



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

[www.pharmacopoeia.com](http://www.pharmacopoeia.com)

## BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE INFORMATION LEAFLET

**FLUVASTATIN IMPURITY F**  
**CATALOGUE NUMBER 1189**  
**CURRENT BATCH: 4589**

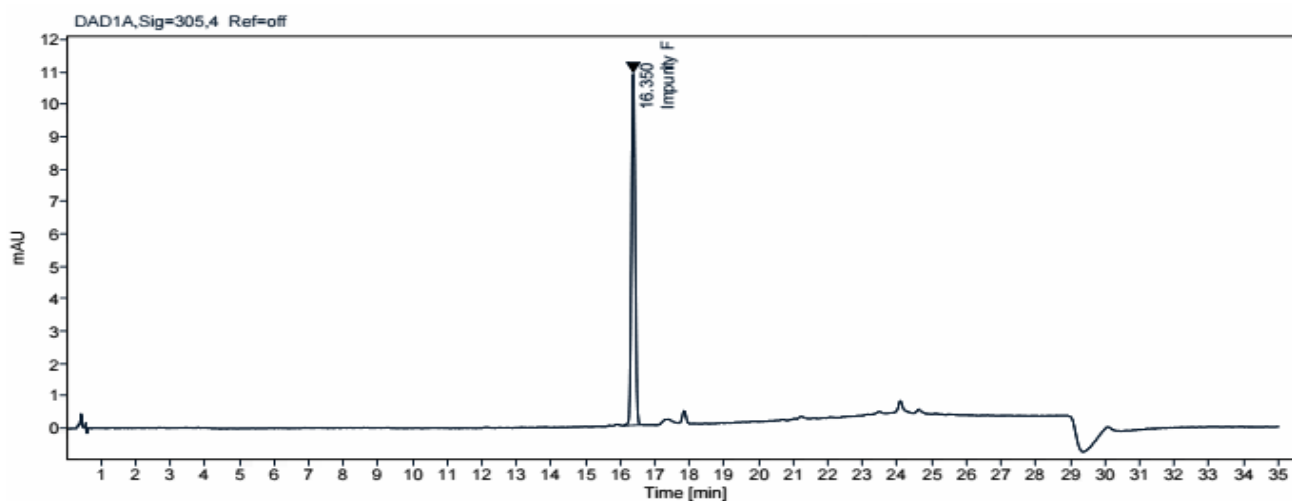
### Declared Content

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)



0.0005% w/v BPCRS 4589

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## Related Substances

**Column:** Inertsil ODS3 C18 (100mm x 4.6mm, 3µm)

**Mobile Phase/Gradient:** As per method

**Column temperature:** 40 °C

**Detector:** 305nm

**Flow Rate:** 2.0 mL/min

**Injection Volume:** 20µL

## Additional Information

Fluvastatin Impurity F BPCRS was identified to have only one peak corresponding to impurity F.

The following correction is required to prepare solution 5 in the test under Related substances for the Fluvastatin Capsules monograph (0.0005% w/v of Fluvastatin Impurity F BPCRS):

- Prepare solution 5 with a concentration of 0.00055% w/v Fluvastatin impurity F BPCRS.

The following correction is required to prepare solution 5 in the test under Related substances for the Prolonged-release Fluvastatin tablets monograph (0.00025% w/v of Fluvastatin Impurity F BPCRS):

- Prepare solution 5 with a concentration of 0.00027% w/v Fluvastatin impurity F BPCRS.

The corrections take into account the purity (91.3%) of the current BPCRS material.

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.

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

<https://www.pharmacopoeia.com>