



ZEE LABORATORIES LTD
Behind 47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. :

Document No. : 252614029

Ref. STS No.	2654	Product Code	FG06021
Product Name	TAB. SITAZEE-M 1000		
Generic Name	Sitagliptin Phosphate & Metformin Hydrochloride Tablets		
Batch No.	425-820	Date Of Sampling	06/05/2025
Batch Size	150000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	04/2025	Exp. Date	03/2028
A. R. No.	ZL25FG03275	Date Of Release	13/05/2025

S NO.	Tests	Specification	Results
1	Description	Brown colour, elongated, biconvex shaped film coated tablets, scored on one side.	Complies
2	Identification	Should be positive for sitagliptin phosphate, Metformin Hydrochloride.	Complies
3	Average Weight of Tablet	1430.0 mg \pm 5.0%	1440.0 mg
4	Uniformity of Weight	Average weight of tablet \pm 5.0%.	-0.34% to + 0.34%
5	Disintegration Test	Not more than 30 minutes	10:10min Min
6	Assay Each film coated tablet contains : Sitagliptin phosphate I.P. Eq. to Sitagliptin phosphate 50 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Sitagliptin phosphate	96.0 %
7	Metformin Hydrochloride 1000 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Metformin Hydrochloride	98.7 %

Remarks The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In house specification.

Particulars	Prepared By	Checked By	Approved By
Sign & Date	13/05/2025	21/05/2025	QC MANAGER 13/05/2025
Name:	Rajiv Kumar QC Manager Zee Laboratories Co. Ltd.	Dheeraj Singh Quality Control Zee Laboratories Co. Ltd.	Thakur Dinesh Singh QC Manager Zee Laboratories Co. Ltd.
Designation:			