

1601000343


Sri Krishna

PHARMACEUTICALS

CERTIFICATE OF ANALYSIS

Report No	: 183	Date	: 29.10.2015
Name of the Sample	: GLIBENCLAMIDE EP/USP	Batch Qty.	: 250 Kg
Batch No	: G-1015026	Date of Mfg.	: AUG 2015
Mfg. Lic. No	: 71/MD/AP/96/B/R	Date of Exp	: JUL 2020

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	64.8 29.5
	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%	0.10%
	Impurity - C (1-cyclohexyl-3-[[4-[2[(cyclohexyl carbamoyl) amino] ethyl]phenyl] sulfonyl]urea)	Not more than 0.15%	Nil
	Unspecified impurities	Not more than 0.10%	Below detectable level
	Total	Not more than 0.8%	0.10%
4.	RELATED SUBSTANCES By USP		
	Impurity elute before main peak	Not more than 1.5%	0.13%
	Other Individual impurity:	Not more than 0.5%	0.03%
	Total impurity	Not more than 2.0%	0.23%
	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%	0.15%
	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%	99.71%
5.	ADDITIONAL TEST		
	Residual Solvent		
	• Acetone:	NMT 5000 ppm	Below detectable level
	• Methanol:	NMT 3000 ppm	102ppm
	• Toluene:	NMT 890 ppm	Below detectable level
6.	PARTICLE SIZE (BY MALVERN; DRY METHOD)	90% Less than 10 µm 100% Less than 30 µm	5.21µm 10.02µm

Storage: Packed in polythene bags tightly in HDPE containers

Report: The sample complies with above specification.

For Sri Krishna Pharmaceuticals Limited



06.11.2015

Q.C. In-charge

Sri Krishna Pharmaceuticals Ltd.

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