



# Hangzhou Huarong Pharm Co., Limited

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## CERTIFICATE OF ANALYSIS

品名 Product Name	阿卡波糖 Acarbose	批号 Batch No.	AC2207001
包装规格 Package	20Kg/Drum	生产日期 Mfg. Date	2022.07.22
批量 Batch Size	261.450kg	复验期 Retest Date	2024.07.21
储存条件 Storage Conditions	密封, 15~30°C保存。 Preserve in tight containers. Store at 15~30°C.		

项目 Tests		标准 Specifications	结果 Results
性状 Characters	外观 Appearance	白色至淡黄色无定形粉末, 无臭。 White to yellowish, amorphous powder, odorless.	符合规定 Conform
	溶解性 Solubility	极易溶于水, 溶于甲醇, 极微溶于乙醇, 不溶于丙酮或乙腈。 Very soluble in water, soluble in methanol, very slightly soluble in ethanol, insoluble in acetone or acetonitrile.	符合规定 Conform
鉴别 Identification	红外鉴别 IR Identification	红外吸收图谱应与对照图谱一致。 The IR spectrum of test specimen should be consistent with the IR spectrum of reference standard.	符合规定 Conform
	液相鉴别 HPLC Identification	样品溶液主峰的保留时间与标准品溶液主峰的保留时间一致。 The retention time of the major peak of the sample solution corresponds to that of the standard solution.	符合规定 Conform
pH		5.5~7.5	6.78
比旋度(以无水物计) Specific optical rotation (On the anhydrous basis)		+168°~+183°	+177°
炽灼残渣 Residue on ignition		≤0.2%	0.040%
水分 Water		≤4.0%	2.7%
有关物质 Related substances	杂质 A Impurity A	≤0.6%	0.24%
	杂质 B Impurity B	≤0.5%	未检出 Not detected
	杂质 C Impurity C	≤1.5%	0.14%
	杂质 D Impurity D	≤1.0%	0.057%
	杂质 E Impurity E	≤0.2%	未检出 Not detected
	杂质 F Impurity F	≤0.3%	未检出 Not detected
	杂质 G Impurity G	≤0.3%	未检出 Not detected
	杂质 H Impurity H	≤0.2%	未检出 Not detected
	任一非特定杂质 Any individual unknown impurity	≤0.2%	低于报告限 Below reporting limit
总杂质 Total impurities		≤3.0%	0.43%
含量(以无水物计) Assay (On the anhydrous basis)		95.0%~102.0%	98.7%
微生物限度 Microbial limit	需氧菌总数 TAMC	≤1000cfu/g	<10cfu/g
	霉菌和酵母菌总数 TYMC	≤100cfu/g	<10cfu/g
	大肠埃希菌 E.Coli	不得检出/g Should be absent/g	未检出 Absent
结论 Conclusion	本品符合美国药典及企业内控标准 The product complies with USP and In-house Specifications.		

