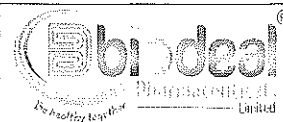


BIODEAL PHARMACEUTICALS LIMITED

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

**CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)**

Page No. 1 of 1

Product Name	: ASTHACAN 200		
Generic name	: Formoterol Fumarate and Budesonide Powder For Inhalation IP (6mcg/200mcg)		
Product Code	: 1849-B	A.R.No.	: FP/24/2882
Batch No.	: 2407180 C	Batch Size	: 1.02 Lac
Manufacturing Date	: 07/2024	Expiry Date	: 06/2027
Sample Quantity	: 120 Caps	Pack Size	: 1 x 30 Caps
Date of Sampling	: 07/08/2024	Date of Analysis	: 07/08/2024
Ref.Doc. No.	: FP/1849	Date of Release	: 12/08/2024
Mfg.LIC.No.	: MNB/06/440		

S.No.	TESTS	SPECIFICATIONS	RESULTS
01.	Description	White to off-white powder filled in size "3" capsule with clear transparent body and blue cap.	White powder filled in size "3" capsule with clear transparent body and blue cap.
02.	Average Weight of capsule	75.0 mg \pm 10.0 % (67.5 mg to 82.5 mg)	75.8 mg
03.	Net Content	25.0 mg \pm 10.0 % (22.5 mg to 27.5 mg)	24.1 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 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. : 104.1% Min. : 102.6% 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%.	Avg.: 101.5% Min.: 100.6% Max.: 102.2%
06.	Assay (By HPLC)		
	Formoterol Fumarate IP...6mcg	90.0 % to 125.0 % of the label claim.	102.4%
	Budesonide IP.....200mcg	90.0 % to 125.0 % of the label claim.	98.9%
07.	Microbial contamination		
	Total viable aerobic bacterial count	Not more than 100 cfu/g	10 cfu/g
	E.coli	To be absent/ g	Absent/ g
	Staphylococcus aureus	To be absent/ g	Absent/ g
	Pseudomonas aeruginosa	To be absent/ g	Absent / g

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

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Signature & date	<i>[Signature]</i> 12/08/2024	<i>[Signature]</i> 12/08/2024	<i>[Signature]</i> 12/08/2024