



FORMAT NO.: QC/FORMAT/FP-001

ANUH PHARMA LTD.

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REPORT NO	:	F - 2012 03 1040	DATE	:	08/04/2012			
CERTIFICATE OF ANALYSIS								
ITEM	:	ERYTHROMYCIN EP7		MFG. DATE	:	MAR. 2012		
QUANTITY	:	100 Kgs	BATCH NO.	:	EB 133 C 12	EXP. DATE	:	FEB. 2015
TESTS		RESULT		SPECIFICATION AS PER EP 7				
Description		White powder, slightly hygroscopic		White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic.				
Solubility		Complies		Slightly soluble in water, freely soluble alcohol, soluble in methanol.				
Identification		Test A: IR Positive		Test A: IR should corresponds with WS				
Specific optical rotation		-73.24°		- 71° to - 78° (On anhydrous basis)				
Thiocyanate		0.120%		Not more than 0.3%				
Related substances:								
1. Any impurity		2.68%		Not more than 3.0%				
2. Total impurities		4.61%		Not more than 7.0%				
Water		1.52%		Not more than 6.5%				
Sulphated Ash		0.08%		Not more than 0.2%				
Assay (By H.P.L.C.)								
1. Erythromycin (A+B+C)		97.61%		Bet 93.0% & 102.0% (On anhydrous)				
2. Erythromycin B		1.51%		Not more than 5.0%				
3. Erythromycin C		0.56%		Not more than 5.0%				
Residual solvent:								
Methylene Chloride		Complies		Max. 600 ppm				
Particle size		Complies		Min. 97% < 200 µm				
REPORT: The sample complies with the prescribed standards of quality as per EP 7								
 Ramesh Mahale Quality Control Manager Date: 08/04/2012								

