黄石法姆药业股份有限公司

HUANGSHI PHARMA CO., LTD.

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METAPHARMACEUTICAL

N DE LOTE:
003062S

02/06/2025

ALLOPURINOL
Certificate of Analysis

Batch No: 20250403
Weight: 50kg

Date of Manufacture: Mar 26, 2025
Date of Expiry: Mar 25, 2029

Item	Standard	Result
Description	White or almost white powder	White powder
Solubility	Very slightly soluble in water and in alcohol (96 percent). It dissolves in dilute solutions of alkali hydroxides.	Complies
Odor	Odourless or almost odourless	Complies
Identification	A. The Ratio of ultraviolet and visible absorption is between 0.52 to 0.62	0.57
	B. Infrared absorption (2.2.24), the IR absorption spectrum of sample exhibits the same spectrum as Reference Standard	Complies
	C. Dissolve 0.3 g in 2.5 mL of dilute sodium hydroxide solution R and add 50 mL of water R. Add slowly and with shaking 5 mL of silver nitrate solution R1. A white precipitate is formed which does not dissolve on the addition of 5 mL of ammonia R.	Complies
	D. Complies as per TLC test	Complies
Loss on Drying	Not more than 0.5%	0.26%
Related Substances	Impurity A: not more than 0.2%	ND
	Impurity B: not more than 0.1%	0.02%
	Impurity C: not more than 0.1%	ND
	Unspecified impurities: not more than 0.10%	0.07%Max
	Sum of impurities other than A, B, C: not more than 0.3%	0.18%
	Impurity D: not more than 0.1%	ND
	Impurity E: not more than 0.1%	ND
	Impurity F: not more than10ppm	ND
Assay (on dried basis)	98.0% ~ 102.0%	101.18%
Particle Size D90	＜50μm	Complies
Sulphated Ash	Not more than 0.1%	0.05%
Residual Solvents	Ethanol NMT 5000ppm	20ppm
	Ethyl actate NMT5000ppm	ND
	Formamide NMT220ppm	ND
Total Aerobic Microbial Count	No more than 10^3 cfu / g	Complies
Total Combined Yeasts/ Molds Count	No more than 10^2 cfu / g	Complies

Result: The above product conforms with standard EP11.

Tested by	Reviewed by	Approved by
汪亚		

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