

MEHTA
API PVT. LTD.

CERTIFICATE OF ANALYSIS

Name of the product : Erythromycin EP			
Batch No	OEBA/0020516	Batch size	: 500.00 Kg
Mfg. Date	: May-2016	A. R. No.	: 2016-17/QCP/FGM/00294
Release Date	: 29/09/2016	Exp. Date	: April-2019

Sr.No	TEST	OBSERVATION	SPECIFICATION
01	Appearance	White powder, slightly hygroscopic.	White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic.
02	Solubility	Slightly soluble in water, freely soluble in alcohol, soluble in methanol.	Slightly soluble in water (the solubility decreases as the temperature rises), freely soluble in alcohol, soluble in methanol.
03	Identification		
	A. By IR	The IR spectrum obtained with test is concordant with the spectrum obtained with Working standard.	The IR spectrum obtained with test should be concordant with the spectrum obtained with Reference standard or Working standard.
	B. By TLC	The principle spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principle spot in the chromatogram obtained with reference solution (a) and its position and colour are different from those of the spots in the chromatogram obtained with reference solution (b).	The principle spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principle spot in the chromatogram obtained with reference solution (a) and its position and colour are different from those of the spots in the chromatogram obtained with reference solution (b).
	C. By chemical test	Red colour develops.	A red colour develops.
	D. By chemical test	Yellow colour develops.	A yellow colour develops.
04	Specific Optical Rotation (anhydrous substance)	-71.2	- 71 to - 78 (anhydrous substance)
05	Related substances By HPLC		
	a) Impurity A	Not detected	Not more than 3.0 %
	b) Impurity B	0.52%	Not more than 3.0 %
	c) Impurity C	1.30%	Not more than 3.0 %
	d) Impurity D	Not detected	Not more than 3.0 %
	e) Impurity E	0.06%	Not more than 3.0 %

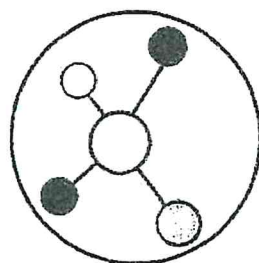
	Prepared By	Reviewed By	Approved By
Name	Rahul Patil	Utpal Sankhe	Prashant Hinkar
Designation	Officer- QC	Executive- QC	Asst. Manager QC
Signature	<i>RA</i>	<i>U</i>	<i>PH</i>
Date	01/10/2016	01/10/2016	01/10/2016

FRM/QCD/053/06/00

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OFFICE ADDRESS : 203, Centre Point, 2nd Floor, Near Hotel Kohinoor, J.B. Nagar, Andheri-Kurla Road, Andheri (East). Mumbai-400059.
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FACTORY ADDRESS : Gut No. 546, 571, 519 & 520 Village-Kumbhavali, Tarapur, Boisar, Dist.-Palghar, Pin-401 506. Maharashtra (India)
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Sr.No	TEST	OBSERVATION	SPECIFICATION
	f) Impurity F	Not detected	Not more than 3.0 %
	g) Any Unknown Impurity	0.42%	Not more than 3.0 %
	h) Total impurities	2.58%	Not more than 7.0%
06	Thiocyanate	0.15%	Not more than 0.3 %
07	Water	2.49% w/w	Not more than 6.5% w/w
08	Sulphated ash	0.04% w/w	Not more than 0.2% w/w
09	Assay By HPLC		
	Sum of the contents of erythromycin A, B and C	100.1%	93.0% to 102.0% (anhydrous substance)
	Erythromycin B	0.4%	Not More than 5.0%
	Erythromycin C	2.4%	Not More than 5.0%
Additional Test			
10	Residual solvent (By GC)		
	Dichloromethane	570 ppm	NMT 600 ppm
11	Particle size by Malvern	22.21 microns	95% less than 25 microns

Remark: The above sample complies as per EP specification no: FG/078/02 and Gemini Exports specification.

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
17H 28-1402-00078

Director Técnico

	Prepared By	Reviewed By	Approved By
Name	Rahul Patil	utpal Sankhe	Poashant Hidakar
Designation	officer-QC	Executive-QC	Asst. Manager QC
Signature			
Date	01/10/2016	01/10/2016	01/10/2016

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