British Pharmacopoeia Commission Secretariat
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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

2-[4-[(7-CHLORO-4-QUINOLINYL)AMINO]PENTYL]AMINO ETHANOL SULFATE

CATALOGUE NUMBER 1101

CURRENT BATCH: 4909

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(s)

None given.

Additional Information

The following should be considered for the current batch of this BPCRS.

- For 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 sulfate 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 sulfate BPCRS.

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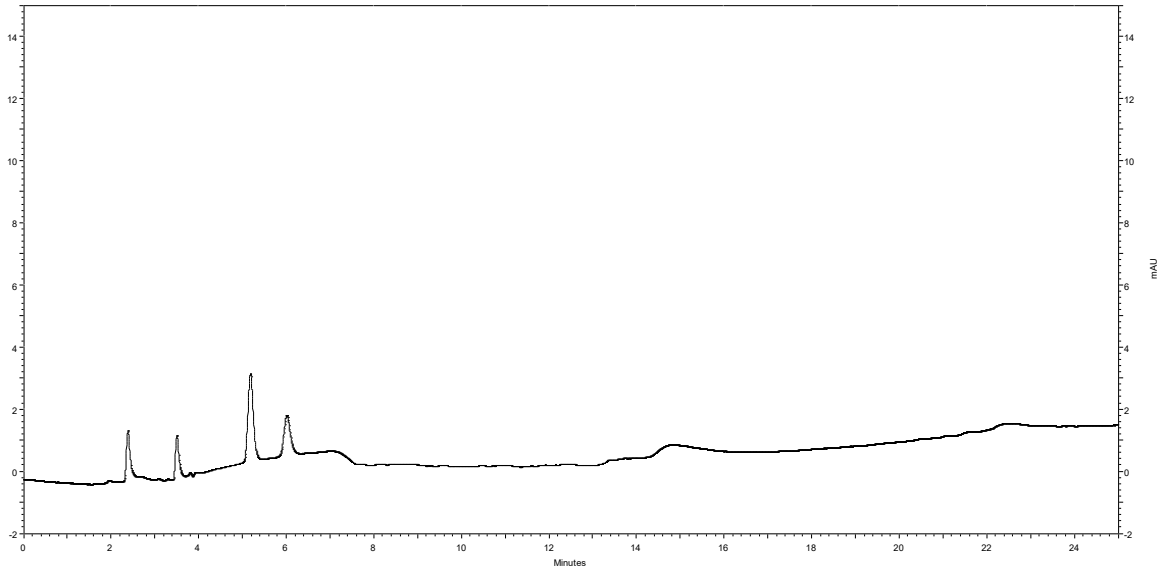
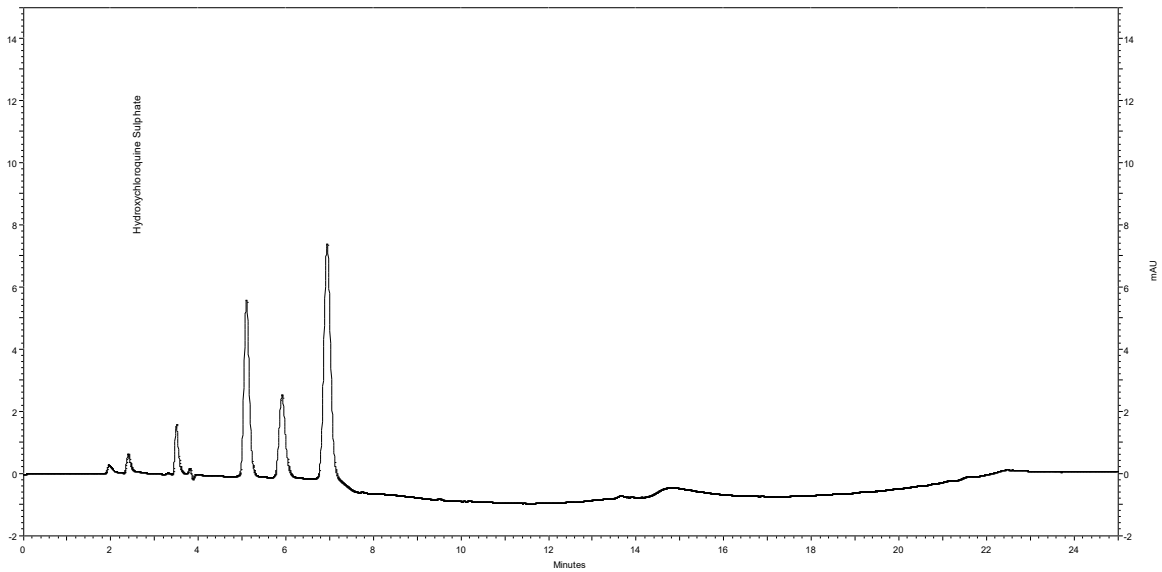


- For solution (4) in the Related Substances test for the Hydroxychloroquine Tablets monograph (0.0001% w/v of Hydroxychloroquine sulfate BPCRS and 0.0001% w/v of 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol sulfate BPCRS), the resolution should be calculated between 2-[4-[(7-chloro-4-quinolinyl)amino]pentyl] amino ethanol sulfate peak 2 and hydroxychloroquine.



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The above chromatograms were obtained using the following conditions under the Related Substances test for the Hydroxychloroquine Tablets monograph 2016. This gradient programme is present up until BP 2025. A modified gradient programme is used in the BP 2026 method but should not affect chromatography observed in the initial 10 minutes of the gradient.

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.

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

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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.
https://www.pharmacopoeia.com