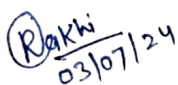
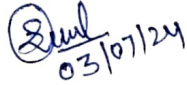



**M/S IVM PHARMACIA**Plot No. 05, Industrial Township,
Bhatoli- Kalan, Baddi (H.P.) -173205**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)****QUALITY CONTROL DEPARTMENT**

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	 03/07/24	 03/07/24	 03/07/24
	Officer-QC	Executive-QC	Quality Head



M/S IVM PHARMACIA

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

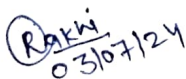
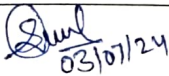
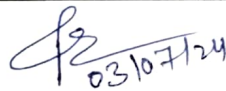
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

QUALITY CONTROL DEPARTMENT

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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 IP/ BP/ USP specification or external lab analysis report.

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