KETOCONAZOLE IMPURITY STANDARD
CATALOGUE NUMBER 1170
CURRENT BATCH: 3884

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 Chromatograms (Related Substances)
Ketoconazole Cream Monograph

**Column:** Phenomenex Kingsorb C18, 5 µm (150 mm x 4.6 mm)
**Mobile Phase A:** Mixture of 25 volumes of acetonitrile and 75 volumes of acetate buffer pH 6.
**Mobile Phase B:** Mixture of 20 volumes of acetate buffer pH 6 and 80 volumes of acetonitrile.
**Gradient:** As per monograph
**Detection Wavelength:** 230 nm
**Flow rate:** 1.2 mL/min
**Column temperature:** 40 °C
Ketoconazole Shampoo Monograph

- **Column:** Phenomenex Kingsorb C18, 5 µm (150 mm x 4.6 mm)
- **Mobile Phase A:** Dissolve 1.42 g of anhydrous disodium hydrogen orthophosphate and 3.1 g of sodium dihydrogen orthophosphate in 1000 mL of water
- **Mobile Phase B:** Acetonitrile
- **Mobile Phase C:** Propan-2-ol R1
- **Gradient:** As per monograph
- **Detection Wavelength:** 230 nm
- **Flow rate:** 0.6 mL/min
- **Column temperature:** 35 °C

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