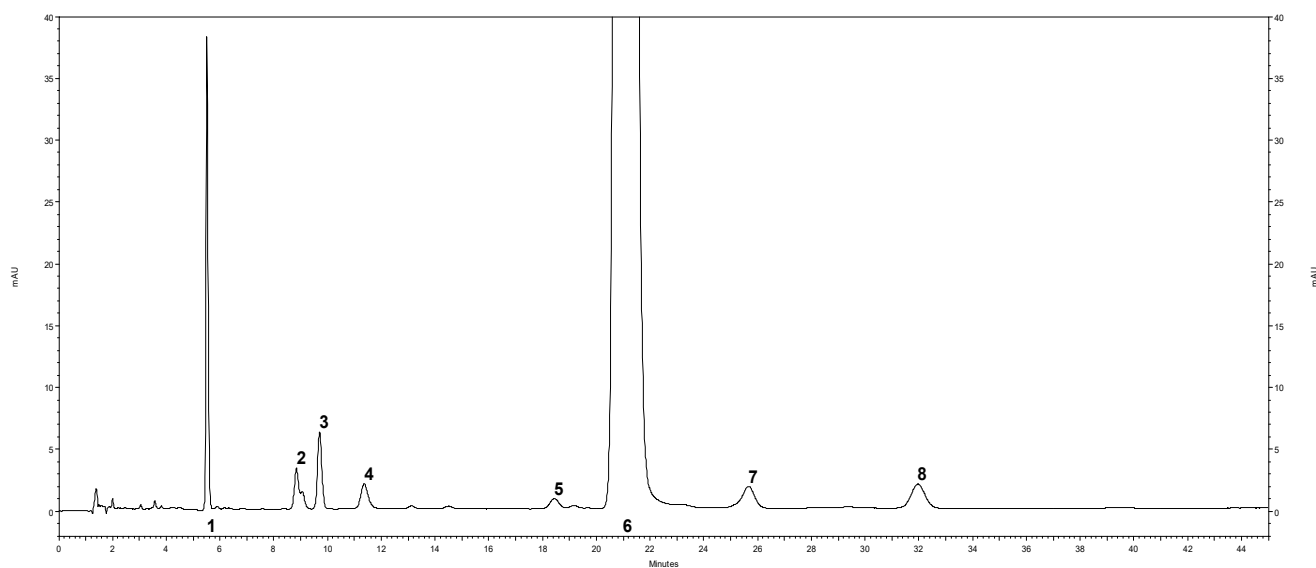




Mycophenolate Mofetil Capsules – BP 2021

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 illustrating the elution of impurity peaks in the Related Substances test for Mycophenolate Mofetil Capsules as published in BP 2021.

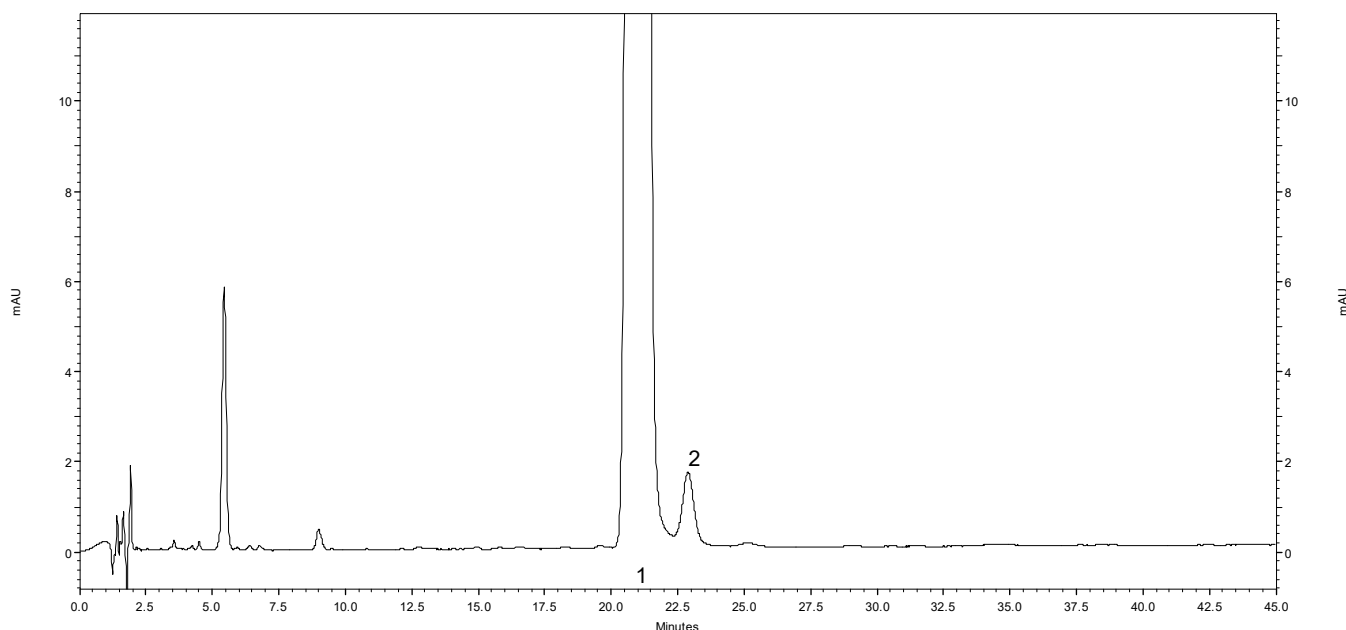


Peak ID: 1: Impurity F; 2: Impurity A; 3: Impurity H; 4: Impurity G; 5: Impurity B; 6: Mycophenolate Mofetil; 7: Impurity D; 8: Impurity E

Note: The chromatogram was produced from a 0.12% w/v mycophenolate mofetil for peak identification EPCRS solution.



