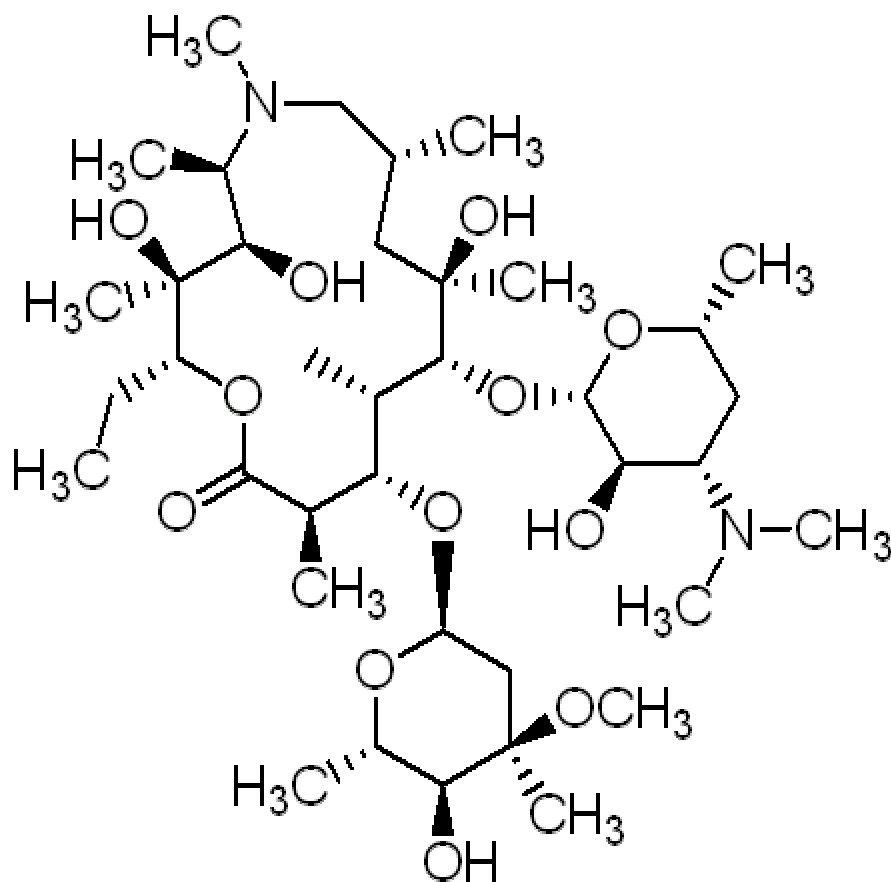


M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : AZITHROMYCIN DIHYDRATE USP 29
MSDS no. BPPL 025	SPECIFICATION NO. FP-025

1. NOMENCLATURE : Azithromycin Dihydrate.
: N-Methyl -11-Aza-10-deoxo-10-
dihydroerythromycin A.
: 9-Deoxo-9a-methyl-9a-Aza-
homoerythromycin A.
: 9-Deoxo-9-methyl-9a-Aza-9-
homoerythromycin A.
2. CAS NO. : 83905-01-5 (Anhy.)
: 117772-70-0 (Dihydrate).
3. EMPIRICAL FORMULA : $C_{38}H_{72}N_2O_{12} \cdot XH_2O$.
4. MOL. WT. : 749.0 (Anhy.)
: 785.03 (Dihydrate).
5. STRUCTURAL FORMULA :



6. DESCRIPTION : White or almost white powder.

7. THERAPEUTIC USE : Anti- Infective. (Antibacterial).

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : AZITHROMYCIN DIHYDRATE USP 29
MSDS no. BPPL 025	SPECIFICATION NO. FP-025

01. DESCRIPTION : White or almost white powder.
02. SOLUBILITY : Particularly insoluble in Water.
: Freely soluble in Ethanol and in
Methylene Chloride.
03. IDENTIFICATION : A) By IR Test. (As per USP)
B) By HPLC. (As per USP)
04. SPECIFIC OPTICAL ROTATION (At 25°C) : Between -45° and -49°
05. CRYSTALLINITY : Meets the requirement as per USP.
06. pH : Between 9.0 and 11.0
07. WATER CONTENT : Between 4.0% and 5.0%.
08. RESIDUE ON IGNITION : NMT 0.30%
09. HEAVE METALS : NMT 0.0025%.

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : AZITHROMYCIN DIHYDRATE USP 29
MSDS no. BPPL 025	SPECIFICATION NO. FP-025

10. RELATED SUBSTANCES :
(By HPLC)
- A) Desosaminylazithromycin : NMT 0.3%
 - B) N- Demethyl–Azithromycin : NMT 0.7%
 - C) Any other individual impurity : NMT 1.0%
 - D) Total impurities : NMT 3.0%
11. ASSAY (By HPLC) : NLT 945.0µg and
(ON DRIED BASIS) NMT 1030.0µg.
12. BITTERNESS VALUE : NMT 200,000.

Prepared by (Q.C. Chemist).

Approved by (Q.C. Manager).

Authorised by (Q.A. Manager).

Effective Date: 01st April '2007.

Review Date : 31st March '2009.