



CERTIFICATE OF ANALYSIS

PRODUCT: COLISTIN SUPHATE EP6.0

QUANTITY: 1000KGS

BATCH NO. 20141201

MANUFACTURING DATE: DEC. 01, 2014

EXPIRY DATE: DEC. 01, 2016

DATE OF ISSUE: DEC. 03, 2016

ITEM		SPECIFICATIONS	RESULTS
CHARACTERS	APPEARANCE	WHITE OR ALMOST WHITE POWDER, HYGROSCOPIC	APPROVED
	SOLUBILITY	FREELY SOLUBLE IN WATER, SLIGHTLY SOLUBLE IN ETHANOL, INSOLUBLE IN ACETONE.	APPROVED
IDENTIFICATION		POSITIVE REACTION	APPROVED
PH		4.0 TO 6.0	5.0
SPECIFIC OPTICAL ROTATION		-63° to -73° (DRIED SUBSTANCE)	-70°
RELATED SUBSTANCES	ANY IMPURITY	≤4.0%	2.0%
	TOTAL	≤23.0%	16.9%
SULPHATE		16.0% TO 18.0%	17.1%
LOSS ON DRYING		≤3.5%	2.4%
SULFATED ASH		≤1.0%	0.2%
LC CONTENT	SUM CONTENT	≥77.0%	82.7%
	E3	≤10.0%	5.0%
	E1-1	≤10.0%	0.6%
	E1-7MOA	≤10.0%	3.2%
POTENCY (DRIED BASES)		≥19000 IU/mg	22951 IU/mg
POTENCY (MOISTURE BASES)		-	22400 IU/mg

CONCLUSION: ELIGIBILITY

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