

British Pharmacopoeia Commission Secretariat
MHRA, 10 South Colonnade, Canary Wharf
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United Kingdom

British Pharmacopoeia Commission Laboratory
10 Priestley Road, Surrey Research Park
Guildford, GU2 7XY
United Kingdom

www.pharmacopoeia.com

BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE INFORMATION LEAFLET

TAMSULOSIN HYDROCHLORIDE IMPURITY STANDARD CATALOGUE NUMBER 877 CURRENT BATCH: 4531

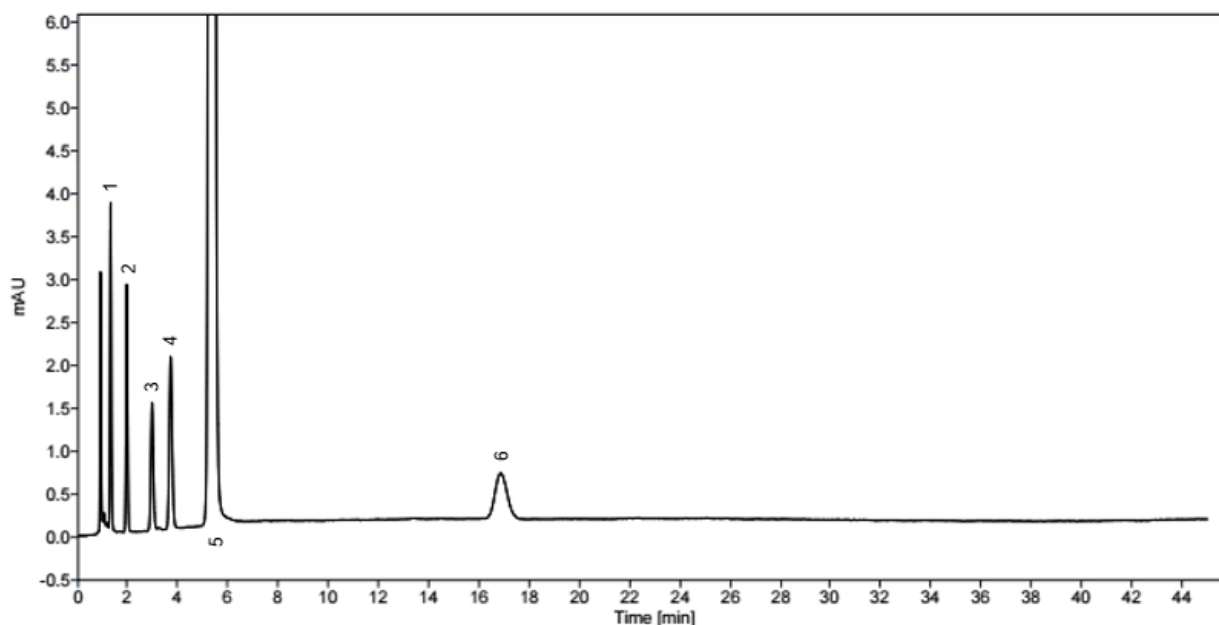
Declared Content

99.9 % of $C_{20}H_{28}N_2O_5S \cdot HCl$

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(s)



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1. 5-[(2R)-2-aminopropyl]-2-methoxybenzenesulfonamide (Tamsulosin Impurity B)
2. 3-(3'-sulfonamide-4-methoxyphenyl)propan-2-one
3. 2-(phenylethylamino)-3-(3'-sulfonamide-4-methoxyphenyl)propane)
4. 2-methoxy-5-[(2R)-2-[[2-(2-methoxyphenoxy)ethyl]amino]propyl] benzenesulfonamide (Tamsulosin Impurity D)
5. Tamsulosin
6. (2R)-N-[2-(2-ethoxyphenoxy)ethyl]-1-(4-methoxyphenyl)propan-2-amine (Tamsulosin Impurity H)

Related Substances

Column: Phenomenex Luna C18 100Å, 5 µm (150 mm × 4.6 mm)

Mobile Phase: 300 volumes of acetonitrile mixed with 700 volumes of water containing 0.44% v/v perchloric acid and 0.15% w/v sodium hydroxide previously adjusted to pH 2.0 with 1 M sodium hydroxide.

Detection Wavelength: 225 nm

Flow rate: 1.5 ml/min

Column temperature: 40 °C

Injection Volume: 20 µl

Additional Information

Note: a correction factor of 1.4 should be applied to calculate the content of 2-(phenylethylamino)-3-(3'-sulfonamide-4-methoxyphenyl)propane) in Prolonged-release Tamsulosin Capsules.

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>