



**BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE
INFORMATION LEAFLET
ADAPALENE IMPURITY STANDARD
CATALOGUE NUMBER 1121
CURRENT BATCH: 4233**

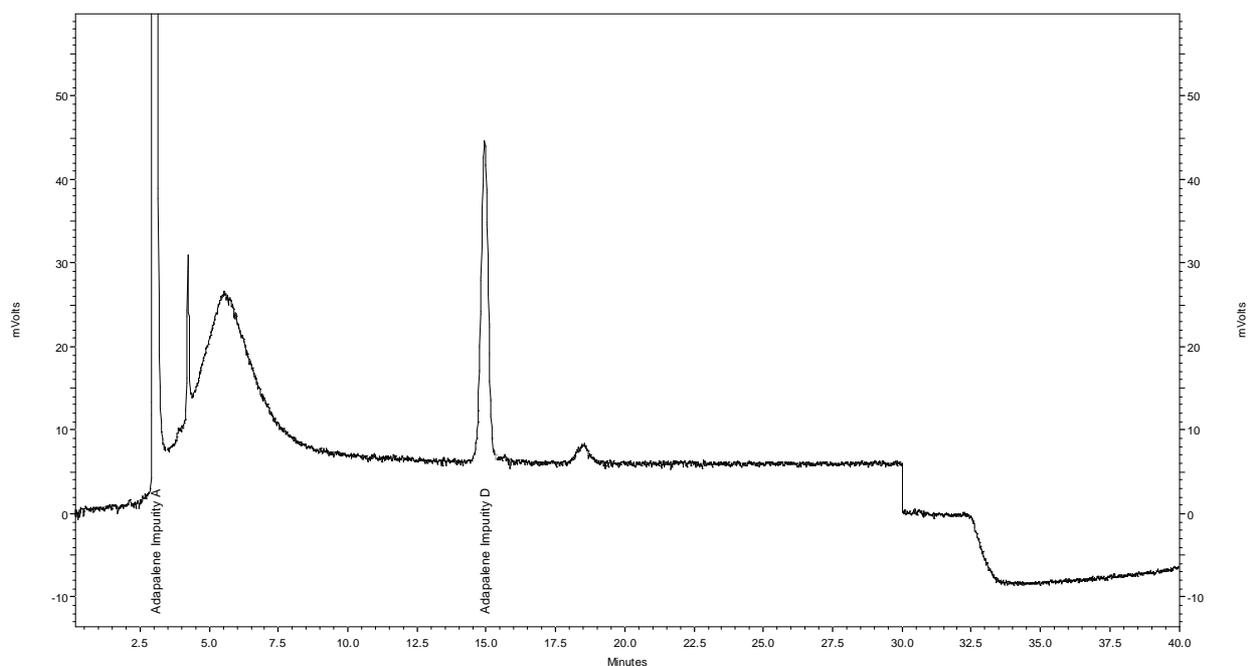
Declared Content

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)



British Pharmacopoeia Commission Secretariat

MHRA, 10 South Colonnade, Canary Wharf
London E14 4PU
United Kingdom



British Pharmacopoeia

British Pharmacopoeia Commission Laboratory

Queen's Road
Teddington, TW11 0LY
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Column: Supelcosil LC-DB C18, 5 µm (250 x 4.6 mm)

Mobile Phase A: 0.2:100 (Trifluoroacetic acid:Water v/v)

Mobile Phase B: 40:60 (Tetrahydrofuran:Acetonitrile v/v)

Gradient Program:

Time (min)	% Mobile Phase A	% Mobile Phase B
0	40	60
3	17	83
30	17	83
31	40	60
40	40	60

Diluent: Water:Tetrahydrofuran (50:50 v/v).

Detection: Fluorimetric Detection

Time (min)	Excitation Wavelength (nm)	Emission Wavelength (nm)
0	260	380
11	260	347
30	260	347
31	260	380
40	260	380

Flow rate: 1.5 mL/min

Column temperature: 25 °C

Injection Volume: 10 µL

Additional Information**Corrections:*****Related substances for Adapalene Cream and Adapalene Gel***

For Solution (3), the content of Impurity D in this BPCRS is only 0.3% of the solution and not 0.5% as stated in the monograph. This is due to a lower amount of Impurity D in this BPCRS. This should be corrected for when calculating the content of Impurity D in solution (1).

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