Jiangxi Qingfeng Pharmaceutical Co.,Ltd.

Product Inspection Report

Report Number: C-GCOIOOIOI-240118 TEM-SMP-QC-0015-01.00

Name	Xiyanping_injection	Batch Number	240102
Specifications:	Each vial contains 2ml:50mg	Production Date	January 2, 2024
Manufacturer	Jiangxi Qingfeng Pharmaceutical Co.,	Sampling Date	January 3, 2024
Packaging	Bottle	Valid Until	June 2025
Inspection Items	Full inspection		
Execution Standard	National Food and Drug Administration Standard, National Drug Standard WS-10863 (ZD-0863)-2002-20112, 2020 edition of "Chinese Pharmacopoeia", Part Four.		
Basis of Inspection	"Quality Standard of Xiyenping Injection" QS-GC-0007.00 "Operating Procedures for Inspection of Xiyenping Injection" SOP-QC-8007.01		

Inspection Item	Standard Requirement	Inspection Result
【Appearance】	The product should be a clear liquid ranging from pale yellow to yellow-green.	The product is a clear liquid of yellow-green color.
【Identification】		
(1)Chemical Reaction	Should show positive reaction	Shows positive reaction.
(2)Chemical Reaction	Should show positive reaction	Shows positive reaction.
(3)Thin Layer Chromatography	At the corresponding positions in the chromatography with 17-Hydroxy-9-Dehydrocortisol-19-Sulfate Sodium reference standard, it should show spots of the same color.	At the corresponding positions in the chromatography with the 17-Hydroxy-9-Dehydrocortisol-19-Sulfate Sodium reference standard, spots of the same color are observed.

【Inspection Items】

Solution Color:	Should meet the specifications	Meets the specifications
pH Value:	Should be between 4.5 and 6.5	5.9
Protein:	Should meet the specifications	Meets the specifications
Tannins:	Should meet the specifications	Meets the specifications
Oxalates:	Should meet the specifications	Meets the specifications
Potassium Ions:	Should meet the specifications	Meets the specifications
Resins:	Should meet the specifications	Meets the specifications
Ash Content:	Should meet the specifications Should not exceed 1.5% (g/ml)	0.8%
Heavy Metals and Harmful Elements:	Based on the maximum daily usage of the product, lead should not exceed 12 μg, cadmium should not exceed 3 μg, arsenic should not exceed 6 μg, mercury should not exceed 2 μg, and copper should not exceed 150 μg.	Lead: 0.05 μg, Cadmium: 0.001 μg, Arsenic: Not detected, Mercury: Not detected, Copper: 0.04 μg
Filling Quantity:	Should meet the specifications	Meets the specifications
Visible Foreign Matter:	Should meet the specifications	Meets the specifications
Insoluble Particles:	Particles of 10 μm and larger should not exceed 6000 per vial. Particles of 25 μm and larger should not exceed 600 per vial.	21.8 particles per vial 0.0 particles per vial
Hemolysis and Aggregation:	Should meet the specifications	Meets the specifications

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Basis of Inspection	"Quality Standard of Xiyenping Injection" QS-GC-0007.00 "Operating Procedures for Inspection of Xiyenping Injection" SOP-QC-8007.01		

Inspection Items	Standard Specification	Test Result
Pyrogens	Should meet the specifications	Meets the specifications
Macromolecular Substances	Macromolecular substances with a molecular weight greater than that of somatostatin should not be detected.	Not detected
Abnormal Toxicity	Should meet the specifications.	Meets the specifications
Allergic Reactions	Should meet the specifications.	Meets the specifications
Sterility	Should meet the specifications.	Meets the specifications
Bacterial Endotoxins	The amount of bacterial endotoxins in each 1 ml should be less than 0.50 EU.	Meets the specifications
【Fingerprint Chromatogram】 【Content Determination】	Should individually correspond to the retention times of the reference chromatogram peaks; the similarity to the reference fingerprint chromatogram should not be less than 0.85.	The chromatographic peaks individually match the retention times of the reference chromatogram peaks; the similarity is 0.96
Total Sulfonates	Each 1 ml of this product should contain total sulfonates of andrographolide expressed as andrographolide sulfonate sodium ($C_{20}H_{29}O_5 \cdot SO_3Na$) in an amount between 85.0% and 115.0% of the labeled amount.	102.5%
17-Hydroxy-9-Dehydroandrographolide-19-Sulfate Sodium	Each 1 ml of this product should contain total sulfonates of andrographolide expressed as 17-Hydroxy-9-Dehydroandrographolide-19-Sulfate Sodium ($C_{20}H_{29}O_5 \cdot SO_3Na$) in an amount not less than 0.50 mg	0.89mg

Conclusion: The product, as tested according to the "Quality Standard for Xiyanping Injection" QS-GC-0007.00 and the "Standard Operating Procedure for Xiyanping Injection Testing" SOP-QC-8007.01, meets the specifications.

Prepared by / Date: Reviewed by / Date: Approved by / Date: