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HEC

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Certificate of Analysis

Test No.: BIC-C1-1809037

Name	Erythromycin	Type of Product	API
Product Code	C00102	Workshop	307
Batch No.	ERY-201809036	Batch Size	1400.58Kg
Manufacture Date	Sep.23,2018	Packaging	20.0Kg/Drum
Report Date	Oct.01,2018	Expiry Date	Sep.22,2022

Tests items		Acceptance criteria	Results
Appearance		White or slightly yellow powder or colorless or slightly yellow crystals	White powder
IR Identification		Infrared spectrum is concordant with that of the reference standard	Conforms
Related substances	Impurity A	Not more than 2.0%	0.68%
	Impurity B	Not more than 2.0%	0.53%
	Impurity C	Not more than 3.0%	0.99%
	Impurity D	Not more than 1.0%	0.23%
	Impurity E	Not more than 1.0%	0.02%
	Impurity F	Not more than 1.0%	0.0009%
	Impurity H	Not more than 1.0%	0.01%
	Impurity L	Not more than 0.4%	0.009%
	Impurity M	Not more than 1.0%	0.07%
	Any other impurity	Not more than 0.4%	0.11%
	Total impurities	Not more than 7.0%	2.5%
Thiocyanate		Not more than 0.3%	0.02%
Water		Not more than 6.5%	0.8%
Sulfated ash		Not more than 0.2%	0.07%
Assay (On anhydrous substance)	Erythromycin B	Not more than 5.0%	0.42%
	Erythromycin C	Not more than 5.0%	0.86%
	Erythromycin (A+B+C)	93.0% - 102.0%	96.7%
Residual Solvent: Methylene chloride		Not more than 600ppm	ND ppm
Microbial Limit	Total Aerobic Microbial Count	Not more than cfu10 ³ /g	- CFU/g
	Total Yeast/Mold Count	Not more than cfu10 ² /g	- CFU/g

Conclusion: The Results Comply With Ph.Eur. 9.5.

QA:)

2018.10.01

QC manager:

Written by:

2018.10.01