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. :		252618719
Ref. STS No.	241			Product Code		FG03333
Product Name	CAP. GABATIX-300					
Generic Name	GABAPENTIN CAPSULES I.P. 300MG					
Batch No.	1725-318			Date Of Sampling		05/06/2025
Batch Size	50000.000 CAP			Sample Quantity		50.000 CAP
Mfg. Date	05/2025			Exp. Date		04/2028
A. R. No.	ZL25FG04264			Date Of Release		05/06/2025

S NO.	Tests	Specification	Results
1	Description	Red colour cap and body hard gelatin capsules filled with white colour fine powder.	Complies
2	Identification By IR	IR spectophotometry compare the spectrum with that obtained with gabapentine ws or with the reference spectrum of gabapentin.	Complies
3	Identification BY HPLC	In the assay,the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution	Complies
4	Average weight of filled capsule	386.0 mg ± 7.5 %	386.0 mg
5	Average weight of filling	310.0 mg ± 7.5 %	307.45 mg
6	Uniformity of weight of filling	Average weight of filling of Capsules ± 7.5%.	Complies
7	Disintegration Test	Not more than 30 minutes	06:25 Min Min
8	Dissolution (%)	Q.Not less than 80 % of the labeled amount of Gabapentin .	94% to 101 %
9	Related compounds	The area of peak gabapentine impurity A NMT 0.4%,the area of any other scondary peak is NMT0.1%, the sum of area of all secondary peak is NMT1.0%	Complies
10	Assay Each Hard gelatin capsule contains Gabapentin I.P. 300 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Gabapentin.	98.5 %

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	05/06/2025	05/06/2025	
Name:	Mahmueen	Dheerenhs	
Designation:	Officer QC	Astt manager	Q.S MANAGER

ZEE/QC/072/02-00