WRS
F9-4

(T4)

CERTIFICATE OF ANALYSIS

Name of the product : **ERYTHROMYCIN STEARATE BP (WORKING STANDARD)**	
Batch No: LT-DESA/007/14-15	Quantity : 1.0 gram
Mfg. Date : Mar-2015	A.R. No : 2014-15/QCP/FGM/00415
Release Date :06/04/2015	Exp Date : Feb-2018

S. No	TEST	SPECIFICATION	OBSERVATION
01	Appearance	White or almost white crystalline powder	White crystalline powder
02	Solubility	Practically insoluble in water, soluble in acetone and in methanol	complies
03	Identification		
	By infrared absorption spectroscopy	The IR spectrum obtained from the test sample is concordant with the IR spectrum obtained from working standard	Complies
	By Thin Layer Chromatography	Result A: The chromatogram obtained with the test solution shows 2 spots, one of which corresponds in position to the principle spot in the chromatogram obtained with reference solution (a) and the other to the principal spot in the chromatogram obtained with reference solution (b) Result B: The spot in the chromatogram obtained with the test solution corresponds in position, color and size to the principal spot in the chromatogram obtained with the reference solution (b)	Complies Complies
04	Free stearic acid (on anhydrous substance)	Maximum 14.0%	5.2%
05	Related substances by HPLC		
	Impurity A	Not more than 3.0%	Not detected
	Impurity B	Not more than 3.0%	0.48%
	Impurity C	Not more than 3.0%	0.12%
	Impurity D	Not more than 3.0%	Not detected
	Impurity E	Not more than 3.0%	0.06%
	Impurity F	Not more than 3.0%	Not detected
	Any unknown impurity	Not more than 3.0%	0.04%
	Total Impurities	Not more than 6.0%	0.81%
06	Water content by KF	Not more than 4.0% w/w	1.64% w/w
07	Sulphated Ash	Not more than 0.5% w/w	0.03% w/w
08	Assay by HPLC (an hydrous substance)		
	Sum of contents of erythromycin A,B and C	Not less than 60.5%	68.7%
	Erythromycin B	Not more than 5.0%	0.4%
	Erythromycin C	Not more than 5.0%	0.5%

	Prepared By	Checked By	Approved By
	06/04/15	06/04/15	06/04/2015

OFFICE ADDRESS: 203,Center Point, 2nd Floor, Near Hotel Kohinoor, JB Nagar, Andheri Kurla Road, Andheri (East), Mumbai-400059.
Tel : + 91 – 22 – 40390400 / 422 Fax: + 91 – 22 – 28395644 CIN : U24230MH1987PTC043003.