

PRODUCT: GLIBENCLAMIDE BP/EP

ITEMS	SPECIFICATIONS
DESCRIPTION	White or almost white crystalline powder
SOLUBILITY	Practically insoluble in water ,sparingly soluble in methylene chloride, slightly soluble in ethanol (95%) and in methanol
IDENTIFICATION a) Melting point b) UV c) IR d) TLC e) Chemical test	<p>169°C~174°C</p> <p>Examined between 230nm and 350nm. The solution shows an absorption maximum at 300nm and a less intense maximum at 275nm. The specific absorbance at the maxima are 61 to 65 and 27 to 32 respectively</p> <p>The infra-red absorption spectrum of the test substance should be concordant with the spectrum of Glibenclamide standard</p> <p>The principal spot obtained with the test solution should be similar in position and size to the principal spot obtained in the chromatogram obtained with the reference solution</p> <p>The solution is colourless and shows blue fluorescence in ultraviolet light at 365 nm. Colour changes to deep yellow and, after about 20 minutes develops a brownish tinge with chloral hydrate</p>

HEAVY METALS	NMT 20 ppm
SULPHATED ASH	NMT 0.1% w/w
RELATED SUBSTANCES BY HPLC <ul style="list-style-type: none"> ➤ Impurity A ➤ Impurity B ➤ Any other impurity ➤ Unknown impurity 1 ➤ Unknown impurity 2 ➤ Total of other impurities 	NMT 0.5 % NMT 0.5 % NMT 0.2 % NMT 0.1 % NMT 0.1 % NMT 0.5 %
LOSS ON DRYING (At 105°C for three hrs)	NMT 1.0 % w/w
ASSAY BY TITRIMETRY (on dried basis)	99.0% w/w ~ 101.0% w/w
PARTICLE SIZE	100% <20 microns