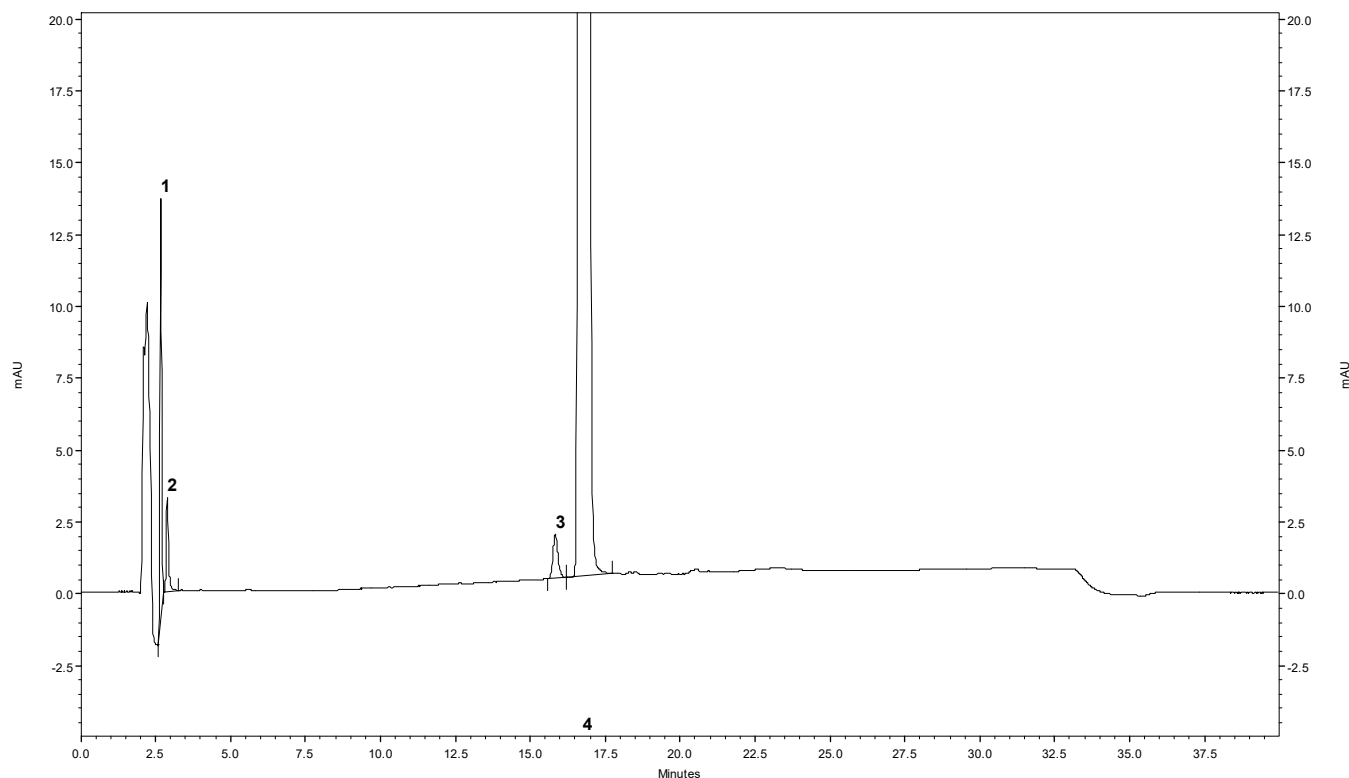




Capecitabine Tablets – BP 2020

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 solution (3) in the Dissolution test for Capecitabine Tablets as published in BP 2020.



Peak ID: 1: Impurity A; 2: Impurity B; 3: Impurity D; 4: Capecitabine

Column : Agilent Zorbax, Eclipse XDB-C18 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Dissolution for the Capecitabine Tablets monograph from BP 2020
Mobile Phase A : Acetonitrile: methanol : 0.1% glacial acetic acid (5: 35: 60, v/v/v)
Mobile Phase B : Acetonitrile: 0.1 % glacial acetic acid : methanol (5: 15: 80, v/v/v)
Diluent : 2.8 % w/v disodium hydrogen phosphate and 1.15 % w/v potassium dihydrogen phosphate in water.

