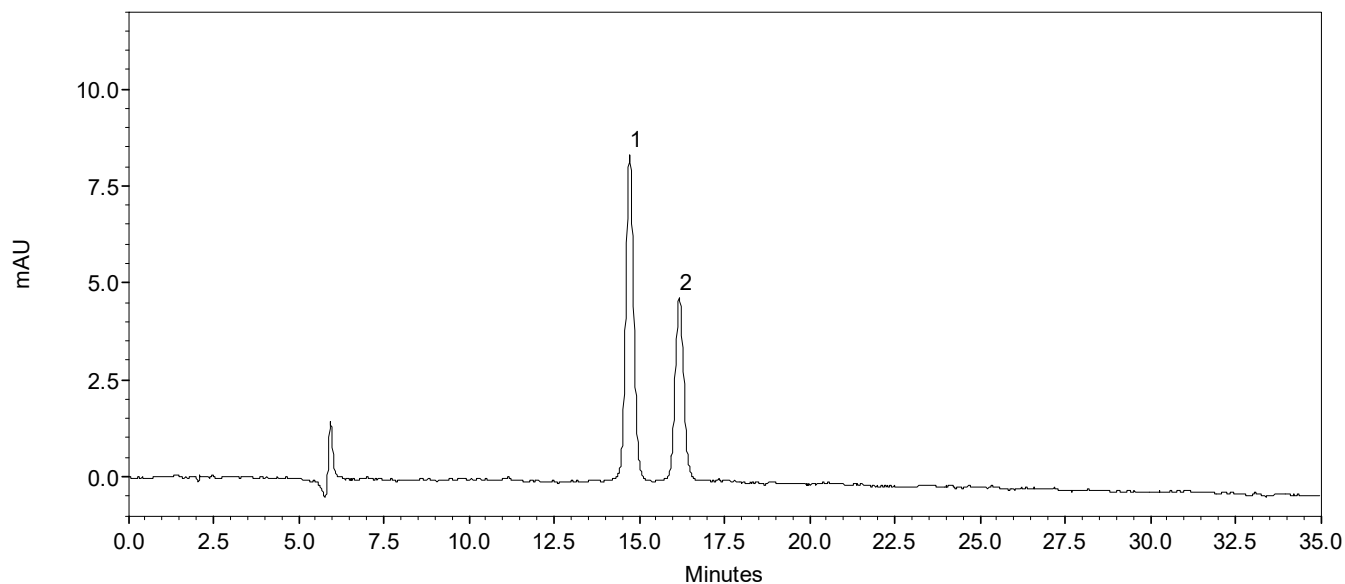




## Risedronate Sodium Tablets – BP 2020

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 Related Substances test A for Risedronate Sodium Tablets as published in BP 2020.

