

## CERTIFICATE OF ANALYSIS

<b>NAME OF PRODUCT</b>	<b>: GLIBENCLAMIDE BP/EP</b>		
BATCH NO.	: XXXX	A.R. NO.	: XXXX
MANUFACTURING DATE	: March - 2007	BATCH SIZE	: XXXX Kg
EXPIRY DATE	: February - 2012	QTY. SAMPLED	: XXXX g
ALL TEST AS PER	: BP/EP	AQTY. OF DISPATCH	: sample

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TEST	REQUIREMENTS	RESULTS
Description	White or almost White Crystalline Powder	White Crystalline Powder
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in alcohol and in methanol; it dissolves in dilute solutions of alkali hydroxides	Complies
Identification A. Melting Point B. By UV  C. By IR  D. By TLC  E. Chemical test	A] Between 166 0C to 174 0C B] The sample solution should show a maximum at 300 nm and a less intense maximum absorbance at 275 nm. The specific absorbance at the maxima should be 61 to 65 and 27 to 32 respectively. C] IR spectrum of sample should be concordant with that of glibenclamideworking standard. D] 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. E] The sample solution should show blue fluorescence in ultraviolet light at 365 nm. Dislove 0.1 gm of chloral hydrate in solution, within 5 min., the colour should change to deep yellow, and after 20 min develops a brownish tinge	Complies
Heavy Metal	Not more then 20 ppm	Complies
Sulphated Ash	Not more then 0.1 % w/w	0.039 % w/w
Related Substances (By HPLC) 1. Impuriety A 2. Impuriety B 3. Other Impurity 4. Total of other impurities	Not more than 0.5 % Not more than 0.5 % Not more than 0.2 % Not more than 0.5 %	Complies Less than 0.5 % Less than 0.5 % Less than 0.2 % Less than 0.5 %
Loss on drying	Not more than 1.0 % w/w	0.52%
Assay (on dry basis)	Not less than 99.0 % w/w and not more than equivalent of 101.0% w/w of C <sub>23</sub> H <sub>28</sub> CLN <sub>3</sub> O <sub>5</sub> S, calculated with reference to the dried substance.	99.32 % w/w

**REMARKS :** The material complies / does not comply with respect to the above (BP/EP) specifications.

TESTED BY	:	CHECKED BY	:
DATE	:	DATE	:

**AN ISO 9001:2000 CERTIFIED COMPANY**

KOHINOOR CHEMICALS  
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