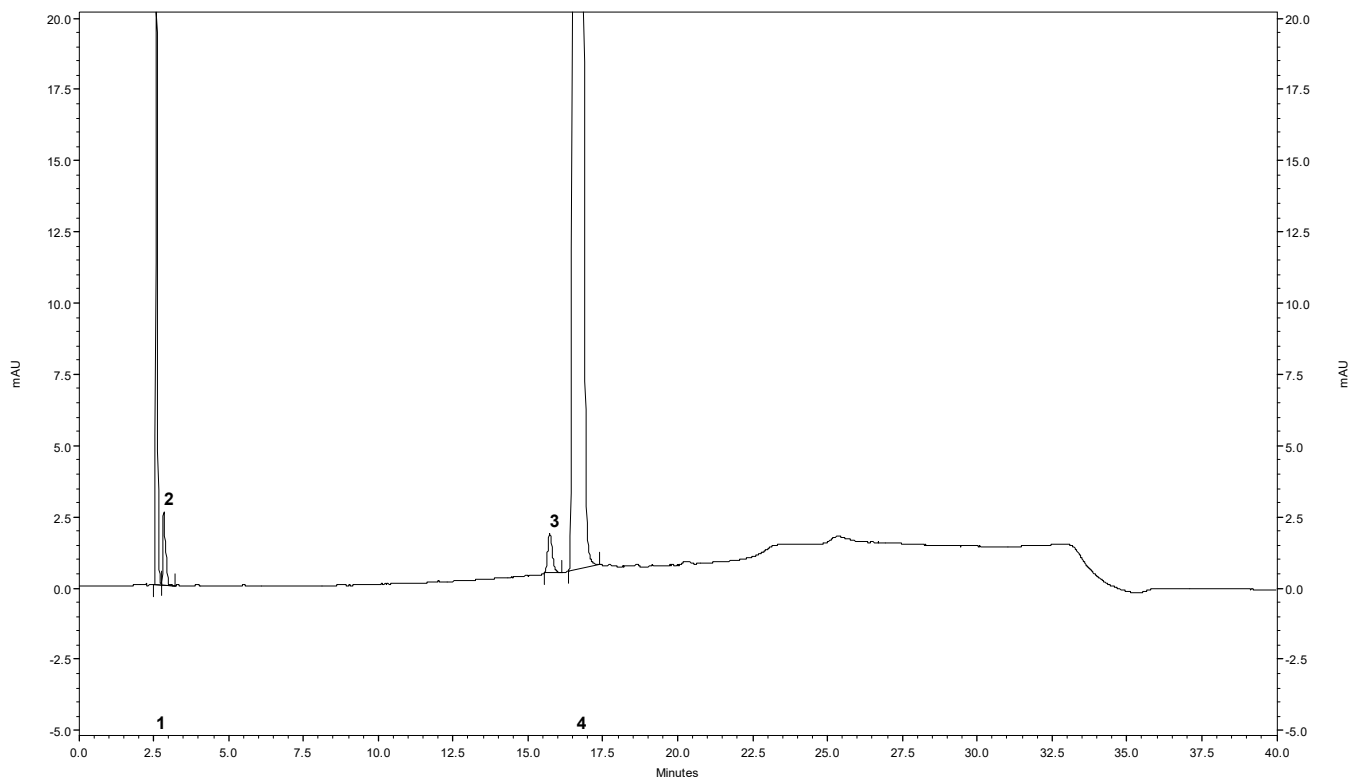
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-5	100	0
5-20	100-49	0-51
20-30	49	51
30-32	49-100	51-0
32-40	100	0

Flow rate : 1.0 mL/min
Column Temp : 40 °C
Injection Volume : 40 µL
Detection : 250 nm



Typical chromatogram for solution (3) in the Related Substances test for Capecitabine Tablets as published in BP 2020.



