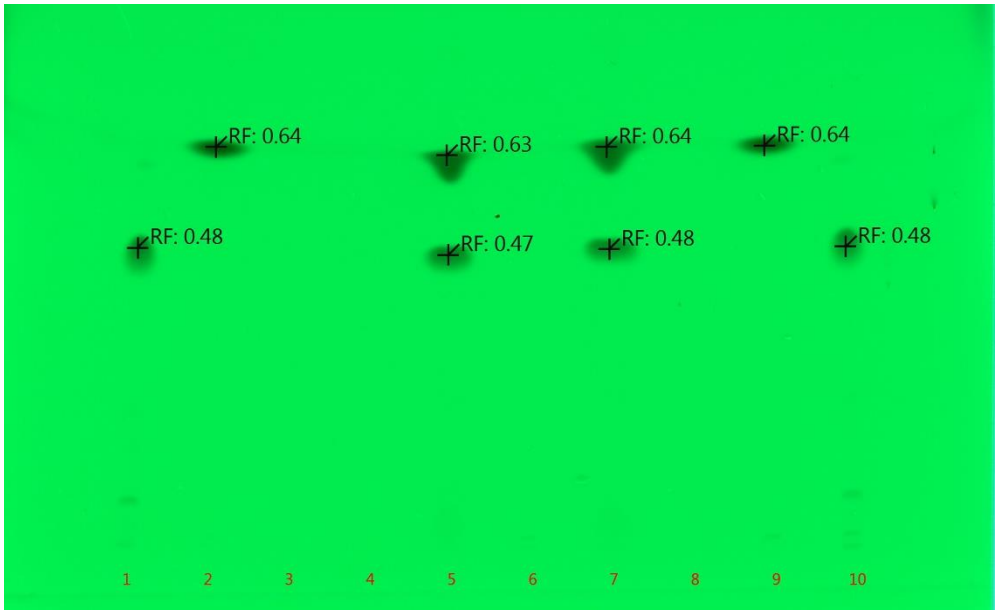
Fusidic Acid Cream – BP 2021

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.

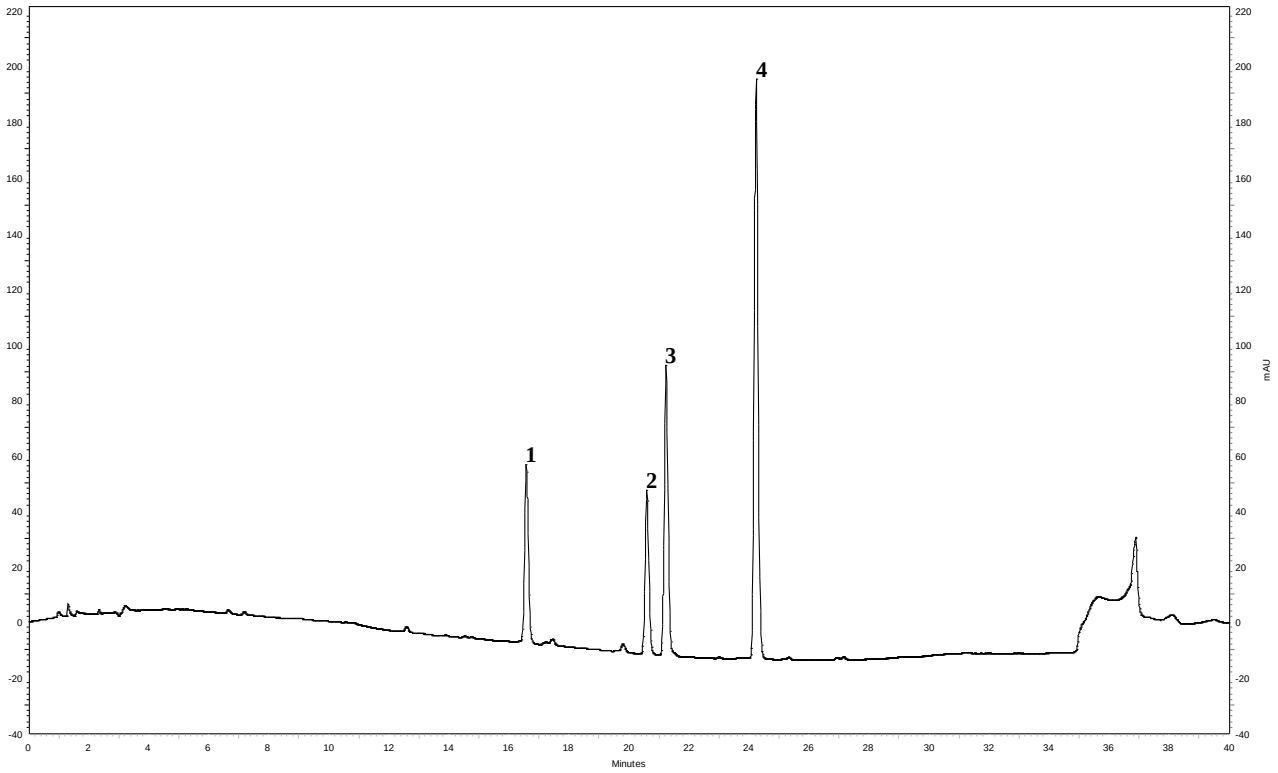
Typical chromatogram for the Identification test for Fusidic Acid Cream by Thin Layer Chromatography as published in BP 2021.



1 & 10	0.5% w/v diethanolamine fusidate
2 & 9	0.05 % w/v potassium sorbate
3 & 6 & 8	Blank (ethanol 96%)
4	Blank (water)
5 & 7	Cream 0.4 % w/v solution

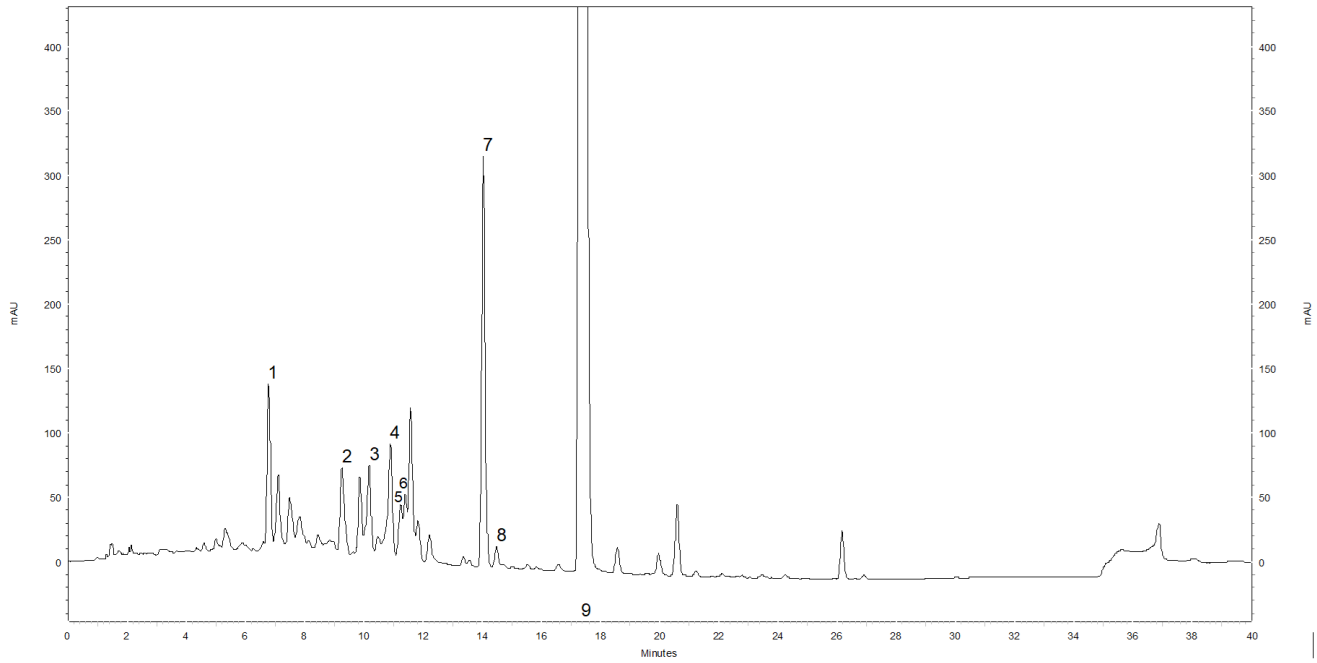
TLC plate	Merck TLC silica gel 60 F_{254} Plate, 20 cm × 20 cm
Plate preconditioning	Pre-heated at 105º for 15 minutes
Diluent	1. Ethanol (96%) for solution 1 and solution 2 2. Water for solution 3
Mobile Phase	Methanol: glacial acetic acid: cyclohexane: dichloromethane (2.5: 10: 10: 80, v/v/v/v)
Mobile 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	125 mm
Development time	36 minutes
Drying time	60 minutes in air
Visualisation	Developed plate examined under UV light (254 nm)