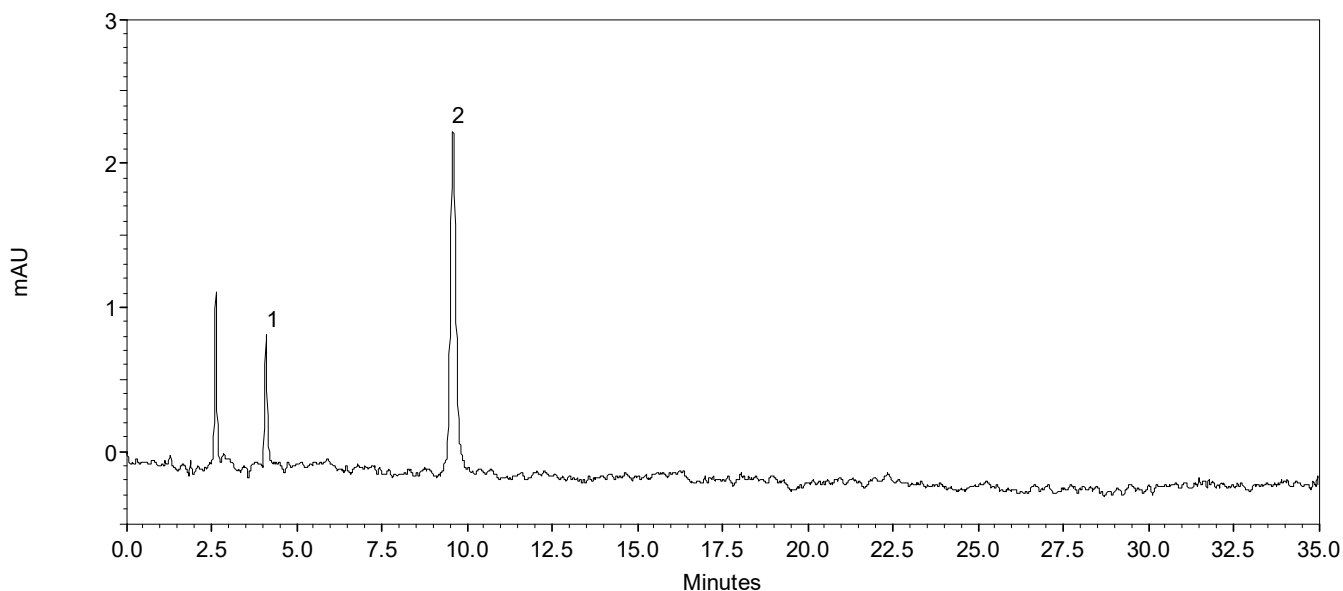


Peak ID: 1: Impurity E; 2: Risedronate

Column	: Phenomenex, Luna C18 100 (150 mm x 4.6 mm, 3 µm)
Method Ref.	: Related Substances A for the Risedronate Sodium Tablets monograph from BP 2020
Mobile Phase	: Acetonitrile : solution A (10:90, v/v)
Solution A	: 0.041% w/v sodium edetate, 0.17% w/v dipotassium hydrogen phosphate and 0.17% w/v tetrabutylammonium dihydrogen phosphate solution adjusted to pH 7.5 with 1M sodium hydroxide.
Diluent	: Mobile phase
Flow rate	: 1.0 mL/min
Column Temp	: 40 °C
Injection Volume	: 20 µL
Detection	: 263 nm



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

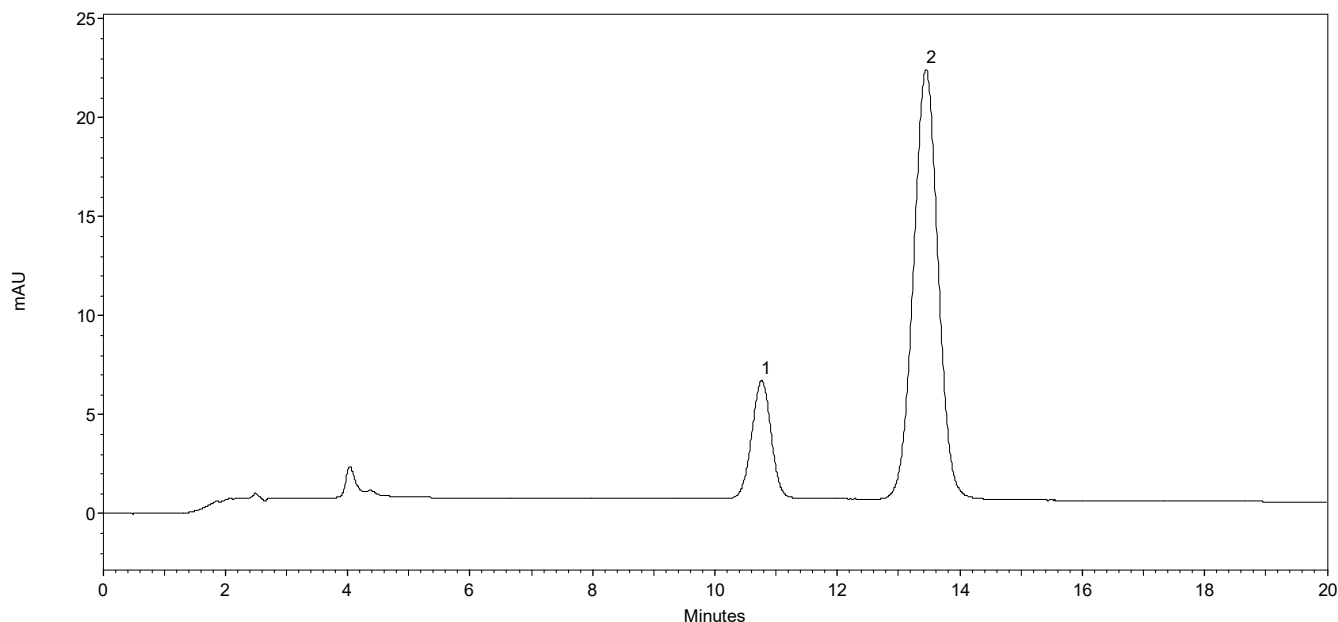


Peak ID: 1: Risedronate; 2: Impurity A

Column : Phenomenex, Luna C18 100 (150 mm x 4.6 mm, 3  $\mu$ m)  
Method Ref. : Related Substances B for the Risedronate Sodium Tablets monograph from BP 2020  
Mobile Phase : Acetonitrile : solution A (25:75, v/v)  
Solution A : 0.041% w/v sodium edetate, 0.17% w/v dipotassium hydrogen phosphate and 0.17% w/v tetrabutylammonium dihydrogen phosphate solution adjusted to pH 7.5 with 1M sodium hydroxide.  
Diluent : Mobile phase  
Flow rate : 1.0 mL/min  
Column Temp : 40  $^{\circ}$ C  
Injection Volume : 10  $\mu$ L  
Detection : 263 nm



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



Peak ID: 1: Impurity E; 2: Risedronate

Column : Dionex, IonPack HPIC AS-7, (250 mm x 4.0 mm, 10 µm)  
Method Ref. : Assay for the Risedronate Sodium Tablets monograph from BP 2020  
Mobile Phase : 0.18% w/v ethylenediaminetetraacetic acid disodium salt dihydrate solution, adjusted to pH 9.5 with 1 M sodium hydroxide solution  
Diluent : Mobile phase  
Flow rate : 0.8 mL/min  
Column Temp : 25 °C  
Injection Volume : 20 µL  
Detection : 263 nm