JIANGSU TASLY DIYI PHARMACEUTICAL CO., LTD

保密 CONFIDENTIAL

仅供[illegible]专用

CERTIFICATE OF ANALYSIS

Product Name		SULPIRIDE	Test Date	2020.12.03
Batch NO.		20201204	Report Date	2020.12.11
Quantity		500kg	MFG Date	2020.11.23
Specification		Ph Eur10.0	Retest Date	2023.11.22
Items		Limits	Results	
Appearance		A white or almost white, crystalline powder	Almost white, crystalline powder	
Solubility		Practically insoluble in water ,sparingly soluble in methanol,slightly soluble in ethanol and in methylene chloride.it dissolves in dilute solutions of mineral acids and alkali hydroxides.	Practically insoluble in water ,sparingly soluble in methanol,slightly soluble in ethanol and in methylene chloride.it dissolves in dilute solutions of mineral acids and alkali hydroxides.	
Melting point		177～181℃	177.5～179.0℃	
Identifications	IR-Absorption	Concordant with the reference spectrum	Concordant with the reference spectrum	
Appearance of solution		Clear and not more intensely coloured than reference solution Y_6	Clear and not more intensely coloured than reference solution Y_6	
Related substance	TLC-related substance	≤0.1%	＜0.1%	
	HPLC-related substance	Single impurity≤0.10%	0.02%	
		Total impurities ≤0.3%	0.03%	
Residual solvents	Methanol	≤3000ppm	Undetected	
	Ethanol	≤5000ppm	477ppm	
Chlorides		≤100 ppm	＜100 ppm	
Iron		≤10 ppm	＜10 ppm	
Loss on drying		≤0.5%	0.05%	
Sulphated ash		≤0.1%	0.03%	
Assay		98.5～101.0% (Calculated on the dried basis)	100.0%	
Conclusion		The product meets the requirements of Ph Eur.10.0		

Chief of QC: Reviewed by: Analyst: