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

ZIDOVUDINE AND LAMIVUDINE IMPURITY STANDARD
CATALOGUE NUMBER 850
CURRENT BATCH: 4387

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)

The reference chromatogram below has been prepared using a solution containing 0.1% w/v of Zidovudine and Lamivudine Impurity Standard BPCRS in a mixture of 95 volumes of mobile phase A and 5 volumes of mobile phase B.

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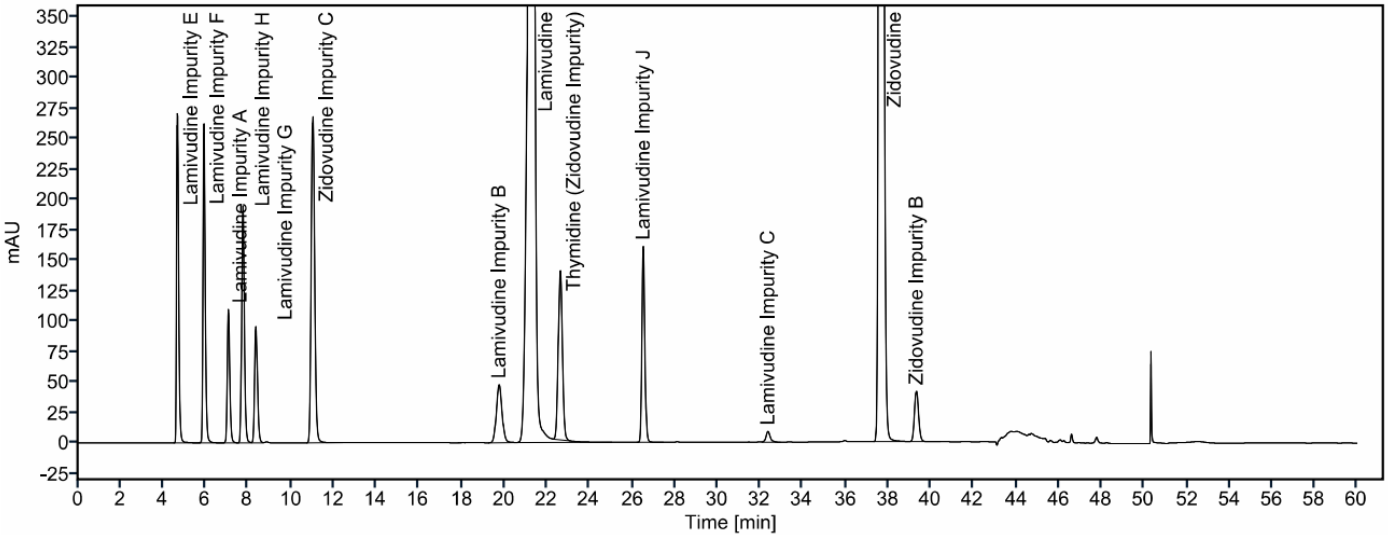

Related Substances
Column: YMC ODS-A, 5 µm (250 mm x 4.6 mm)
Mobile Phase A: 0.025 M ammonium acetate (pH adjusted to 4.0 with glacial acetic acid)
Mobile Phase B: Methanol
Mobile Phase C: Acetonitrile
Gradient Program:

Time (minutes)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)	Mobile Phase C (% v/v)
0	95	5	0
15	95	5	0
30	70	30	0
38	70	30	0
39	0	0	100
45	0	0	100
46	95	5	0
60	95	5	0

Detection Wavelength: 270 nm
Flow Rate: 0.7 ml/min
Column Temperature: 30 °C

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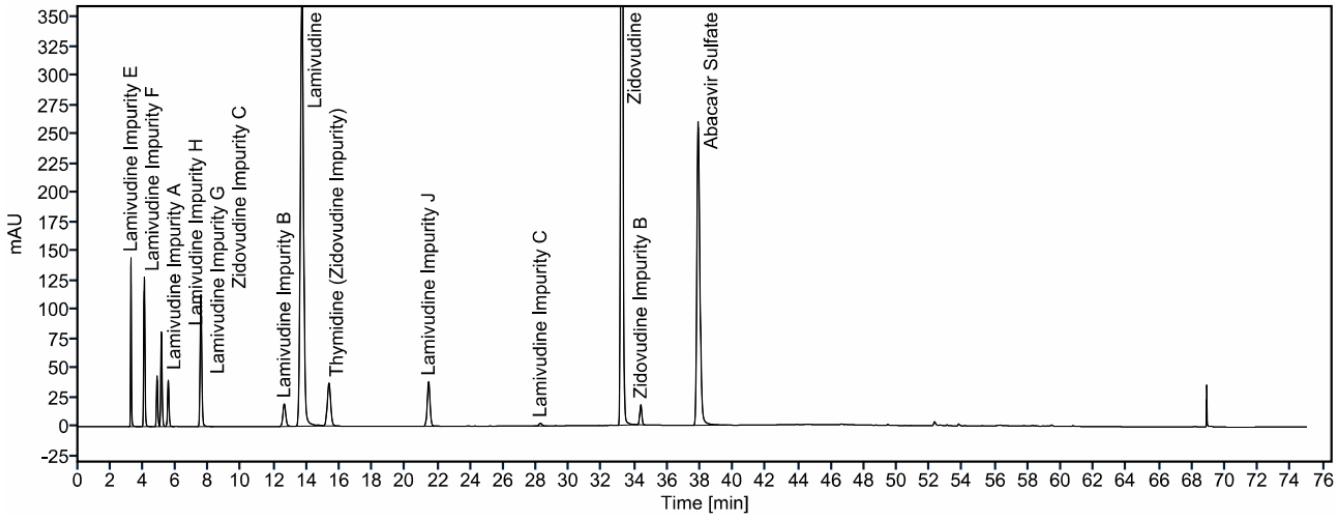
The reference chromatogram below has been prepared using a solution containing 0.075% w/v of Zidovudine and Lamivudine Impurity Standard BPCRS and 0.025% w/v Abacavir Sulfate BPCRS in a solution prepared by dissolving 1.9 g of ammonium acetate in 900 mL of water, adjusting the pH to 3.9 with glacial acetic acid, and diluting to 1 L with water.



Related Substances
Column: YMC ODS-A, 5 µm (250 mm x 4.6 mm)
Mobile Phase A: 0.025 M ammonium acetate (pH adjusted to 3.9 with glacial acetic acid)
Mobile Phase B: Methanol
Mobile Phase C: Acetonitrile
Gradient Program:

Time (minutes)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)	Mobile Phase C (% v/v)
0	95	5	0
15	95	5	0
30	70	30	0
38	70	30	0
39	0	0	100
45	0	0	100
46	95	5	0
60	95	5	0

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Detection Wavelength: 270 nm
Flow Rate: 1.0 ml/min
Column Temperature: 30 °C

Additional Information

For additional information on BPCRS please visit the British Pharmacopoeia website.
https://www.pharmacopoeia.com

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.