



XI'AN JULONG BIO-TECH CO.,LTD

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Certificate of Analysis- Paliperidone

Product Name	Paliperidone	Batch No	JL-20210420
Quantity	1069 G	Analysis Date	Apr.20th,2021
Mfg. Date	Apr.20th,2021	Exp. Date	Apr.19th,2023
Package	25G/Foil Bag	Standard	EP USP
Items	Standards	Results	
Appearance	White to pale yellow solid powder	Complies	
Identification	By IR	Complies	
	By HPLC	Complies	
Melting Point	176.0°C~182.0°C	180.3°C~181.6°C	
Water Content(KF)	≤ 1.00%	0.06%	
Heavy Metals	≤ 20ppm	Complies	
Residue on Ignition	≤ 0.20%	Complies	
Solvents Residual	DMF ≤800ppm	700ppm	
	Acetone ≤5000ppm	3000ppm	
Related Substances	Maximum single impurity: ≤0.50%	0.48%	
	Total Impurities: ≤1.00%	0.80%	
Assay	98.0%~102.0%	99.06%	
Reference Standard	In-house Standard		
Conclusion	The product complied to In-house standard.		
Storage	Preserve in tight,light-resistant containers in a cool place		

QC MANAGER: 董卓 INSPECTOR: 张赞 ANALYST: 王胜利