Typical chromatogram illustrating the elution of peaks due to mycophenolate mofetil and impurity C, in the Related Substances test for Mycophenolate Mofetil Capsules as published in BP 2021.

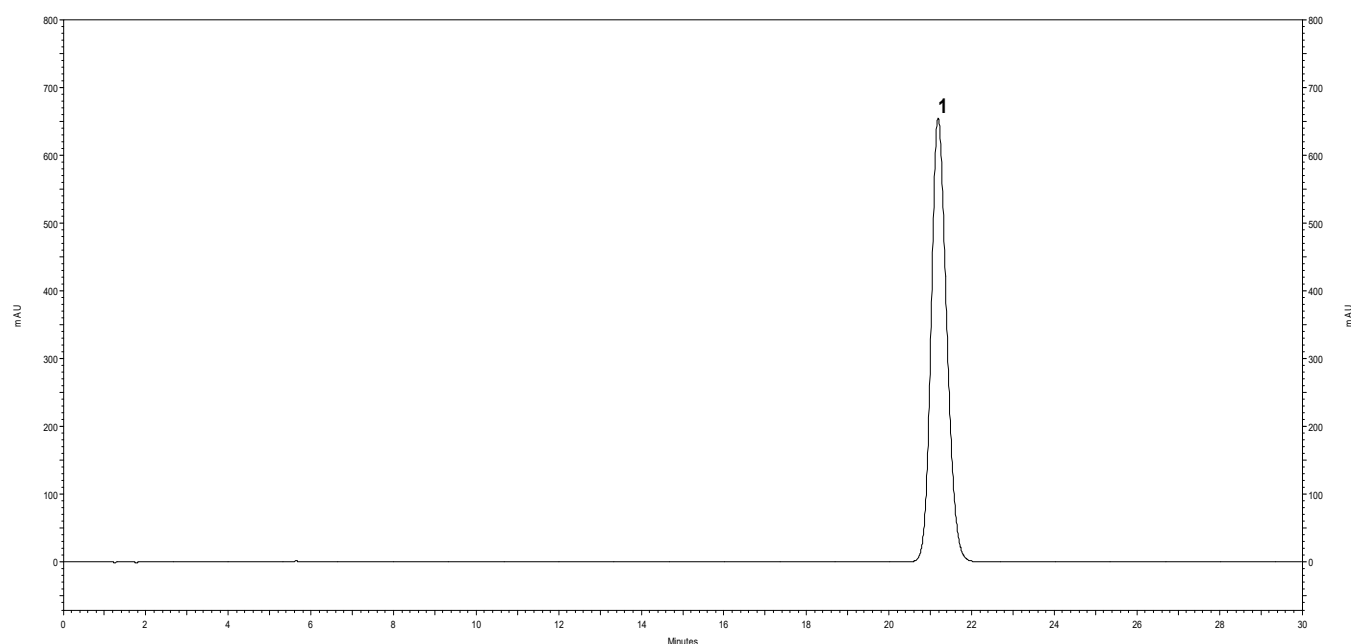


Peak ID: 1: Mycophenolate Mofetil; 2: Impurity C

Column	: Zorbax, SB-C8 (250 mm x 4.6 mm, 5 µm)
Method Ref.	: Related Substances for the Mycophenolate Mofetil Capsules monograph from BP 2021
Mobile Phase	: Buffer: acetonitrile: water (20: 35: 45, v/v/v)
Buffer (Mobile phase)	: 1.0 % v/v triethylamine and 0.5 % v/v orthophosphoric acid adjusted to pH 5.4 with 2 M potassium hydroxide
Diluent	: Acetonitrile: buffer (35: 65, v/v)
Buffer (Diluent)	: 7.5 g of ammonium dihydrogen orthophosphate were dissolved in 1300 mL water then 0.55 mL orthophosphoric acid was added and mixed. The pH of the solution was 3.0.
Flow rate	: 1.5 mL/min
Column Temp	: 45 °C
Injection Volume	: 10 µL
Detection	: 249 nm



Typical chromatogram for solution (2) in the Assay test for Mycophenolate Mofetil Capsules as published in BP 2021.



Peak ID: 1: Mycophenolate Mofetil

Column	: Zorbax, SB-C8 (250 mm x 4.6 mm, 5 μ m)
Method Ref.	: Assay for the Mycophenolate Mofetil Capsules monograph from BP 2021
Mobile Phase	: Buffer: acetonitrile: water (20: 35: 45, v/v/v)
Buffer	: 1.0 % v/v triethylamine and 0.5 % v/v orthophosphoric acid adjusted to pH 5.4
(Mobile phase)	: with 2 M potassium hydroxide
Diluent	: Acetonitrile: buffer (35: 65, v/v)
Buffer (Diluent)	: 7.5 g of ammonium dihydrogen orthophosphate were dissolved in 1300 mL water then 0.55 mL orthophosphoric acid was added and mixed. The pH of the solution was 3.0.
Flow rate	: 1.5 mL/min
Column Temp	: 45 °C
Injection Volume	: 10 μ L
Detection	: 249 nm