

PROCHEM PHARMACEUTICALS PVT. LTD

140-141, Makkanpur Bhagwanpur, Roorkee, Dist. Haridwar (UK)

CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

(The Drug & Cosmetic Act 1940 and the rule there under)

Mfg. Lic. No.-78/UA/2016

REPORT No : PTT/24/1866

PRODUCT : Azithromycin Tablets IP 500mg
AZEETOP- 500

BATCH No : THP-241866

Mfg. Date : 09/2024

Exp. Date : 08/2026

Date of Receipt : 25/09/2024

Batch Size : 5.0Lac

Sample Qty. : 50 Tabs

Test	Specifications	Results
Description	White colour, elongated biconvex, film coated tablets.	Complies
Identification	Positive test for Azithromycin IP	Complies
Average Weight	610mg	612.83mg
Uniformity of Weight	Not more than two of the individual weights deviate from the average weight by more than $\pm 5\%$ and none deviates by more than $\pm 10\%$	Min: 601.43mg (-1.86)% Max: 626.16mg (+2.17)%
Dissolution Test	Q-NLT 75%	(92.78 – 95.73)%
Related Substances	A) Individual impurity : NMT 2.0% (Impurity B)	Not Detected
	B) Total impurity : NMT 3.0%	Not Detected

Assay : Each Film coated tablet contains:-

Ingredients:-	Claim	Found	% of Claim	Limit
Azithromycin IP eq to Anhydrous Azithromycin	500 mg	491.52mg	98.30 %	(450-550)mg 90%-110%

Conclusion : In the Opinion of the under signed, the sample referred to above is of STANDARD QUALITY/NOT OF STD. QUALITY as defined in the act and the rules made there under IP,BP,USP & I H S .

ANALYSE BY <i>Mohd. Hameed</i>	CHECKED BY <i>AJ Singh</i>	APPROVED BY <i>[Signature]</i>
DATE: 01/10/2024	DATE: 01/10/2024	DATE: 01/10/2024