Sildenafil Tablets – BP 2018

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.


1 Blank
2 0.25 % w/v sildenafil citrate standard
3 System suitability
4 – 12 Tablets 0.25 % w/v solution
13 0.25 % w/v sildenafil citrate standard
14 System suitability
TLC plate: Merck TLC silica gel 60 F254 Plate, 10 cm × 20 cm, h x w
Plate preconditioning: N/A
Diluent: Methanol
Mobile Phase: Methanol: ethyl acetate (40 : 80, v/v)
Mobile Phase volume: 120 mL
Band application: 3 mm band size with a spotting volume of 10 µL
Chamber saturation: Minimum 60 minutes at room temperature
Development: 8 cm
Development time: 9 minutes
Drying time: 2 minutes under a warm current of air
Derivatisation: N/A
Visualisation: UV light (254 nm)
Typical chromatogram for solution (3) in the Related Substances test for Sildenafil Tablets as published in BP 2018.

Peak ID: 1. Sildenafil Citrate, 2. Impurity B

Column : Waters, Symmetry C18 (150 mm x 3.9 mm x 5 µm)
Method Ref. : Related substances for the Sildenafil Tablets Monograph from BP 2018
Mobile Phase : 0.7 % v/v of Triethylamine pH 3.0: Acetonitrile: Methanol (58: 17: 25, v/v/v)
Diluent for solution (3) : Formic acid: Hydrogen peroxide (1:2, v/v): Mobile phase (1: 250, v/v)
Diluent for solution (1) : 90 % Acetonitrile: Mobile phase (50: 50, v/v)
Flow Rate : 1.0 mL/min
Column Temp : 30 °C
Injection Volume : 20 µL
Detection : UV, 290 nm
Typical chromatogram for solution (3) in the Assay test for Sildenafil Tablets as published in BP 2018.

Peak ID: 1. Sildenafil Citrate, 2. Impurity B

Column: Waters, Symmetry C18 (150 mm x 3.9 mm x 5 µm)
Method Ref.: Related substances for the Sildenafil Tablets Monograph from BP 2018
Mobile Phase: 0.7% v/v of Triethylamine pH 3.0: Acetonitrile: Methanol (58: 17: 25, v/v/v)
Diluent for solution (1): 90% Acetonitrile: Mobile phase (1: 50, v/v)
Flow Rate: 1.0 mL/min
Column Temp: 30 °C
Injection Volume: 20 µL
Detection: UV, 290 nm