

METAPHARMACEUTICAL

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28/03/2025



寿光富康制药有限公司

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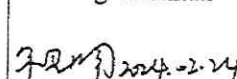
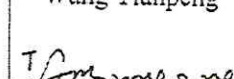
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CERTIFICATE OF ANALYSIS

REPORT NO: QC24020303

REGISTER NO:SMR-QC-01861

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PRODUCT		Trimethoprim	PHARMACOPOEIA	EP11.3
BATCH NO.		A-20112402009	GROSS WEIGHT	27.5Kg/Drum
BATCH QUANTITY		2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE		FEB.17,2024	RETEST DATE	JAN.2029
ANALYSIS DATE		FEB.19,2024	REPORT DATE	FEB.24,2024
TEST ITEM		STANDARDS REQUIRED		TEST RESULTS
Characters	Appearance	White or yellowish-white powder		Complies
Identification	C:IR	IR Conforms to the CR.S (2.2.24)		Complies
Test	Appearance of solution	The solution is not more intensely coloured than reference solution BY ₇ (2.2.2, Method II)		Complies
	Loss on drying	≤1.0% (2.2.32)		0.1%
	Sulphated ash	≤0.1%(2.4.14)		0.03%
Related substances (2.2.29)	Any impurity	≤0.10%		0.036%
	Total impurities	≤0.2%		0.07%
Impurity K. (GC)		≤5ppm (2.2.28)		1ppm
Assay% on dry basis		99.0%-101.0%(2.2.20)		100.2%
Residual solvent		Methanol≤1000ppm		13ppm
		DMSO≤500ppm		Not detected
Conclusion: The commodity meets the standard of EP11.3. CEP NO. CEP 2005-115-Rev 02.				
Examiner	Shan Fang  2024.2.24	Checker	Song Chennan  2024.2.24	Approver Wang Tianpeng  2024.2.24