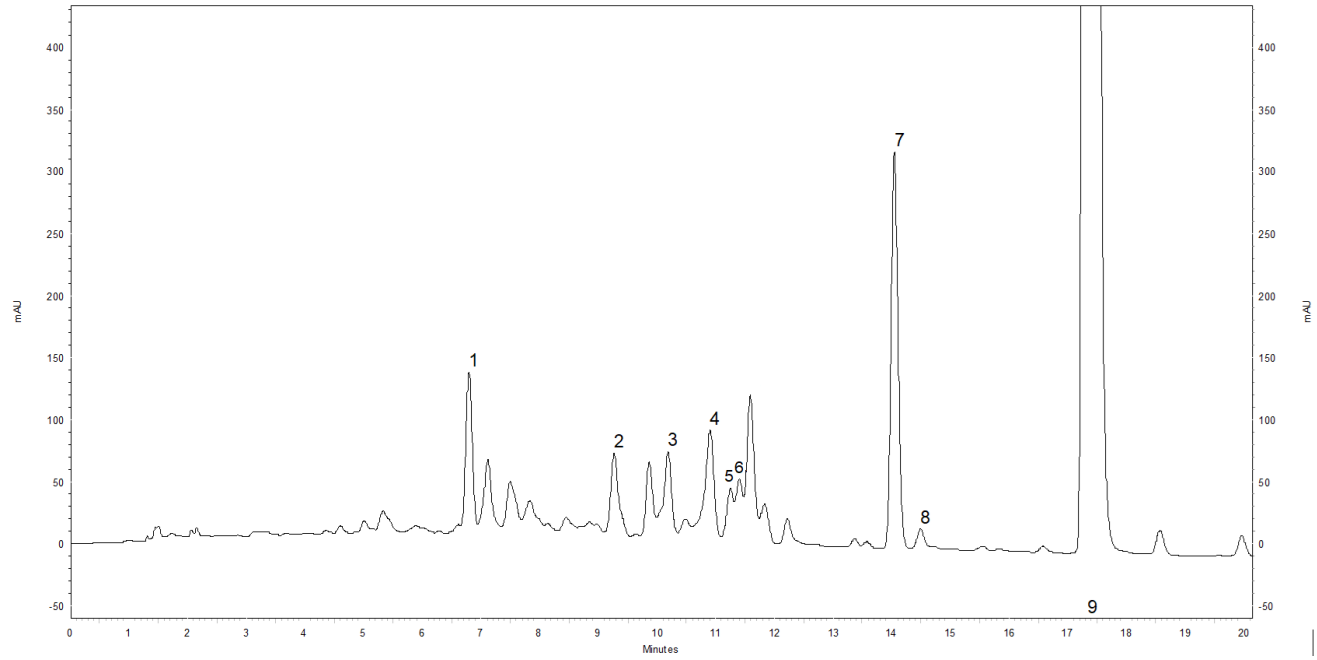
Typical chromatogram for solution (3) in the Related Substances test for Fusidic Acid Cream as published in BP 2021.



Peak ID: 1: Impurity I; 2: Impurity K; 3: Impurity L; 4: Impurity M

Typical chromatogram for solution (4) in the Related Substances test for Fusidic Acid Cream as published in BP 2021.

