



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. : 252618956

Ref. STS No.	2654	Product Code	FG05999
Product Name	TAB. SITAZEE-100		
Generic Name	Sitagliptin Phosphate Tablets I.P.		
Batch No.	425-1067	Date Of Sampling	07/06/2025
Batch Size	140000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	05/2025	Exp. Date	04/2028
A. R. No.	ZL25FG04298	Date Of Release	14/06/2025

S NO.	Tests	Specification	Results
1	Description	Brown colour, rounded, biconvex shaped film coated tablets, scored on one side.	Complies
2	Identification	Should be positive for sitagliptin phosphate.	Complies
3	Average Weight of Tablet	310.0 mg \pm 5.0%	306.0 mg
4	Uniformity of Weight	NMT two of the individual weights deviate from the Average weight by more than the 5% and none deviates by more than 10%.	-3.01% to + 1.60%
5	Disintegration Test	Not more than 30 minutes	02:25 Min
6	Related substances	Any secondary peak NMT 0.2% The area of all the secondary peak is NMT 0.5%	Complies
7	Assay Each film coated tablet contains : Sitagliptin phosphate I.P. Eq. to Sitagliptin phosphate 100 mg	NLT 95.0% and NMT 105.0% of the labeled amount of Sitagliptin phosphate	98.3 %

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	21/06/2025	21/06/2025	
Name:	Rajyuees	Dheerans	Thakur Deen Singh
Designation:	Officer in charge	Audit manager	