

ADDRESS: 3-A, Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli, Mumbai 400018.

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CERTIFICATE OF ANALYSIS

FORMAT NO.: QC/F/233-00

PRODUCT DETAILS

Item Name : Azithromycin USP (Dihydrate)

Report No : F 2020 06 0370

Date : 30 / 06 / 2020

BATCH DETAILS

Batch No. : AZI 010 F 20

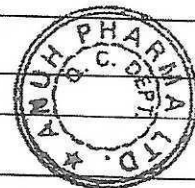
Batch Quantity : 400.000 kg


Manufacturing Date : JUN. 2020

Expiry Date : MAY. 2024

TEST	RESULTS	SPECIFICATIONS AS PER USP 42
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Description	White powder	White or almost white powder.
Solubility	Complies	Freely soluble in anhydrous ethanol and in methylene chloride; practically insoluble in water
Identification		
Identification A	Test A: Complies	Test A: IR spectrum of sample should be concordant to that of similarly recorded spectrum of WRS of Azithromycin.
Identification B	Test B: Complies	Test B: The retention time of Azithromycin peak in sample solution corresponds to that of the standard solution, as obtained in the assay.
Assay (By HPLC)	1019.07 µg	NLT 945 µg and NMT 1030 µg of Azithromycin per mg (On anhydrous basis)
Residue on Ignition	0.03%	Not more than 0.3%
Organic Impurities (Procedure 2)		
Azithromycin - N-oxide	Below detection limit	Not more than 0.5%
3'-(N,N-Didemethyl)-3'-N-formylazithromycin	Below detection limit	Not more than 0.5%
Erythromycin A iminoether	Below detection limit	Not more than 0.5%
3'-(N,N-Didemethyl) azithromycin (aminoazithromycin)	Below detection limit	Not more than 0.5%
Azithromycin related compound F	0.05%	Not more than 0.5%
Desosaminylazithromycin	Below detection limit	Not more than 0.3%
3'-N-[[4-(Acetylamino)phenyl]sulfonyl] - 3'3'-didemethylazithromycin	Below detection limit	Not more than 0.15%
N-Demethylazithromycin	Below detection limit	Not more than 0.7%
Erythromycin A oxime	Below detection limit	Not more than 0.5%
Azithromycin C (3"-O-demethylazithromycin)	Below detection limit	Not more than 0.5%
3'-De(dimethylamino)-3-oxoazithromycin	Below detection limit	Not more than 0.5%



Analyst : Tushar	 Sign.	Approved : Surendra Rai	 Sign.
Designation : QC Chemist		Designation : AGM QC	
Date : 30/06/2020		Date : 30/06/2020	

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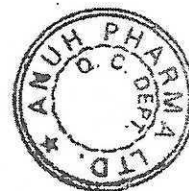
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TEST	RESULTS	SPECIFICATIONS AS PER USP 42
3'-N-[[4-(Acetylamino)phenyl]sulfonyl]-3'-demethylazithromycin	Below detection limit	Not more than 0.5%
Azaerythromycin A	Below detection limit	Not more than 0.5%
Azithromycin impurity P	Below detection limit	Not more than 0.2%
2-Desethyl-2-propylazithromycin	0.10%	Not more than 0.5%
3'-N-Demethyl-3'-N-[[4-methylphenyl]sulfonyl] Azithromycin	Below detection limit	Not more than 0.5%
3-Deoxyazithromycin (azithromycin B)	0.11%	Not more than 1.0%
Any individual, unidentified impurity	Below detection limit	Not more than 0.2%
Total impurities	0.26%	Not more than 3.0%
Optical Rotation	-46.99°	Between -45° to -49° at 20° C
Crystallinity	Complies	The particles show birefringence & extinction position, when the microscope stage is revolved.
pH	9.60	Between 9.0 to 11.0
Water Determination (By KF)	4.73%	Between 4.0% to 5.0%
Residual solvents		
Acetone	458.98 ppm	Not more than 5000 ppm

REMARKS

The sample complies with the prescribed standards of quality as per USP 42

RELEASE



Analyst : Tushar
Designation : QC Chemist
Date : 30/06/2020

AL

Sign.

Approved : Surendra Rai
Designation : AGM QC
Date : 30/06/2020

SR

Sign.