M/S IVM PHARMACIA

Plot No. 05, Industrial Township,
Bhatoli- Kalan, Baddi (H.P.) -173205

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

QUALITY CONTROL DEPARTMENT

PRODUCT NAME	**Levosalbutamol Hydrochloride and Budesonide Inhalation Suspension**	**BATCH NO.**	**I2124001**
GENERIC NAME	**Levosalbutamol Hydrochloride and Budesonide Inhalation Suspension**	**A. R. NO.**	**QC/FP/24/0939**
MFG. DATE	**06/2024**	**PRODUCT CODE**	**21**
EXP .DATE	**05/2026**	**BATCH SIZE**	**150 LTR**
SAMPLE SIZE	**70 X 2 ml**	**PACK SIZE**	**2 ML**
DATE TEST STARTED	**19/06/2024**	**DATE TEST COMPLETED**	**---**
MFG. LIC. NO.	**MB/18/1020**	**SPECIFICATION NO.**	**FPS/F059-00**

S.NO.	TEST	OBSERVATION	SPECIFICATION
1	Description	A white homogenous redispersible suspension.	A white homogenous redispersible suspension.
2	Identification A) For Levosalbutamol Hydrochloride (BY HPLC) B) For Budesonide (BY HPLC)	Complies Complies	The retention time of major peak in Sample preparation solution is concordant with standard preparation solution. The retention time of major peak in Sample preparation solution is concordant with standard preparation solution.
3	pH	4.38	3.5 to 5.0
4	Extractable Volume	2.1 ml	Not less than 2.0 ml
5	Sterility	Under test	There should be no observed microbial growth within 18 days.
6	Uniformity of Content	Average = 98.8% Minimum = 89.1% Maximum =108.4%	The preparation complies with the test if. each individual content is 85 to 115 per cent of the average content. The preparation fails to comply with the test if more than one individual content is outside these limits or if one individual content is outside, the limits of 75 to 125 per cent of the average content. If one individual content is outside the limits of 85 to 115 per cent of the average content but within the limits of 75 to 125 per cent, repeat the determination using another 20

	ANALYSED BY	CHECKED BY	APPROVED BY
Signature/ Date	Rakhi 03/07/24	03/07/24	03/07/24
	Officer-QC	**Executive–QC**	**Quality Head**

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			dosage units. The preparation complies with the test if not more than one of the individual contents of the total sample of 30 dosage units is outside 85 to 115 per cent of the average content and none is outside the limits of 75 to 125 per cent of the average content.
7	Assay (By HPLC): Each 2.0 ml respule contains: Levosalbutamol Hydrochloride IP .....1.25mg Budesonide IP.....0.5mg	 1.241mg/2 ml (99.3%) 0.494 mg/2ml (98.8%)	 1.125mg/2ml to 1.375mg/2ml (90.0% and 110.0%) 0.463mg/2ml to 0.550mg/2ml (92.5% and 110.0%)

Remark: The above sample complies / ~~does not comply~~ as per IH/ ~~IP/BP/USP~~ specification or external lab analysis report.

	ANALYSED BY	**CHECKED BY**	**APPROVED BY**
Signature/ Date	Rakhi 03/07/24	03/07/24	03/07/24
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