7;9-10 Tablet sample 0.01 % w/v solutions

TLC plate	Merck TLC silica gel 60 F254 plate (20 cm × 20 cm)
Plate preconditioning	N/A
Diluent	Methanol
Mobile Phase	Methanol : toluene: dichloromethane (25: 30: 45, v/v/v)
Mobile Phase volume	100 mL
Band application	3 mm band size with a spotting volume of 25 µL
Chamber saturation	Minimum 60 minutes at room temperature
Development	50 mm
Development time	7 minutes
Drying time	15 minutes in air
Derivatisation	N/A
Visualisation	Developed plate examined under UV light (254 nm)



Typical chromatogram for solution (4) in the Related Substances test for Repaglinide Tablets as published in BP 2022.



Peak ID: 1: Repaglinide; 2: Impurity 1

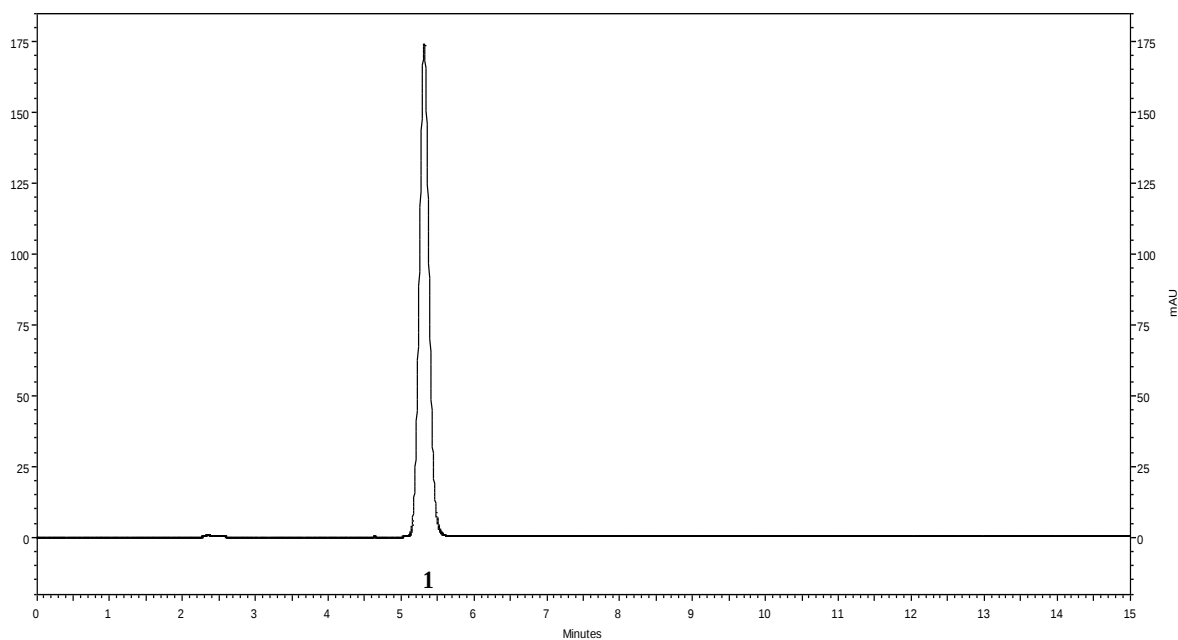
Column : Agilent, Zorbax Eclipse XDB-C8 (150 mm x 4.6 mm, 5 µm)
Method Ref. : Related substances for the Repaglinide Tablets monograph from BP 2022
Mobile Phase A : Buffer
Mobile phase B : Acetonitrile
Gradient :

Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0 – 4	75	25
4 – 30	75 → 50	25 → 50
30 – 40	50	50
40 – 41	50 → 75	50 → 25
41 – 50	75	25

Buffer : 0.02 M potassium dihydrogen phosphate adjusted to pH 2.9 with orthophosphoric acid.
Diluent : Buffer : acetonitrile (50:50, v/v)
Flow rate : 1.5 mL/min
Column Temp : 40 °C
Injection Volume : 20 µL
Detection : 240 nm



Typical chromatogram for solution (2) in the Uniformity of Content/Assay test for Repaglinide Tablets as published in BP 2022.



Peak ID: 1: Repaglinide

Column	: Agilent, Zorbax Eclipse XDB-C8 (150 mm x 4.6 mm, 5 µm)
Method Ref.	: Assay for the Repaglinide Tablets monograph from BP 2022
Mobile Phase	: Buffer: methanol (25: 75, v/v)
Buffer	: 0.007 M of potassium dihydrogen orthophosphate, adjusted to pH 2.5 with orthophosphoric acid
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 45 °C
Injection Volume	: 10 µL
Detection	: 242 nm