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19/02/2024

CERTIFICATE OF ANALYSIS

REPORT NO: QC23010394

REGISTER NO:SMR-QC-018b1

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PRODUCT		Trimethoprim	PHARMACOPOEIA	EP10
BATCH NO.		A-20112301026	GROSS WEIGHT	27.5Kg/Drum
BATCH QUANTITY		2000Kg	NET WEIGHT	25Kg/Drum
MANUFACTURE DATE		JAN.14,2023	RETEST DATE	DEC.2027
ANALYSIS DATE		JAN.15,2023	REPORT DATE	JAN.27,2023
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)		0.3%
	Sulphated ash	≤0.1%(2.4.14)		0.02%
Related substancesA: (HPLC)(2.2.29)	Any impurity	≤0.10%		0.02%
	Total impurities	≤0.2%		0.06%
Related substancesB: (HPLC)(2.2.29)	Any impurity	≤0.10%		0.02%
	Total impurities	≤0.2%		0.02%
Impurity K. (GC)		≤5ppm (2.2.28)		1ppm
Assay% on dry basis		98.5%-101.0%(2.2.20)		100.3%
Conclusion: The commodity meets the standard of EP10. CEP NO. R1-CEP 2005-115-Rev 01.				
Examiner	Liu Cuixia	Checker	Song Chennan	Approver
	21/01/2023.01.27		21/01/2023.01.27	Wang Tianpeng
				21/01/2023.01.27