3609000300

CERTIFICATE OF ANALYSIS

Sri Krishna PHARMACEUTICALS

Report No	: 115	Date	:20.08.2016
Name of the Sample	: GLIBENCLAMIDE EP/USP	Batch Qty.	: 175 Kg
Batch No	: G-0816031	Date of Mfg.	: JUL 2016
Mfg. Lic. No	: 71/MD/AP/96/B/R	Date of Exp.	: JUN 2021

S. No.	TEST	SPECIFICATION	RESULTS
1.	**CHARACTERS**		
	Appearance	White or almost white crystalline powder	White crystalline powder
	Solubility	Practically insoluble in Water, sparingly soluble in Methylene chloride, slightly soluble in ethanol (96 per cent) and in methanol.	Complies
		Polymorphism	Exhibits polymorphism & is concordant with reference standard
2.	**IDENTIFICATION** First identification: C Second identification: A,B,D,E		
	A. Melting point: (2.2.14)	169°C to 174°C	170-172°C
	B. By UV Method: (2.2.25)	• Specific absorbance at maxima at about 300nm should between 61 and 65	63.54
		• Specific absorbance at maxima at about 275nm should between 27 and 32	29.05
	C. By IR absorption: (2.2.24)	Sample spectrum should be super imposable with that produced by Glibenclamide W.S.	Superimposable
	D. By TLC: (2.2.27)	Principle spot eluted by test solution should be concordant with that eluted by reference solution prepared with working standard.	Complies
	E. By Color test:	Should comply.	Complies
3.	**TESTS**		
	Related substances: By HPLC: (2.2.29)		
	Specified Impurities		
	Impurity - A (5-chloro-2-methoxy-n-[2-(4-sulphamoyl phenyl)ethyl]benzamide)	Not more than 0.3%	0.05%
	Impurity – C (1-cyclohexyl-3-[[4-[2[(cyclohexyl carbamoyl) amino] ethyl]phenyl] sulfonyl]urea)	Not more than 0.15%	0.004%
	Unspecified impurities	Not more than 0.10%	0.05%, 0.05%
	Total	Not more than 0.8%	0.16%
4.	**RELATED SUBSTANCES By USP**		
	Impurity elute before main peak	Not more than 1.5%	0.06%
	Other Individual impurity:	Not more than 0.5%	0.04%
	Total Impurity	Not more than 2.0%	0.17%
	Heavy metals (Test G) (2.4.8)	Not more than 20ppm	Less than 20ppm
	Loss on drying (2.2.32)	Not more than 1.0%	0.17%
	Sulfated ash (2.4.14)	Not more than 0.1%	0.040%
4.	**ASSAY (ON DRIED BASIS)** (2.2.20)	99.0% to 101.0%	99.63%
5.	**ADDITIONAL TEST**		
	Residual Solvent		
	• Acetone:	NMT 5000 ppm	Not Detected
	• Methanol:	NMT 3000 ppm	1442 ppm
	• Toluene:	NMT 890 ppm	Not Detected
6.	**PARTICLE SIZE (BY MALVERN; DRY METHOD)**	90% Less than 10 µm	4.3µm
		100% Less than 30 µm	10.02 µm

Storage: Packed in polythene bags tightly in HDPE containers.

Report: The sample complies with above specification.

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For **Sri Krishna Pharmaceuticals Limited**

20/08/2016

Q.C. In-charge