



**BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE  
INFORMATION LEAFLET**

**TAMSULOSIN HYDROCHLORIDE IMPURITY STANDARD  
CATALOGUE NUMBER 877  
CURRENT BATCH: 3189**

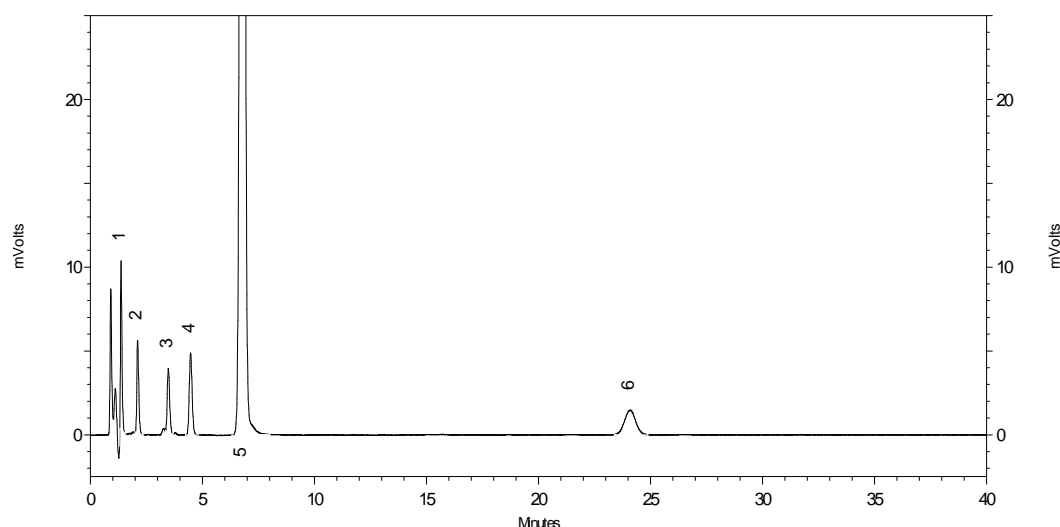
**Declared Content**

None given.

**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)**



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

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# British Pharmacopoeia

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4. 2-methoxy-5-[(2*R*)-2-[[2-(2-methoxyphenoxy)ethyl]amino]propyl] benzenesulfonamide (Tamsulosin Impurity D)
5. Tamsulosin
6. (2*R*)-*N*-[2-(2-ethoxyphenoxy)ethyl]-1-(4-methoxyphenyl)propan-2-amine (Tamsulosin Impurity H)

**Additional Information**

This BPCRS is issued only for the purpose of validation of the Related substances test described in the British Pharmacopoeia for the Prolonged-release Tamsulosin Capsules monograph.

The reference chromatogram overleaf has been prepared using a solution containing 0.0016% w/v Tamsulosin Hydrochloride Impurity Standard BPCRS in mobile phase, using the following chromatographic conditions:

**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

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.

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