

Quality standards

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www.pharmacopoeia.com

BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE INFORMATION LEAFLET

SALMETEROL XINAFOATE IMPURITY 1 CATALOGUE NUMBER 1182 CURRENT BATCH: 4015

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.

Corrections:

Related Substances for Fluticasone and Salmeterol Inhalation Powder, pre-metered:

For solution (4) use a concentration of 0.00027% w/v for Salmeterol Xinafoate Impurity 1 BPCRS, this takes into account the Hydrochloride salt form of this BPCRS and a correction to the monograph.

For solution (5) use a concentration of 0.00011% w/v for Salmeterol Xinafoate Impurity 1 BPCRS, this takes into account the Hydrochloride salt form of this BPCRS and a correction to the monograph.

Related Substances for Salmeterol Inhalation Powder, pre-metered:

For solution (3) use a concentration of 0.00011% w/v for Salmeterol Xinafoate Impurity 1 BPCRS, this takes into account the Hydrochloride salt form of this BPCRS.

Reference Chromatogram(s)

None given.



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Additional Information

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>