

1609000500



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 • Specific absorbance at maxima at about 275nm should between 27 and 32	63.54 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 100% Less than 30 µm	4.3µm 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

[Signature]
20/08/2016
Q.C. In-charge