Karunesh Remedies

Plot No.: 417/2, Phase-II, G.I.D.C. Estate,
Panoli - 394 116,Ta. -Ankleshwar
Dist. Bharuch, Guj. (India).
Telefax: (02646) 272049,
E-mail : karuneshremedies@yahoo.co.in
kremedies@gmail.com

Certificate of Analysis

Product	: GLIMEPIRIDE USP	**Control No**	: FP/QA/080/15-16
Batch No.	: GLM/ 002 /15-16	**Date of Receipt**	: 30/09/2015
Mfg. Date	: OCTOBER, 2015	**Date of Completion**	: 01/10/2015
Exp. Date	: SEPTEMBER, 2020	**Q'ty**	: 18 KG

Sr.No	Test	Specifications	Results
1	Description	A white or almost white crystalline powder.	*Almost white crystalline powder*
2	Solubility	Practically insoluble in water, soluble in dimethylformamide, slightly soluble in methylene chloride, very slightly soluble in methanol.	*Practically insoluble in water, soluble in dimethylformamide, slightly soluble in methylene chloride, very slightly soluble in methanol.*
3	Identifications by IR	IR Spectrum matches with that of standard	*Complies*
4	Relative Impurities Impurity B Impurity D Impurity C Unspecified Impurities Sum of Impurities other than B	 Not More than 0.4% Not More than 0.2% Not More than 0.1% Not More than 0.1% Not More than 0.5%	 0.22% Not detected Not detected 0.069% 0.23%
5	Impurity A	Not More than 0.8%	*0.26%*
6	Water (By K.F)	Not more than 0.5% w/w	*0.27%*
7	Heavy Metals	Not more than 10 ppm	*Complies*
8	Residue on ignition	Not more than 0.1% w/w.	*0.083%*
9	Assay By HPLC	97% to 102% (anhydrous basis)	*99.67 %*

Remarks : The Product Complies with the above specifications

Analysed By 01/10/15

Checked By 01/10/15

Approved By 01/10/15