Certificate of Analysis

Product name: **Ivermectin**

Number of analysis: T0008287

Batch number / Weight: **23I18-H08-00747 / 5g**

Producer / Producer Batch Number: Zhejiang Hisun Pharmaceutical Co. Ltd/4025021N230406

Analysed according to: **PH.EUR 11.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish-white, crystalline powder, slightly hygroscopic	Conform		
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol	Conform		
Identification A	Conform	Conform		IR
Identification B	Conform	Conform		Assay
Appearance of solution	Clear and colourless	Conform		2%m/V toluene
Appearance of solution	<= BY7	Conform		2%m/V toluene; DP
Specific optical rotation	-20,0 - -17,0	-20,0	°	Anhydrous substance
Related substances	Conform	Conform		HPLC; DP
Impurity with a relative retention of 1,3 to 1,5 with reference to the principal peak	<= 2,5	0,94	%	HPLC; DP
Any other impurity (apart from the 2 principal peaks)	<= 1	0,3	%	HPLC; DP
Total impurities	<= 5	1,9	%	HPLC; DP
Ethanol and formamide	Conform	Conform		GC; DP
Ethanol	<= 5,0	4,3	%	GC; DP
Formamide	<= 3,0	2,3	%	GC; DP
Water	<= 1,0	0,16	%	KF
Sulfated ash	<= 0,1	0,0	%	DP
Assay Ivermectin (H2B1a + H2B1b)	95,0 - 102,0	98,6	%	HPLC, anhydrous; DP
Assay ratio H2B1a/(H2B1a + H2B1b)	>= 90,0	99,8	%	HPLC; DP
Residual solvents	Conform	Conform		DP
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		DP

Analysis performed by the authorized internal lab.

Release:
Konstantina Tziolia
Pharmacist - QA Manager / QP

20/09/2023

Expiration: 28-04-2026

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Conclusion: APPROVED

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