



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. : 252630415

Sample Rec No. : 252642670

QC No. : 252656231

Ref. STS No.	3552	Product Code	FG04186
Product Name	RESPULES BUDEZEX		
Generic Name	BUDESONIDE NEBULISER SUSPENSION B.P.		
Batch No.	2726-001	Date Of Sampling	14/03/2026
Batch Size	100000.000 Amp.	Sample Quantity	20.000 Amp.
Mfg. Date	01/2026	Exp. Date	12/2027
A. R. No.	ZL26FG02080	Date Of Report	16/03/2026

S NO.	Tests	Specification	Results
1	Description	A clear colour less Sluspension filled in plastic Respules.	Complies
2	Identification	Should be positive for Budesonide.	Complies
3	pH	Between 4.0 to 5.0	4.70
4	Extractable -volume	2.0 ml	2.0ml
5	Related Substances	Complies to B.P	Complies
6	Epimer A	40% to 51.0%	43.5 %
7	Assay Composition: Each 2ml Respule Contains: Budesonide 0.5mg	NLT 80.0% and NMT 120.0% of the labeled amount of Budesonide	97.7 %

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	Analysis By	Prepared By	Checked By	QC MANAGER Approved By
Sign & Date	<i>[Signature]</i> 16/03/26	<i>[Signature]</i> 16/03/2026	<i>[Signature]</i> 16/03/26	<i>[Signature]</i> 16/03/26
Name:	Phishant	Raghuvver	nikhil	Heen
Designation:	office ccc	officer ccc	chief	Aut Manager