



河北玉星生物工程股份有限公司

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## Specification Sheet 产品规格表 (JP)

Product name 产品名称	Mecobalamin (Methylcobalamin)甲钴胺		
Country of origin 原产地	China 中国	Date	2017-08-30
Shelf-life 有效期	3Years 3年		
According as 检测依据	JP XVII and in house standard 日本药典 XVII 和内控标准		
Test items 检测项目	Specifications 规格	Test methods 检测方法	
Characters 性状	Dark red crystals or crystalline powder 深红色结晶或结晶性粉末	JP Monograph Visual method 日本药典专论目视法	
Identification 鉴别	(1) UV: Compare the spectrum with the reference spectrum, Both spectra exhibit similar intensities of absorption at the same wavelengths. 样品与标准品光谱在相同的波长下有类似的吸收强度	JP Monograph/JP <2.24> 日本药典专论/附录<2.24>	
	(2) Cobalt: Meets JP requirement 钴原子: 符合日本药典要求	JP Monograph 日本药典专论	
Clarity and color of solution 溶液的澄清和颜色	The solution is clear and red color 红色澄清	JP Monograph 日本药典专论	
Related substances 有关物质	Each area of the peaks other than mecobalamin is not more than 0.5% of the peak area of mecobalamin 除甲钴胺峰外任一杂质峰面积不大于甲钴胺峰面积的 0.5%	JP Monograph/JP <2.01>	
	The total area of the peaks other than mecobalamin is not more than 2.0% 除甲钴胺峰外, 其它峰总面积不大于 2.0%	日本药典专论/附录<2.01>	
Water 水分	≤11.5%	JP Monograph/JP<2.48> 日本药典专论/附录<2.48>	
Assay(Calculated on the anhydrous basis)含量(干基)	98.5%-101.0%	JP Monograph 日本药典专论	
Acetone 丙酮	≤5000ppm	In house/(GC)内控/(GC)	
The total aerobic microbial count 需氧菌总数	≤1000 cfu/g	ChP <1105>	
The total combined yeasts/mould count 酵母菌和霉菌总数	≤100 cfu/g	中国药典 <1105>	
Staphylococcus Aureus 金黄色葡萄球菌	Absence (cfu/g) 不得检出 (cfu/g)	ChP 2015 <1106>	
Salmonella 沙门菌	Absence (cfu/10g) 不得检出 (cfu/10g)	ChP 2015 <1106>	
E.coli 大肠埃希菌	Absence (cfu/10g) 不得检出 (cfu/10g)	ChP 2015 <1106>	
Bile-Tolerant Gram-Negative Bacteria 耐胆盐革兰阴性菌	Absence (cfu/g) 不得检出 (cfu/g)	ChP 2015 <1106>	
铅 (Pb) (mg/kg)	≤0.5	Atomic absorption spectrometry	
砷 (As) (mg/kg)	≤1.5	Chp2015<0822>	
镉 (Cd) (mg/kg)	≤0.2	Atomic absorption spectrometry	
汞 (Hg) (mg/kg)	≤0.1	In house /ICP-MS	
Conclusion : 结 论 :	The product complies with the specification of JP XVII and in house standard 产品符合日本药典 XVII 版和内控标准		

