

江西森泰药业有限公司
JIANGXI SENTAI PHARMACEUTICAL CO., Ltd.
 NO.5 GONGYE ROAD, INDUSTRIAL PARK, YINGTAN CITY, JIANGXI PROVINCE, CHINA
 TEL-86-701-6655286/6655288, FAX-86-701-6655287

检 验 报 告 单
CERTIFICATE OF ANALYSIS **No.:** 201600365

DATE: MAR.14, 2016

品名 Product :	VITAMIN B6 (PYRIDOXINE)
批号 Batch/LOT No:	160216
数量 Quantity:	3000KG
制造日期 MFG. DATE/Date of manufacture:	FEB. 22, 2016
失效期 EXPIRY/RE-EVALUATION DATE/Date of Expiry :	FEB. 21, 2020
检验依据 (Standard):	美国药典 36 版 (USP36) / 英国药典 2011 版 (BP2011) / 欧洲药典 7 版 (EP7)

检验项目 (Tests)	标准规定 (Specifications)	检验结果 (Results)
性状 (Description)	白色粉末或结晶 White or almost white, crystalline powder	白色粉末 White Powder
鉴别 (Identification)	A. Infrared Absorption B. It responds to the tests for chloride	Conform Conform
熔点 (Melting point)	205.0--209.0 °C	206.8--207.1 °C
酸度 (Acidity) PH	2.4--3.0	2.61
干燥失重 (Loss on drying)	≤0.2%	0.06%
炽灼残渣 (Residue on ignition)	≤ 0.10%	0.04%
硫酸盐灰分 (Sulphated ash)	≤ 0.10%	0.035%
重金属 (Heavy metals)	≤10 PPM	<1 PPM
含量 (Assay)	99.0% -101.0%	99.7%
溶液澄清度与色泽 (Clarity and Colour of Solution)	Clear and not more intensely colored than reference solution Y7	Clear<Y7 solution Conform
氯含量 (Chloride content)	16.9-17.6%	17.1%
有关物质 (Related substances)	≤ 0.25%	Conform
溶剂残留 (residual solvents)		
乙醇 (Ethanol ug/g)	≤5000	<5
甲苯 (Toluene ug/g)	≤890	no
邻二甲苯 (o-Xylene ug/g)	≤195.3	no
Organic volatile impurities	Meet the requirements	Conform

Solubility: Completely soluble in water, slightly soluble in ethanol, insoluble in chloroform or aether.

Storage: Preserve in tight, light-resistant containers.

结 论: 检验结果符合 美国药典 36 版/英国药典 2011 版/欧洲药典 7 版规定。

Conclusion: The product meet standard of USP36, BP2011 and EP7.

化验员: 樊德贞

质检科长: 樊德贞

质量控制: 吴继平

ANALYST

QC

QA

樊德贞

樊德贞

吴继平