Peak ID: 1: Impurity A; 2: Impurity B; 3: Impurity D; 4: Capecitabine

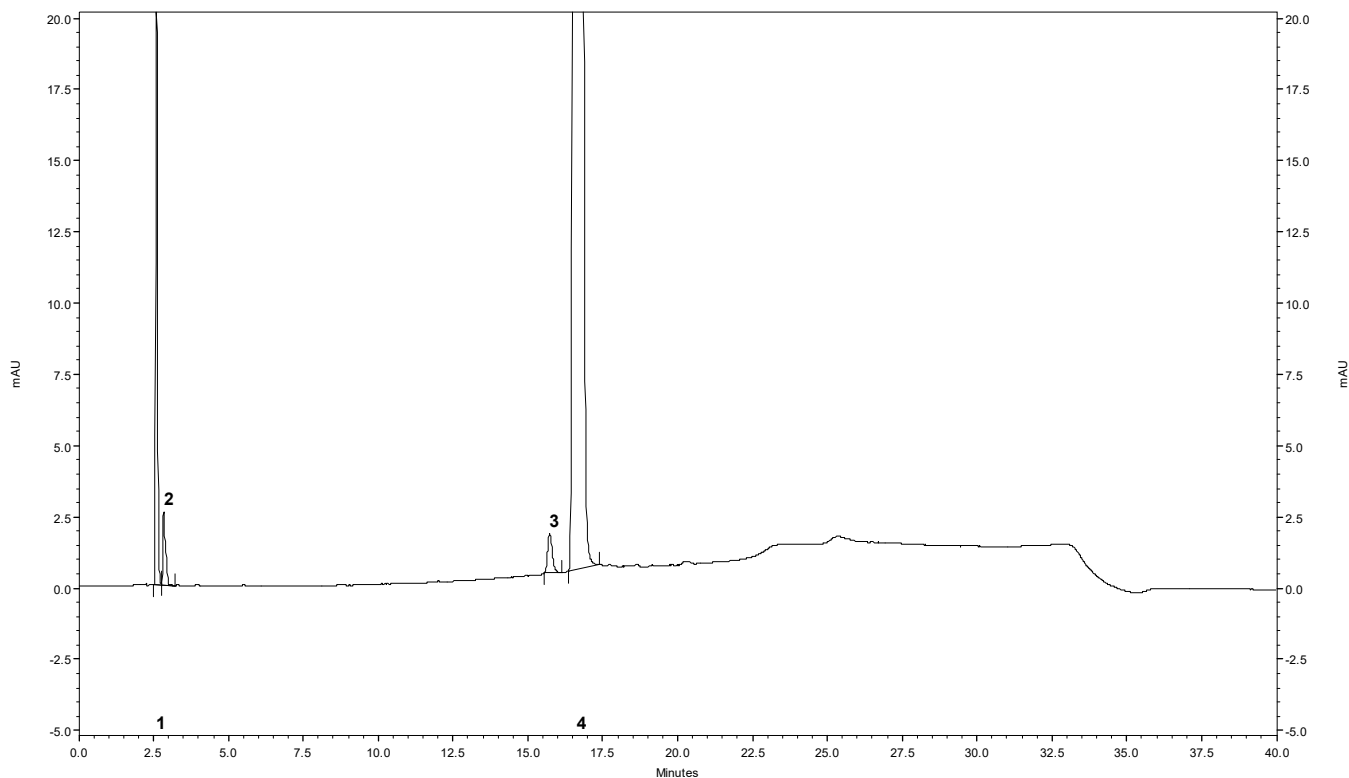
Column : Agilent Zorbax, Eclipse XDB-C18 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Related Substances for the Capecitabine Tablets monograph from BP 2020
Mobile Phase A : Acetonitrile: methanol : acetic acid 0.1% (v/v) (5: 35: 60, v/v/v)
Mobile Phase B : Acetonitrile: methanol: 0.1 % v/v glacial acetic acid (5:80:15, v/v/v)
Diluent : Acetonitrile: methanol: water (5: 35: 60, v/v/v)
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-5	100	0
5-20	100-49	0-51
20-30	49	51
30-32	49-100	51-0
32-40	100	0

Flow rate : 1.0 mL/min
Column Temp : 40 °C
Injection Volume : 10 µL
Detection : 250 nm



Typical chromatogram for solution (3) in the Assay test for Capecitabine Tablets as published in BP 2020.



Peak ID: 1: Impurity A; 2: Impurity B; 3: Impurity D; 4: Capecitabine

Column : Agilent Zorbax, Eclipse XDB-C18 (250 mm x 4.6 mm, 5 µm)
Method Ref. : Assay for the Capecitabine Tablets monograph from BP 2020
Mobile Phase A : Acetonitrile: Methanol : Acetic acid 0.1% (v/v) (5: 35: 60, v/v/v)
Mobile Phase B : Acetonitrile: methanol: 0.1 % v/v glacial acetic acid (5:80:15, v/v/v)
Diluent : Acetonitrile: methanol: water (5: 35: 60, v/v/v)
Gradient :

Time (min)	Mobile Phase A (%)	Mobile Phase B (%)
0-5	100	0
5-20	100-49	0-51
20-30	49	51
30-32	49-100	51-0
32-40	100	0

Flow rate : 1.0 mL/min
Column Temp : 40 °C
Injection Volume : 10 µL
Detection : 250 nm