



INNOVA CAPTAB LTD.
81-B, EPIP, PHASE-I, JHARMAJARI, BADDI (HP)

CERTIFICATE OF ANALYSIS

Serial No.: 12418381

Ref STP NO.: IC/STP/1759

ATR NO.: F-12418380

Batch no: 17594002

Mfg. Date: 03/2024

Analysis started on: 28/03/2024

Reference: IP

GLYCITOP-80

(Gliclazide Tablets IP 80mg)

Batch size: 2.00 Lac

Sampling done by : SK

Exp. Date: 02/2026

Analysis completed on: 04/04/2024

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Each uncoated tablet contains:

Gliclazide IP

80mg

Excipients

QS

Sr. No	Tests	Specifications	Results
1.	Description	White coloured flat round shaped uncoated tablets having break line on one side.	White coloured flat round shaped uncoated tablets having break line on one side.
2.	Identification	The infrared absorption spectrum is concordant with the reference spectrum of Gliclazide.	Complies
3.	Average weight of tablet	300mg (limit $\pm 5\%$)	302.5mg
4.	Uniformity of weight	It should not deviate $\pm 5\%$.	+2.82% to -3.01%
5.	Disintegration	Not more than 15 min.	Within 1min.
6.	Thickness	Between 3.00mm and 3.60mm	3.41mm to 3.48mm
7.	Diameter	Between 9.40mm and 10.00mm	9.56mm to 9.58mm
8.	Hardness	Not less than 3.0 kg/cm ²	8.64-9.84 kg/cm ²
9.	Friability	Not more than 1.0%w/w	0.16%w/w
10.	Related substances	1-(3-azabicyclo[3.3.0]oct)-3-o-tolysulphonylurea : NMT 0.2% Ind. Unknown Imp.: NMT 0.2 Total Unknown Imp.: NMT 0.4%	Complies
11.	Dissolution	NLT 70%Q	103.1% to 107.1%
12.	Assay Each uncoated tablet contains: Gliclazide IP 80mg	Between 76mg and 84mg (Between 95% and 105%)	80.09mg (100.1%)

Remarks: The above sample is complies as per Specification No.: IC/FPS/1759

Prepared by
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