

羟丙甲纤维素空心胶囊检验报告书


Certification of Analysis

控制号: 230504Z0001

Control Number: 230504Z0001

编号: REC-QC-001-001-A00

NO.: REC-QC-001-001-A00

产品名称 Product	羟丙甲纤维素空心胶囊 HPMC Empty Capsule	批号 Batch No.	22305002
数量 Quantity	120万粒 1,200,000pcs	规格 Size	0#, 颜色: 透明/透明 0#, Color: Transparent / Transparent
包装规格 Package	9万粒/箱 90,000pcs/ctn	生产日期 Production date	2023.05.04
检验项目 Test items	全检 Full inspection	报告日期 Report date	2023.05.12
有效期至 Expire date	2027.04	检验依据 Test Ref.	中国药典2020年版四部 Chinese Pharmacopoeia (2020 Edition Volume IV)
检验项目 Test item	检定标准 Standard	检验结果 Result	
【性状】 Characteristics	本品呈圆筒状, 系由可套合和锁合的帽和体两节组成的质硬且有弹性的空囊。囊体应光洁、色泽均匀、切口平整、无变形、无异臭。分为透明、半透明、不透明。 This product is cylindrical, hard, elastic empty capsule, which consist of telescoping & locking cap and body pieces. The capsule body should have a clean, smooth and uniformly coloured surface, without distortion, neatly cut and odourless. Divided into transparent, translucent and opaque.	本品呈圆筒状, 系由可套合和锁合的帽和体两节组成的质硬且有弹性的空囊。囊体光洁、色泽均匀、切口平整、无变形、无异臭。为透明。 This product is cylindrical, hard, elastic empty capsule, which consist of telescoping & locking cap and body pieces. The capsule body should have a clean, smooth and uniformly coloured surface, without distortion, neatly cut and odourless. Transparent.	
【鉴别】(1) Identification (1)	应符合规定。 Meet the requirements.	符合规定。 Conforms.	
【鉴别】(2) Identification (2)	应先呈红色, 并在100分钟内变成紫色。 Should be red first and turn purple within 100 mins.	符合规定。 Conforms.	
【鉴别】(3) Identification (3)	絮凝温度 $\geq 50^{\circ}\text{C}$ 。 The flocculation temperature $\geq 50^{\circ}\text{C}$	62 $^{\circ}\text{C}$	
【检查】 Inspection			
松紧度(粒) Tightness (Pcs)	≤ 1	无漏粉 No leakage	
脆碎度(粒) Friability (Pcs)	≤ 2	无破裂 No breakage	
崩解时限(min) Disintegration time (min)	≤ 15	8	
干燥失重(%) Loss on drying (%)	≤ 8.0	5.6	
炽灼残渣(%) Residue on ignition	<input checked="" type="checkbox"/> ≤ 3.0 (透明 Transparent) <input type="checkbox"/> ≤ 5.0 (半透明 Translucent) <input type="checkbox"/> ≤ 9.0 (不透明 Opaque)	1.5	
重金属(mg/kg) Heavy metals (mg/kg)	≤ 20	<20	
砷盐(mg/kg) Arsenic salts (mg/kg)	≤ 2	<2	
需氧菌总数(cfu/g) Aerobic plate count (cfu/g)	$\leq 10^3$	<10	
霉菌和酵母菌总数(cfu/g) Mold & Yeast count (cfu/g)	$\leq 10^2$	<10	
大肠埃希菌(/g) E. coli (/g)	不得检出 Negative	未检出 Negative	
检验结论 Test Conclusion	本品按《中国药典》2020年版四部检验, 结果符合规定。 This product is tested according to Chinese Pharmacopoeia (2020 Edition Volume IV), and the results are complied with the requirements.		
备注 Remark	/		
授权人签名 Authorized signature		签发日期 Issue date	2023.05.12.

