

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

LOPERAMIDE N-OXIDE CATALOGUE NUMBER 636 CURRENT BATCH: 4482

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 corrections are required to prepare the relevant solution in the tests below:

- Prepare solution (2) with a concentration of 0.22% w/v of BPCRS 4482 under Identification A for the Loperamide Oral Solution monograph.
- Prepare solution (2) with a concentration of 0.22% w/v of BPCRS 4482 under Identification A for the Loperamide Oral Suspension monograph.
- Prepare solution (3) with a concentration of 0.000039% w/v of BPCRS 4482 under Related Substances and Assay for the Loperamide Oral Solution monograph.
- Prepare solution (3) with a concentration of 0.000039% w/v of BPCRS 4482 under Related Substances and Assay for the Loperamide Oral Suspension monograph.
- Prepare solution (4) with a concentration of 0.000039% w/v of BPCRS 4482 under Related Substances for the Loperamide Capsules monograph.
- Prepare solution (4) with a concentration of 0.000039% w/v of BPCRS 4482 under Related Substances for the Loperamide Orodispersible Tablets monograph.
- Prepare solution (4) with a concentration of 0.000039% w/v of BPCRS 4482 under Related Substances for the Loperamide Tablets monograph.

This correction takes into account the purity (89.7%) of the current BPCRS material.

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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>