



RAKSHIT DRUGS PRIVATE LIMITED.,

425/3RT, Door No. 7-1-621/328, Sanjeeva Reddy Nagar, Hyderabad-500038, Telangana, INDIA.

Phones: 91-40-23810385, 23705066, 23818158, Fax: 91-40-23812709, 23801673

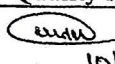
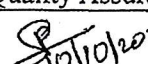
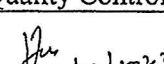

E-mail: sales@rakshitdrugsprivltd.com/ purchase@rakshitdrugsprivltd.com,

CIN No.: U24230TG2000PTC034018

CERTIFICATE OF ANALYSIS

Product Name	PIMOBENDAN		
Reference	USP/IN-HOUSE	Mfg. Date	07/10/2023
Batch No.	DB/PBD/2310002	Retest / Expiry Date	06/10/2026
Date of Analysis	10/10/2023	Dispatch / Sample Qty.	5.00 Kg
Name of the Customer	M/s TERVIS THERAPEUTICS LLC	Specification Ref. No.	STP/S/FP/6026/002-00

S. No.	Test	Specification	Result
1.	Description	White to Slightly yellowish powder	White powder
2.	Solubility	Practically insoluble in Water, Freely soluble in Dimethyl formamide and slightly soluble in Acetone and Methanol	Complies
3.	Identification		
	a) By IR Spectroscopy	The IR spectrum of sample should match with the standard spectrum.	Complies
	b) By HPLC	The retention time of the major peak of the sample solution should correspond to that of the standard as obtained in the assay by HPLC	Complies
4.	Water content by KF (% w/w)	Not more than 1.0	0.35
5.	Residue on ignition (%w/w)	Not more than 0.10	0.07
6.	Assay by HPLC (%w/w, On anhydrous basis)	Not less than 98.0 and Not more than 102.0	100.4
7.	Related substances by HPLC (% w/w)		
	Related compound-A	Not more than 0.1	Not Detected
	Related compound-B	Not more than 0.1	Not Detected
	Any individual unspecified impurity	Not more than 0.1	0.06
	Total Impurities	Not more than 0.2	0.11

	Prepared By	Reviewed By		Approved By
Department	Quality Assurance	Quality Assurance	Quality Control	Quality Assurance
Sign & Date	 10/10/2023	 10/10/2023	 10/10/2023	 10/10/2023

RAKSHIT STANDS FOR ASSURED QUALITY

WORKS: UNIT-III: Sy. No: 156, 157, 158, 187, 189, 190 and 261 (Plot No.4), JNPC, Parawada, Thadi, Anakapalli Dist., AP-531021, India.
Format No.: QAD/028-F10-05-12/04/2023



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S. No.	Test	Specification	Result
8.	Residual solvents by GC-HS (ppm)		
	a) Methanol	Not more than 3000	Not Detected
	b) Ethanol	Not more than 5000	Not Detected
	c) Isopropyl alcohol	Not more than 5000	Not Detected
	d) Ethyl acetate	Not more than 5000	959 ppm
	e) Tetrahydrofuran	Not more than 720	Not Detected
	f) Toluene	Not more than 890	Not Detected
	g) Dichloromethane	Not more than 600	Not Detected
	h) N,N dimethyl formamide	Not more than 880	Not Detected
	i) Acetone	Not more than 5000	Not Detected
9.	Acetic acid Content by HPLC (ppm)	Not more than 5000	Not Detected

Note / Remarks: The material complies as per above specification.

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Department	Prepared By	Reviewed By		Approved By
	Quality Assurance	Quality Assurance	Quality Control	Quality Assurance
Sign & Date	 10/10/2023	 10/10/2023	 10/10/2023	 10/10/2023