British Pharmacopoeia Commission Secretariat
MHRA, 10 South Colonnade, Canary Wharf
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British Pharmacopoeia Commission Laboratory
10 Priestley Road, Surrey Research Park
Guildford, GU2 7XY
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www.pharmacopoeia.com

BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE
INFORMATION LEAFLET

AMISULPRIDE FOR SYSTEM SUITABILITY
CATALOGUE NUMBER 1143
CURRENT BATCH: 3681

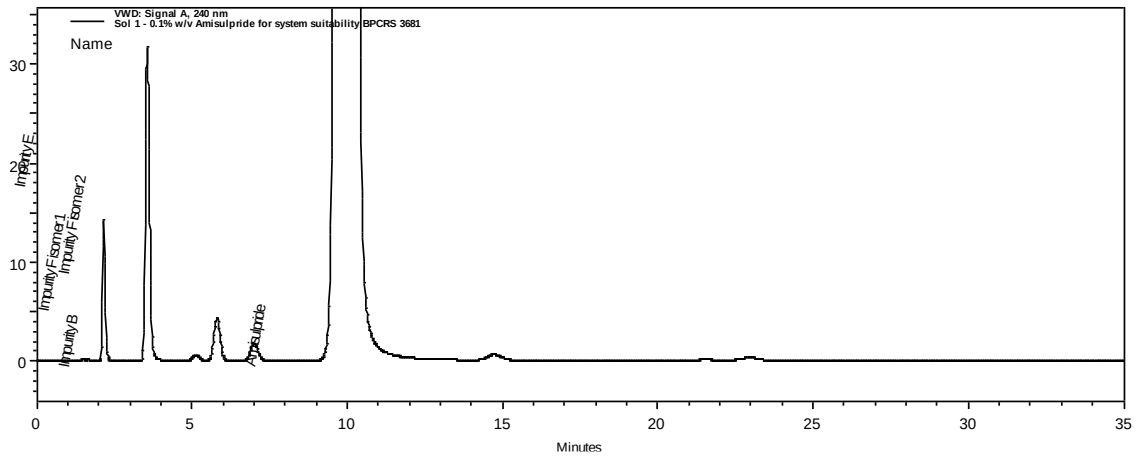
Declared Content

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/Assay)



Related Substances

Column: XTerra RP 8, 5 µm (150 x 4.6 mm)

Mobile Phase: 20 volumes of methanol and 80 volumes (0.68% w/v of potassium dihydrogen orthophosphate adjusted to pH 8.0 with 6M ammonia).

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Diluent: Mobile phase

Detection Wavelength: 240 nm

Flow rate: 1.0 mL/min

Column temperature: 30 °C

Injection Volume: 20 µL

Note:

When the chromatograms are recorded under the prescribed conditions the retention times relative to amisulpride (retention time about 10 minutes) are impurity E, about 0.2; impurity B, about 0.4; impurity F isomer 1, about 0.5 and impurity F isomer 2, about 0.6.

Related Substances and Assay for Amisulpride Tablets and Amisulpride Oral Solution.

System Suitability

The test is not valid unless, in the chromatogram obtained with solution (3):

the resolution between the peaks due to impurity E and impurity B is at least 2.0;

the resolution between the peaks due to impurity F isomer 1 and impurity F isomer 2 is at least 1.5.

Limits

Identify any peaks in the chromatogram obtained with solution (1) corresponding to impurity B and impurity F using the chromatogram obtained with solution (3) and the chromatogram supplied with amisulpride for system suitability BPCRS.

Multiply the area of any peak corresponding to impurity B by a correction factor of 0.28.

Combine the areas of the 2 isomer peaks corresponding to impurity F and multiply by a correction factor of 1.45.

Additional Information

When a British Pharmacopoeia Chemical Reference Substance (BPCRS) is directed to be used in an Assay or quantitative determination described in a monograph of the British Pharmacopoeia or the British Pharmacopoeia (Veterinary) the following statements apply.

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Where a “declared content” is required the content stated on this leaflet is of the current batch of the BPCRS and is quoted on an ‘as is’ basis. This figure is to be used in calculating the results of the assay.

It is the responsibility of the analyst using any BPCRS for quantitative purposes to assure himself or herself that the batch number on the label corresponds with the batch number given on this leaflet.

For additional information on BPCRS please visit the British Pharmacopoeia website.
https://www.pharmacopoeia.com