

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : GLIBENCLAMIDE
MSDS no. BPPL 015	SPECIFICATION NO. FP-015

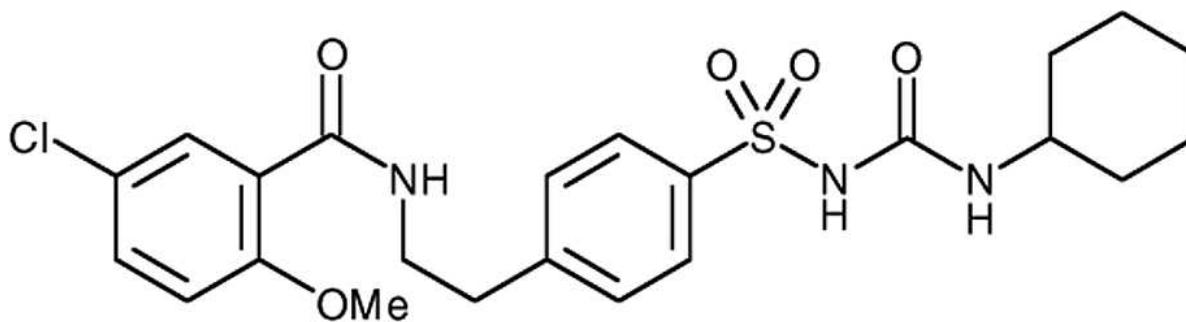
1. NOMENCLATURE : 1-[[4-[2-[(5-Chloro-2-Methoxy Benzoyl) Amino]ethyl]phenyl] Sulphonyl]-3-Cyclohexylurea.
: Glybenclamide
: Glyburide

2. CAS NO. : 10238-21-8

3. EMPIRICAL FORMULA : C₂₃H₂₈ClN₃O₅S

4. MOL. WT. : 494.0

5. STRUCTURAL FORMULA :



6. DESCRIPTION : White or almost White Crystalline Powder., Practically insoluble in Water.

7. THERAPEUTIC USE : Hypoglycaemic.

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1. DESCRIPTION : White or almost White Crystalline Powder.

2. SOLUBILITY : Practically insoluble in Water;
Sparingly soluble in Methylene Chloride;
Slightly soluble in Ethanol (95%) and in Methanol;
It dissolves in dilute solutions of Alkali Hydroxides.

3. IDENTIFICATION : A. Melting Point : 169°C to 174°C
B. By UV
C. By IR
D. By TLC
E. Chemical Test

4. MELTING POINT : 169°C to 174°C

5. RELATED SUBSTANCES : 1. Impurity A : NMT 0.5%
2. Impurity B : NMT 0.5%
3. Other Impurity : NMT 0.2%
4. Total of other impurities : NMT 0.5%

6. CLARITY & COLOUR OF SOLUTION (APPEARANCE OF SOLUTION) : 1% Solution in Alcohol is Clear and Colorless.

7. HEAVY METALS : Not more than 20 ppm.

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8. LOSS ON DRYING : Not more than 1.0% w/w
9. RESIDUAL SOLVENTS BY HSGC : Methanol : NMT 1000 ppm
Acetone : NMT 2000 ppm
10. SULPHATED ASH : Not more than 0.1% w/w
11. ASSAY (ODB) : Not less than 99.0% w/w/ and not more than equivalent of 101.0% w/w of $C_{23}H_{28}ClN_3O_5S$, calculated with reference to the dried substance.
12. PACKING : 10 Kgs. / 25 Kgs. Fibre drums with double PE liners.