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分析证明书

CERTIFICATE OF ANALYSIS

Product name 品名: Pimobendan 匹莫苯丹 EP10.0	
Batch no. 批号: 20230310	Quantity 数量: 45.2KG
Manuf. date 生产日期: 2023/03/25	Expiry date 有效期: 2025/03/24

Items	Specification	Results
Appearance	White or slightly yellowish Powder, hygroscopic.	White powder
Related substances(HPLC)	Impurity A \leq 0.10	Not detected
	Impurity B \leq 0.10	Not detected
	Any other impurity \leq 0.10	0.01%
	Total impurity \leq 0.20%	0.08%
Melting point	About 242°C	242°C
Solubility	Practically insoluble in water, freely soluble in dimethylformamide, slightly soluble in acetone and in methanol.	conforms
Water	\leq 1.0%	0.08%
Heavy metals	\leq 10ppm	conforms
Sulphated ash	\leq 0.1%	0.09%
Identification	Infrared absorption spectrophotometry, Comparison pimobendan CRS.	conforms
Assay	98.0-101%	99.68%
Conclusion	THE PRODUCT CONFORMS TO THE EP10.0	

复核人 Checker:

化验人 Analyst:

