

浙江诚意药业股份有限公司检验报告单  
ZHEJIANG CHENG YI PHARMACEUTICAL CO., LTD.  
CERTIFICATE OF ANALYSIS

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产品名称 6-巯基嘌呤 (一水合物) 编号 0705-006-2016  
Product Name 6-MERCAPTOPURINE (MONOHYDRATE) Number  
批号 0705-2016-05001 数量 128.16kg  
Batch Number Quantity  
制造日期 2016-05-26 29. SEP. 2016 报告日期 2016-06-11  
Manufacture Date Report Date  
有效期 2019-04  
Expiry Date

项 目	指 标	结 果
Test	Specifications	Results
外观 Characteristics	黄色结晶性粉末 A Yellow crystalline powder	符合规定 Conforms
鉴别 Identification		
最大吸收波长 Wavelength of maximum absorbance	325±2nm	符合规定 Conforms
硫 (醋酸汞) 鉴别 Sulphur (Mercuric acetate)	白色沉淀 A white precipitate	符合规定 Conforms
硫 (醋酸铅) 鉴别 Positive for Sulphur (lead acetate)	黄色沉淀 A yellow precipitate.	符合规定 Conforms
次黄嘌呤 (TLC) Hypoxanthine	≤2.0% (w/w)	<2.0%
水分 Water Content	10.0%~12.0% (w/w)	10.7%
硫酸盐灰份 Sulphated Ash	≤0.1% (w/w)	0.06%
含量 Assay	含巯嘌呤 (C <sub>4</sub> H <sub>4</sub> N <sub>4</sub> S) 98.5%~101.0% (w/w) Mercaptopurine	99.5%
粒度 Particle size		
D (v, 0.1)	≤15μm	8μm
D (v, 0.5)	8~45μm	24μm
D (v, 0.9)	≤90μm	63μm
外来颗粒 Foreign particles	≤10ppm	<10ppm
含量 (HPLC) Assay by HPLC	97.5%~102.0% (w/w)	99.4%
相关物质 (HPLC) Related Substances by HPLC		
次黄嘌呤 Hypoxanthine	≤0.30% (w/w)	0.04%
二硫化物 Disulphide	≤1.75% (w/w)	0.13%
单一未知杂质 Unknown impurity	≤0.10% (w/w)	0.04%
总杂质 Total impurities	≤2.2% (w/w)	0.3%
残留溶剂 Residual solvent	吡啶 ≤200ppm pyridine	未检出 Absence

结 论: 符合 葛兰素公司标准 规定  
Conclusion This batch meets the specification of GSK'S standard

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