

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

GEMFIBROZIL IMPURITY E CATALOGUE NUMBER 303 CURRENT BATCH: 3541

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

This substance corresponds to Gemfibrozil Impurity A in the monograph for Gemfibrozil (drug substance) up to and including BP 2005. The monograph was harmonized with the European Pharmacopoeia monograph in the BP 2007 and the substance now corresponds to Gemfibrozil Impurity E in the drug substance monograph.

Note: In BP 2005 to BP 2013 the monographs for Gemfibrozil Capsules and Gemfibrozil Tablets refers to Gemfibrozil Impurity A BPCRS.

In BP 2014, the name of this compound has been changed to Gemfibrozil Impurity E.

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

The systematic names for the BPCRS are as follows:

2,2-dimethyl-5-(4-propen-1-yl-2,5-xylyloxy) valeric acid

or

5-[2,5-dimethyl-4-(prop-1-enyl) phenoxy]-2,2-dimethylpentanoic acid

This BPCRS is a mixture of the *trans* and *cis* isomers in an approximate ratio of 95:5 (*trans:cis*) of gemfibrozil impurity E. A shoulder peak or separate peak due to the *cis* isomer may elute before the peak due to the *trans* isomer of gemfibrozil impurity E. For calculation purposes, as per the monograph requirement, use the total area of the peaks due to the *cis* and *trans* isomers of gemfibrozil impurity E BPCRS 3541.

For additional information on BPCRS please visit the British Pharmacopoeia website.

<https://www.pharmacopoeia.com>