



ANUH PHARMA LTD.

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FORMAT NO.: QC/FORMAT/FP-001

REPORT NO.:	F - 2012 05 164	DATE	09/05/2012
ITEM :	ERYTHROMYCIN EP7/BP2010	MFG. DATE	APR. 2012
BATCH QTY.	25.0 Kgs	BATCH NO.	EB 020 D12
EXP. DATE	MAR. 2015	SPECIFICATION AS PER	EP7/BP2010

CERTIFICATE OF ANALYSIS

TESTS	RESULT	SPECIFICATION AS PER EP7/BP2010
Description	White powder, slightly hygroscopic	White or slightly yellow powder or colorless or slightly yellow crystals, slightly hygroscopic.
Solubility	Complies	Slightly soluble in water (solubility decreases as the temperature rises), freely soluble in alcohol, soluble in methanol.
Identification	Test A: Complies	Test A: IR should correspond with WS
Specific optical rotation	-73.40°	-71° to -78° (On anhydrous basis)
Thiocyanate	0.057%	Not more than 0.3%
Related substances:	1. Any impurity 2. Total impurities	1.19% 2.16% Not more than 3.0% Not more than 7.0%
Water	1.89%	Not more than 6.5%
Sulphated Ash	0.05%	Not more than 0.2%
Assay (By H.P.L.C.)	1. Erythromycin (A+B+C) 2. Erythromycin B 3. Erythromycin C	96.15% 1.55% 1.14% Bet 93.0% & 102.0% (On anhydrous basis) Not more than 5.0% Not more than 5.0%

REPORT: The sample complies with the prescribed standards of quality as per EP7/BP2010

Ramesh Mahale
Quality Control Manager
Date: 09/05/2012

Factory: E-17/3 & 17/4, M.I.D.C., Tarapur, BOP-401 508, INDIA Tel/fax: (02525) 605 361 / 605 362

