

BIODEAL PHARMACEUTICALS LIMITED

NALAGARH – ROPAR ROAD, VILLAGE SAINIMAJRA, NALAGARH, DIST.SOLAN (HP) INDIA.

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

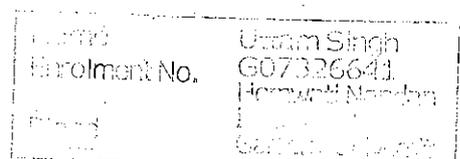
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Product Name	: ASTHACAN- 400		
Generic name	: Formoterol Fumarate & Budesonide Powder For Inhalation IP		
Product Code	: 1850-BA	A.R.No.	: FP/25/5449
Batch No.	: 2508248D	Batch Size	: 1.02 Lac.
Manufacturing Date	: 08/2025	Expiry Date	: 07/2028
Sample Quantity	: 120 Capsules	Pack Size	: 1 x 30's Capsules
Date of Sampling	: 03/10/2025	Date of Analysis	: 04/10/2025
Ref.Spec. No.	: FP/1850	Date of Release	: 13/10/2025
Mfg. LIC. No.	: MNB/06/440		

S.No.	TESTS	SPECIFICATIONS	RESULTS
01.	Description	White powder filled in size "3" capsule with clear transparent body and blue coloured cap.	White powder filled in size "3" capsule with clear transparent body and blue coloured cap.
02.	Average Weight	75.0 mg \pm 10.0 % (67.5 mg to 82.5 mg)	74.5 mg
03.	Net Content	25.0 mg \pm 10.0 % (22.5 mg to 27.5 mg)	25.0 mg
04.	Identification	In the assay, the principal peaks due to Formoterol and Budesonide in the chromatogram obtained with test solution should correspond to the principal peaks in the chromatogram obtained with the reference solution (c).	Complies
05.	Uniformity of content		
	For Formoterol Fumarate	Not more than one individual values is outside the limits 85.0% to 115.0% of the average value and none are outside the limits of 75.0% to 125.0%.	Min. : 93.9 % Max : 104.8 %
	For Budesonide	Not more than one individual values is outside the limits 85.0% to 115.0% of the average value and none are outside the limits of 75.0% to 125.0%.	Min.: 92.0 % Max.: 108.0 %
06.	Assay (By HPLC)		
	Formoterol Fumarate IP...6mcg	90.0 % to 125.0 % of the label claim.	100.7 %
	Budesonide IP.....400mcg	90.0.% to 125.0 % of the label claim.	95.4 %

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Shalikaant	Uttam Singh
Signature			
Date	13/10/2025	13/10/2025	13/10/2025

Form no.: QC013-F05-07



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07.	Microbial contamination		
	Total viable aerobic bacterial count	Not more than 100,cfu/g	10 cfu/g
	<i>E.coli</i>	To be absent/ g	Absent/ g
	<i>Staphylococcus aureus</i>	To be absent/ g	Absent/ g
	<i>Pseudomonas aeruginosa</i>	To be absent/ g	Absent / g

Remarks: The product ~~meets/does not meets~~ the specification ASTHACAN- 400 and hence ~~is/is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Charvi Kant	Uttam Singh
Signature			
Date	13/10/2025	13/10/2025	13/10/2025

Form no.: QC013-F05-07

