

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-BL	A.R.No.	: FP/25/0794
Batch No.	: 2412070E	Batch Size	: 1.04 Lac.
Manufacturing Date	: 12/2024	Expiry Date	: 11/2027
Sample Quantity	: 120 Capsules	Pack Size	: 1 x 30's Capsules
Date of Sampling	: 11/02/2025	Date of Analysis	: 11/02/2025
Ref.Doc. No.	: FP/1849	Date of Release	: 25/02/2025
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 of net content	75.0 mg \pm 10.0 % (67.5 mg to 82.5 mg)	74.0 mg
03.	Net Content	25.0 mg \pm 10.0 % (22.5 mg to 27.5 mg)	24.92 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%.	Avg. : 105.6% Min. : 100.6% Max : 113.5%
	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%.	Avg.: 103.8% Min.: 98.1% Max.:108.8%
06.	Assay (By HPLC)		
	Formoterol Fumarate IP...6mcg	90.0 % to 125.0 % of the label claim.	99.4%
	Budesonide IP.....200mcg	90.0 % to 125.0 % of the label claim.	99.4%

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Rishi	Shamkant	Meenakshi
Signature			
Date	25/02/2025	25/02/2025	25/02/2025

Form no.: QC013-F05-05

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07.	Microbial contamination		
	<i>Total viable aerobic bacterial count</i>	Not more than 100 cfu/g	40 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 of **ASTHACAN 200** and hence ~~is~~ ~~is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Ravi	Sharmaant	Meenakshi
Signature			
Date	28/02/2025	28/02/2025	25/02/2025

Form no.: QC013-F05-05