

# Hubei Gedian Humanwell Pharmaceutical Excipients Co., Ltd.

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人福医药

## CERTIFICATE OF ANALYSIS

品名(Product): Propylene Glycol (丙二醇)

批号(Batch No.): F108C211101

数量(Quantity): 9913.000kg

规定(Specification): USP43

生产日期(Mfg. date): 2021.11.14

有效期至(Expiry date): 2023.11.13

报告日期(Report date): 2021.11.25

检验 Items	检验项目 Test Items	标准规定 Standard Specifications	检验结果 Results
【性状】 【Characters】	外观 Appearance	本品为无色澄清的黏稠液体 This product is colorless and clear viscous liquid	无色澄清的黏稠液体 Colorless and clear viscous liquid
	相对密度 Relative density	1.035-1.037	1.035
【鉴别】 【Identification】	鉴别 (A) Identification (A)	本品的红外光吸收图谱与对照的图谱一致 The infrared absorption spectrum of this product should be consistent with that of the control	符合规定 Conform
	鉴别 (B) Identification (B)	二甘醇不度过 0.10%; Diethylene glycol shall not exceed 0.10%;	未检出 Undetected
	鉴别 (C) Identification (C)	鉴别 B 中所得色谱图, 供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time of propylene glycol peak of the test solution should be consistent with that of the reference solution in the chromatogram recorded by the identification test item B.	符合规定 Conform
【检查】 【Tests】	酸度 Acidity	≤0.20ml	0.02ml
	氯化物 Chloride	≤0.007%	<0.007%
	硫酸盐 Sulfate	≤0.006%	<0.006%
	水分 Water	≤0.2%	0.04%
	炽灼残渣 Residue on ignition	遗留残渣不得过 3.5mg The residue weighs not more than 3.5 mg	1.1mg
【含量】 【Content】	含量测定 Content	≥99.5%	99.6%

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结论: 符合 USP43 的要求

Conclusion: Complies with the requirements of USP43

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