

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 200		
Generic name	: Formoterol Fumarate & Budesonide Powder For Inhalation IP		
Product Code	: 1849-BC	A.R.No.	: FP/26/0921
Batch No.	: 2601145E	Batch Size	: 1.02 Lac.
Manufacturing Date	: 01/2026	Expiry Date	: 12/2028
Sample Quantity	: 120 Capsules	Pack Size	: 1 x 30's Capsules
Date of Sampling	: 16/02/2026	Date of Analysis	: 17/02/2026
Ref.Spec. No.	: FP/1849	Date of Release	: 23/02/2026
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 ± 10.0 % (67.5 mg to 82.5 mg)	74.7 mg
03.	Net Content	25.0 mg ± 10.0 % (22.5 mg to 27.5 mg)	25.2 mg
04.	Uniformity of Weight	±10 % of net content.	Min: -6.0% Max: +5.1%
05.	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
06.	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. : 99.0 % Max : 101.4 %
	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.: 98.7 % Max.: 101.7 %
07.	Assay (By HPLC)		
	Formoterol Fumarate IP...6mcg	90.0 % to 125.0 % of the label claim.	112.5 %
	Budesonide IP.....200mcg	90.0 % to 125.0 % of the label claim.	106.0 %

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Rajeev Kumar	Uttam Singh
Signature			
Date	23/02/2026	23/02/2026	23/02/2026

Form no.: QC013-F05-07

Name: Uttam Singh
 Enrolment No.: G07326641
 Place: Hemwati Nandan Bhuiguna, Garhwal University

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08.	Microbial contamination		
	Total viable aerobic bacterial count	Not more than 100 cfu/g	10 cfu/g
	Total fungal count	Not more than 10 cfu/g	< 10cfu/g
	Enterobacteriaceae	Should be absent / g	Absent/ g
	Staphylococcus aureus	Should be absent / g	Absent/ g
	Pseudomonas aeruginosa	Should be absent / g	Absent / g

Remarks: The product ~~meets/does not meet~~s the specification ASTHACAN 200 and hence ~~is/is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Shivani Kapoor	Rajeev Kumar	Uttam Singh
Signature			
Date	23/02/2026	23/02/2026	23/02/2026

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Name	Uttam Singh
Enrolment No.	GU7326641
Place	Hernwati Nandan Bhuuguna Garhwal University