



**BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE
INFORMATION LEAFLET**

PHENTOLAMINE IMPURITY STANDARD

CATALOGUE NUMBER 1099

CURRENT BATCH: 3672

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.

CORRECTION TO THE PHENTOLAMINE INJECTION RELATED SUBSTANCES TEST TO BE MADE BY MEANS OF THE BP 2016

CORRECTED TEXT:

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

- (1) Dilute the injection to give a solution containing 0.05% w/v of Phentolamine Mesilate with the mobile phase.
- (2) Dilute 1 volume of solution (1) to 100 volumes in the mobile phase.
- (3) Dilute 1 volume of solution (2) to 20 volumes in the mobile phase.
- (4) 0.05% w/v of *phentolamine impurity standard BPCRS* in the mobile phase.
- (5) Heat a 0.01% w/v solution of *phentolamine impurity standard BPCRS* in 0.05M *sodium acetate*, previously adjusted to pH 4.0 with *glacial acetic acid*, at 60° for 4 hours (generation of phentolamide).



In the chromatogram obtained with solution (4):
identify any peak due to impurity A

In the chromatogram obtained with solution (5):
identify any peak due to phentolamide

Column: Zorbax SB-Phenyl, 5 µm (250 x 4.6 mm)

Mobile Phase: 33 volumes of acetonitrile and 67 volumes of a 0.05% w/v solution of ammonium acetate previously adjusted to pH 5.9 with dilute acetic acid.

Diluent: Mobile phase

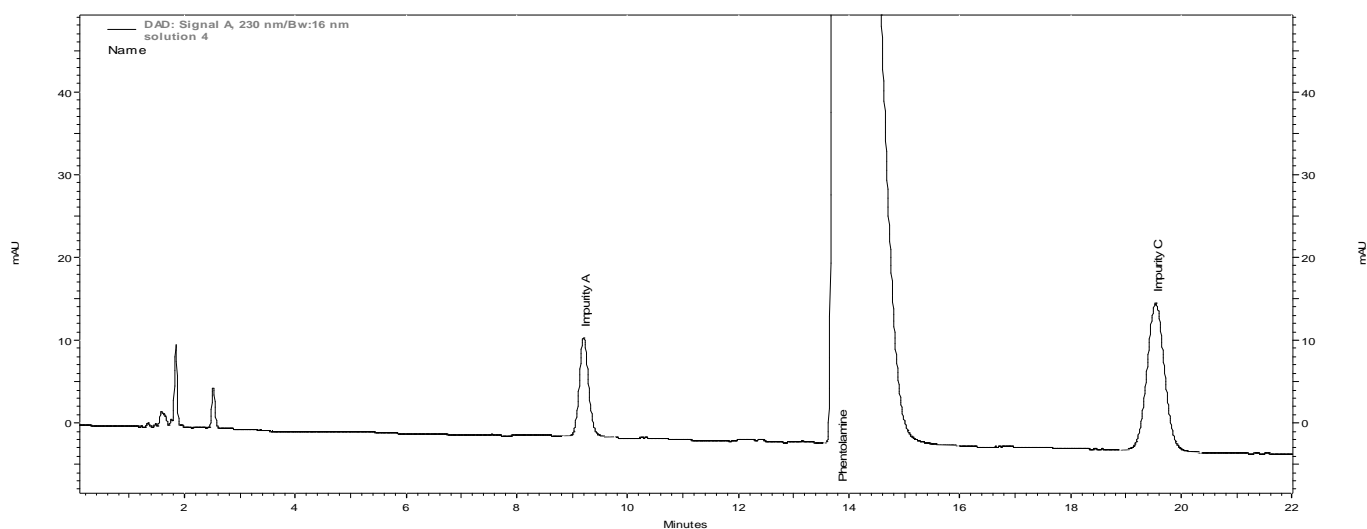
Detection Wavelength: 230 nm

Flow rate: 1.5 mL/min

Column temperature: 30 °C

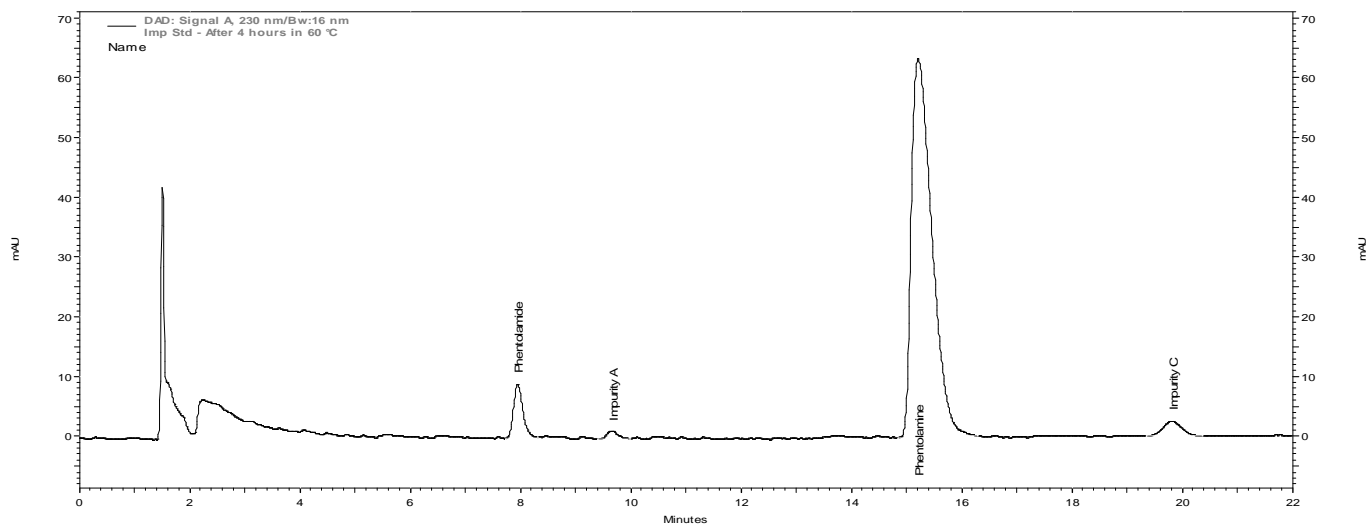
Injection Volume: 10 µL

Reference Chromatogram (Related Substances Solution (4)/Assay Solution (3))





Reference Chromatogram (Related Substances Solution (5))



Additional Information

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

<https://www.pharmacopoeia.com>