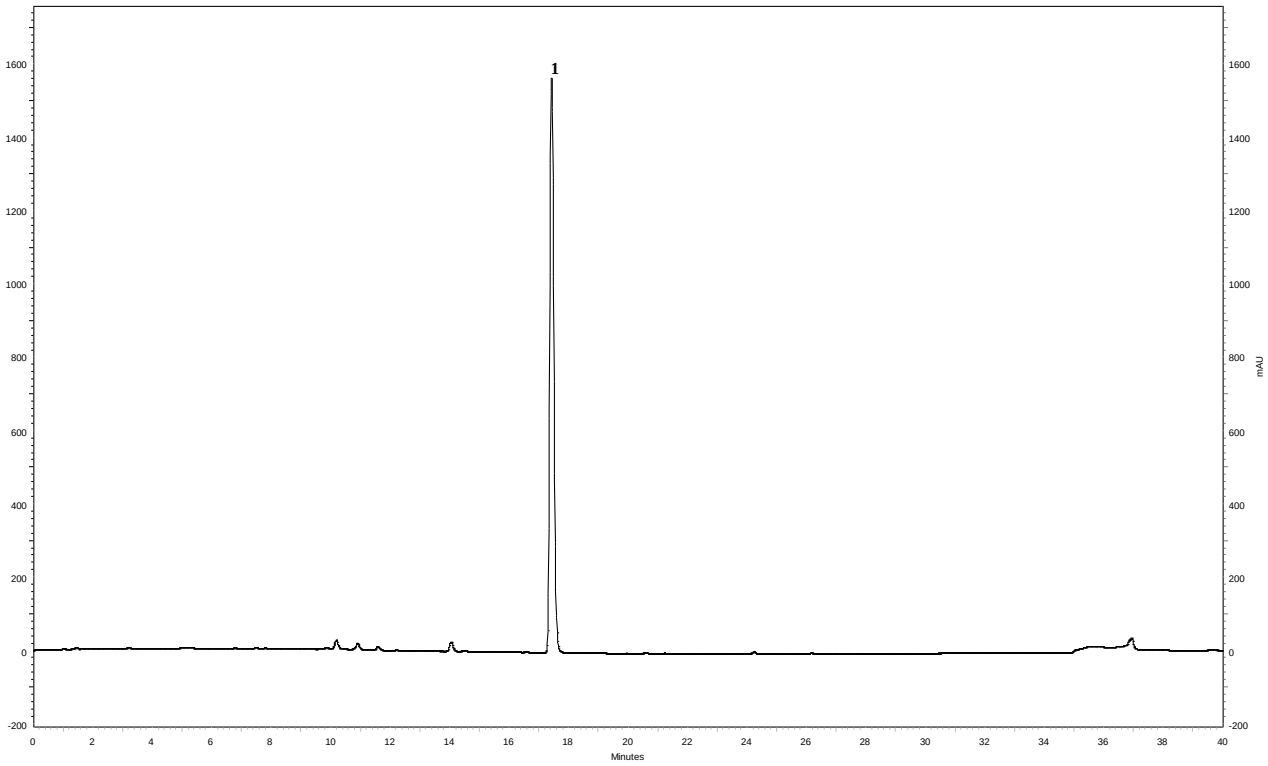




Peak ID: 1: Impurity A; 2: Impurity B; 3: Impurity C; 4: Impurity D; 5: Impurity N; 6: Impurity F; 7: Impurity G; 8: Impurity H and 9: Fusidic acid

<table>
<tr><td>Column</td><td>Waters, Symmetry C18 (150 mm x 4.6 mm, 3.5 µm)</td></tr>
<tr><td>Method Ref.</td><td>Related Substances for the Fusidic Acid Cream monograph from BP 2021</td></tr>
<tr><td>Mobile Phase A</td><td>Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile
(20: 40: 40, v/v/v)</td></tr>
<tr><td>Mobile Phase B</td><td>5 g/L solution of orthophosphoric acid: methanol: acetonitrile
(10: 20: 70, v/v/v)</td></tr>
<tr><td>Gradient</td><td><table>
<tr><th>Time (minutes)</th><th>Mobile phase A (% v/v)</th><th>Mobile phase B (% v/v)</th></tr>
<tr><td>0 - 3</td><td>100</td><td>0</td></tr>
<tr><td>3 - 28</td><td>100 - 0</td><td>0 - 100</td></tr>
<tr><td>28 - 33</td><td>0</td><td>100</td></tr>
<tr><td>33 - 34</td><td>0 - 100</td><td>100 - 0</td></tr>
<tr><td>34 - 40</td><td>100</td><td>0</td></tr>
</table></td></tr>
<tr><td>Diluent</td><td>Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile
(10: 40: 50, v/v/v)</td></tr>
<tr><td>Flow rate</td><td>1.0 mL/min</td></tr>
<tr><td>Column Temp</td><td>30 °C</td></tr>
<tr><td>Injection Volume</td><td>20 µL</td></tr>
<tr><td>Detection</td><td>235 nm</td></tr>
</table>

Typical chromatogram for solution (2) in the Assay test for Fusidic Acid Cream as published in BP 2021.



Peak ID: 1: Fusidic Acid

<table>
<tr><td>Method Ref.</td><td>Assay for the Fusidic Acid Cream monograph from BP 2021</td></tr>
<tr><td>Mobile Phase A</td><td>Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile
(20: 40: 40, v/v/v)</td></tr>
<tr><td>Mobile Phase B</td><td>5 g/L solution of orthophosphoric acid: methanol: acetonitrile
(10: 20: 70, v/v/v)</td></tr>
<tr><td>Gradient</td><td><table>
<tr><th>Time (minutes)</th><th>Mobile phase A (% v/v)</th><th>Mobile phase B (% v/v)</th></tr>
<tr><td>0 - 3</td><td>100</td><td>0</td></tr>
<tr><td>3 - 28</td><td>100 - 0</td><td>0 - 100</td></tr>
<tr><td>28 - 33</td><td>0</td><td>100</td></tr>
<tr><td>33 - 34</td><td>0 - 100</td><td>100 - 0</td></tr>
<tr><td>34 - 40</td><td>100</td><td>0</td></tr>
</table></td></tr>
<tr><td>Diluent</td><td>Methanol: 5 g/L solution of orthophosphoric acid: acetonitrile
(10: 40: 50, v/v/v)</td></tr>
<tr><td>Flow rate</td><td>1.0 mL/min</td></tr>
<tr><td>Column Temp</td><td>30 °C</td></tr>
<tr><td>Injection Volume</td><td>20 µL</td></tr>
<tr><td>Detection</td><td>235 nm</td></tr>
</table>