

BIODEAL PHARMACEUTICALS LIMITED

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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

Page No. 1 of 2

Product Name	: ASTHACAN-400		
Generic name	: Formoterol Fumarate & Budesonide Powder For Inhalation IP		
Product Code	: 1850-BA	A.R.No.	: FP/26/1163
Batch No.	: 2602084B	Batch Size	: 1.02 Lac.
Manufacturing Date	: 02/2026	Expiry Date	: 01/2029
Sample Quantity	: 120 Capsules	Pack Size	: 1 x 30's Capsules
Date of Sampling	: 27/02/2026	Date of Analysis	: 28/02/2026
Ref.Spec. No.	: FP/1850	Date of Release	: 09/03/2026
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)	74.4 mg
03.	Net Content	25.0 mg \pm 10.0 % (22.5 mg to 27.5 mg)	25.1 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 are 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.: 96.8 % Max : 102.3 %
	For Budesonide	Not more than one individual values are 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.: 96.3 % Max.: 101.7 %
06.	Assay (By HPLC)		
	Formoterol Fumarate IP...6mcg	90.0 % to 125.0 % of the label claim.	105.1 %
	Budesonide IP.....400mcg	90.0 % to 125.0 % of the label claim.	98.5 %

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Shashikant	Uttam Singh
Signature			
Date	09/03/2026	09/03/2026	09/03/2026

Form no.: QC013-F05-07

Name	Uttam Singh
Enrolment No.	G07326641
Place	Hemwati Nandan Bhuucuna Garhwal University

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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 meet~~ the specification **ASTHACAN-400** and hence ~~is/is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Shashi Kant	Uttam Singh
Signature			
Date	09/03/2026	09/03/2026	09/03/2026

Form no.: QC013-F05-07

Name: Uttam Singh
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