

British Pharmacopoeia Commission Secretariat MHRA, 10 South Colonnade, Canary Wharf London, E14 4PU 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

2-[4-[(7-CHLORO-4-QUINOLINYL)AMINO]PENTYL]AMINO ETHANOL CATALOGUE NUMBER 1101 CURRENT BATCH: 4393

Declared Content

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

<u>Use</u>

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)

None given.

Additional Information

This BPCRS is the 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol sulfate. The following corrections take into account the purity (70.7%) of the current batch of this BPCRS.

• Solution (3) in the Related Substances test for the Hydroxychloroquine Tablets monograph (0.00004% w/v of 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol BPCRS). Prepare solution (4) with a concentration of 0.000057% w/v of 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol BPCRS. The impurity should be calculated using the sum of the area of the two peaks observed for 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol BPCRS.



British Pharmacopoeia Commission Secretariat MHRA, 10 South Colonnade, Canary Wharf London, E14 4PU United Kingdom British Pharmacopoeia Commission Laboratory 10 Priestley Road, Surrey Research Park Guildford, GU2 7XY United Kingdom

www.pharmacopoeia.com



• Solution (4) in the Related Substances test for the Hydroxychloroquine Tablets monograph (0.0001% w/v of Hydroxychloroquine sulfate BPCRS and 0.0001% w/v of 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol BPCRS). Prepare solution (4) with a concentration of 0.00014% w/v of 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol BPCRS. The resolution should be calculated between 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol pentyl] amin



British Pharmacopoeia Commission Secretariat MHRA, 10 South Colonnade, Canary Wharf London, E14 4PU United Kingdom

www.pharmacopoeia.com

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



The above chromatograms were obtained using the following conditions under the Related Substances test for the Hydroxychloroquine Tablets monograph:

Column: Inertsil ODS3 C18, 5 µm (250 mm x 4.6 mm)

Mobile Phase:

Mobile phase A: 0.2 volumes of orthophosphoric acid, 10 volumes of acetonitrile and 90 volumes of water.

Mobile phase B: 0.1 volumes of orthophosphoric acid, 20 volumes of water and 80 volumes of acetonitrile.



British Pharmacopoeia Commission Secretariat MHRA, 10 South Colonnade, Canary Wharf London, E14 4PU United Kingdom British Pharmacopoeia Commission Laboratory 10 Priestley Road, Surrey Research Park Guildford, GU2 7XY United Kingdom

www.pharmacopoeia.com

Gradient:

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-2	100	0	isocratic
2-10	100→85	0→15	linear gradient
10-18	85→100	15→0	linear gradient
18-25	100	0	isocratic

Detection Wavelength: 220 nm Flow rate: 1.0 mL/min Column temperature: 35 °C

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.

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. <u>https://www.pharmacopoeia.com</u>