



## XI'AN JULONG BIO-TECH CO.,LTD

Address:FULI BAILU BAY ,BAQIAO DISTRICT ,XI'AN,SHAANXI PROVINCE, CHINA.

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### Certificate of Analysis-Nifedipine

Product Name	Nifedipine	Batch No	JL20201213
Quantity	10kg	Analysis Date	Dec,14th,2020
Mfg. Date	Dec,13th,2020	Exp. Date	Dec,12th,2022
Package	25KG per drum	Standard	USP/EP/BP
<b>Items</b>	<b>Standards</b>		<b>Results</b>
Appearance	Yellow crystalline powder		Yellow crystalline powder
Solubility	Practically insoluble in water, slightly soluble in alcohol and practically insoluble in methylene chloride.		Complies
Loss on drying	≤0.5%		0.4%
Heavy metal(Pb)	≤0.002 %		Complies
Sulphated ash	≤0.1%		0.05%
Identification By IR	The IR spectrum matches the reference standard spectrum		Complies
Related substance	Impurity A ≤0.05% Impurity B ≤0.3% Impurity C ≤0.3% Impurity D ≤0.3% Impurity E ≤0.3% Single unspecified impurities ≤0.1% Total impurities other than E ≤0.5% Total ≤0.5% Disregard limit ≤0.05%		0.02% 0.04% Not Detected Not Detected 0.03% 0.02% Conforms 0.11% Not Detected
Particle size	D90<50μm		Conforms
Bulk density	0.34g/ml-0.45g/ml		0.34g/ml
UV. Absorption	The specific absorption at about 367nm is between 940-1000		960

QC MANAGER: 董卓

INSPECTOR: 张赞

ANALYST: 王胜利

