



BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE
INFORMATION LEAFLET

GLIMEPIRIDE FOR SYSTEM SUITABILITY
CATALOGUE NUMBER 1141
CURRENT BATCH: 3670

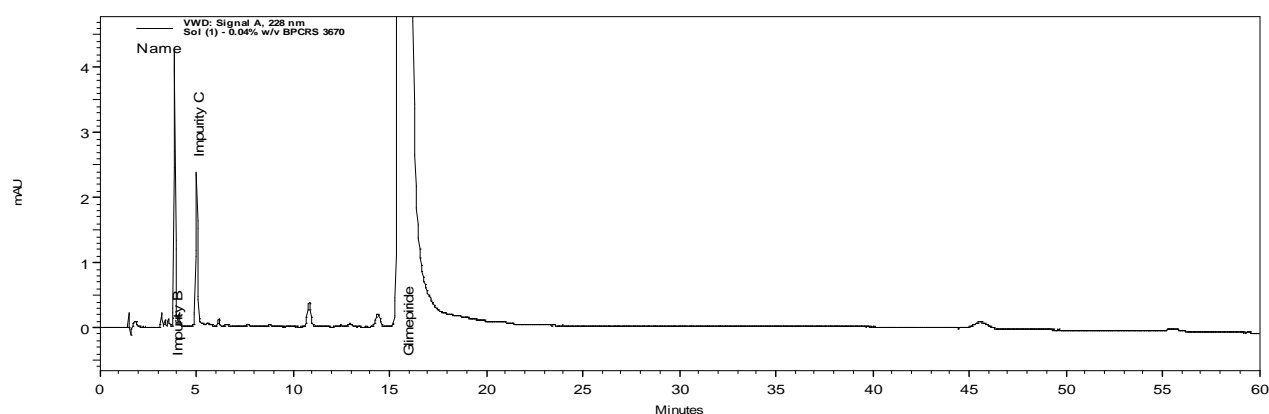
Declared Content

No declared content figure is given as the standard is not used for assay purposes.

Use

This British Pharmacopoeia Chemical Reference Substance (BPCRS) is to be used as directed in the monograph(s) of the British Pharmacopoeia and is not intended for any other purpose.

Reference Chromatogram (Related Substances)



Related Substances

Column: Supersphere RP18, 4 µm (250 x 4.0 mm)



Mobile Phase: 50 volumes (0.1% w/v of sodium dihydrogen orthophosphate dihydrate adjusted to pH 2.5) and 50 volumes of acetonitrile

Diluent: 1 volume of water and 4 volumes of acetonitrile

Detection Wavelength: 228 nm

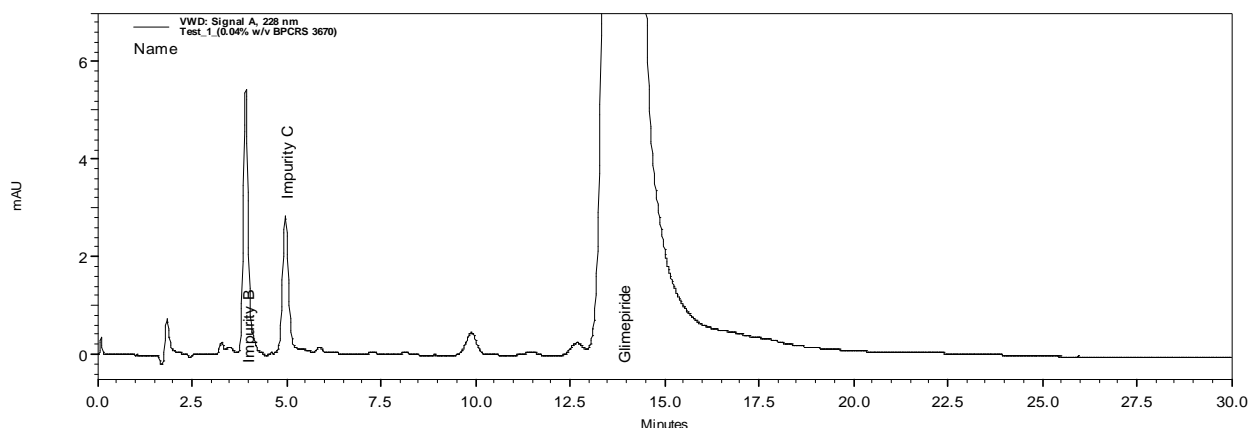
Flow rate: 1.0 mL/min

Column temperature: 25 °C

Auto sampler Temperature: 12 °C

Injection Volume: 10 µL

Reference Chromatogram (Uniformity of Content/Assay)



Uniformity of Content/Assay

Column: Lichrosphere RP18-5, 5 µm (100 x 4.6 mm)

Mobile Phase: 50 volumes of 0.1% w/v of sodium dihydrogen orthophosphate dihydrate and 50 volumes of acetonitrile, the pH adjusted to 2.5.

Diluent: 1 volume of water and 4 volumes of acetonitrile

Detection Wavelength: 228 nm

Flow rate: 0.5 mL/min

Column temperature: 25 °C

Auto sampler Temperature: 12 °C

Injection Volume: 10 µL

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Correction to the Uniformity of content and Assay tests in the Glimepiride Tablets BP

Monograph

Prepare solution (2) and (3) as follows:

(2) 0.01% w/v of glimepiride BPCRS in 1 volume of water and 4 volumes of acetonitrile.

(3) 0.04% w/v of glimepiride for system suitability in 1 volume of water and 4 volumes of acetonitrile.

Additional Information

For additional information on BPCRS please visit the British Pharmacopoeia website.

<https://www.pharmacopoeia.com>