



Kopran

Certificate Of Analysis AZITHROMYCIN DIHYDRATE EP

BATCH No. : AZ/P1708025	ANALYTICAL REPORT No. FPPA/170788	MFG. DATE : AUG.2017
DISPATCH QTY. : 250.00 Kg		EXP.DATE : JUL.2021

Sr. No.	TESTS	RESULTS	SPECIFICATIONS
1	DESCRIPTION	Almost white powder	White or almost white powder
2	SOLUBILITY	Complies	Practically insoluble in water, freely soluble in anhydrous Ethanol and in Methylene chloride.
3	IDENTIFICATION BY IR BY HPLC	Complies Complies	To comply as per EP To comply as per EP
4	APPEARANCE OF SOLUTION	Complies	Solution S is clear and colourless.
5	pH	9.91	9.0 to 11.0
6	SPECIFIC OPTICAL ROTATION (ON ANHYDROUS BASIS)	-48.04°	-45° to -49°
7	RELATED SUBSTANCES (%) EP 1) Impurity B 2) Impurities A 3) Impurities C 4) Impurities E 5) Impurities F 6) Impurities H 7) Impurities I 8) Impurities L 9) Impurities M 10) Impurities N 11) Impurities O 12) Impurities P 13) Sum of Impurities D & J 14) Impurity G 15) Any other Impurity 16) Total Impurities	0.40 % BDL BDL Not Detected BDL Not Detected BDL Not Detected BDL Not Detected 0.11 % BDL BDL BDL BDL 0.51 %	NMT 2.0 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.5 % NMT 0.2 % NMT 0.2 % NMT 3.0 %
8	WATER CONTENT	4.29 %	Between 1.8 & 6.5 % w/w
9	SULPHATED ASH	0.11 %	NMT 0.2 %
10	ASSAY (ON ANHYDROUS BASIS)	99.29 %	96.0 % to 102.0 %
11	ADDITIONAL TESTS		
11.1	RESIDUAL SOLVENTS 1) Methanol 2) Acetone	Not Detected 368 ppm	NMT 3000 ppm NMT 5000 ppm
11.2	BULK DENSITY Tapped	0.67 g/cc	Informative

THIS PRODUCT CONFORMS TO EP

DATE: 01/09/2017

PREPARED BY	CHECKED BY	APPROVED BY
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Sr. Executive- QA	Manager-QC	Sr. Manager -QC

Date of Sampling -05th August 2017

Date of Analysis -08th August 2017



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