

CERTIFICATE OF ANALYSIS

Product Name : Azithromycin 7.5 % Granules / Powder
Batch Number : AZI/7.5/522324
Batch Size : 301.0 Kg
Date of Sampling : 24/02/2024

A.R.No. : PJD/FP/3632324
Date of Analysis : 26/02/2024
Date of Mfg. : February, 2024
Date of Exp. : January, 2027

SR NO.	TEST	RESULT	SPECIFICATION
1	Description	White to slightly off white free flowing granular powder , which after reconstitution gives a white to off white coloured vanilla flavoured bitterless & sweet in taste suspension.	White to slightly off white free flowing granular powder , which after reconstitution gives a white to off white coloured vanilla flavoured bitterless & sweet in taste suspension.
2	Identification	Complies	The retention time for Azithromycin test preparation in test corresponds to that exhibited in the Chromatogram of the standard preparation of the Assay.
3	Water (By Karl Fischer) (Reagent used: ethylene glycol monomethyl ether)	1.29 %	Limit: not more than 1.5%
4	pH (reconstituted Suspension)	10.17	Limit : 8.5 to 11.0
5	Assay: Each 100gm contains Azithromycin dihydrate USP/BP Eq. to Azithromycin..... 7.5 gm	7.58 gm (101.07 %)	6.75 gm to 8.25 gm (90.0 % to 110.0%)

REMARKS: The Sample complies as per specification

Prepared by:

Name: Maheshkumar B. Mistry

Designation: Manager (Q.C)

Signature: 

Date: 26/02/2024

Checked by:

Name: M.d Fahad

Designation: Manager (Q.A)

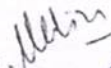
Signature: 

Date: 26/02/2024

Approved by:

Name: Nalin R Patel

Designation: AGM (Q.C)

Signature: 

Date: 26/02/2024

