BIODEAL PHARMACEUTICALS LIMITED

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

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	:	**ASTHACAN 400**			
Generic name	:	Formoterol Fumarate & Budesonide Powder For Inhalation IP			
Product Code	:	1850-BA	A.R.No.	:	FP/24/5330
Batch No.	:	2411182B	Batch Size	:	1.04 Lac.
Manufacturing Date	:	11/2024	Expiry Date	:	10/2027
Sample Quantity	:	120 Capsules	Pack Size	:	1 x 30's Capsules
Date of Sampling	:	16/12/2024	Date of Analysis	:	16/12/2024
Ref.Doc. No.	:	FP/1850	Date of Release	:	24/12/2024
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 violet coloured cap.	White powder filled in size "3" capsule with clear transparent body and violet coloured cap.
02.	Average Weight of net content	75.0 mg ± 10.0 % (67.5 mg to 82.5 mg)	74.78mg
03.	Net Content	25.0 mg ± 10.0 % (22.5 mg to 27.5 mg)	24.9mg
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. : 94.8% Min. : 93.1% Max : 95.9%
	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.: 99.1% Min.: 97.2% Max.: 99.9%
06.	Assay (By HPLC)		
	Formoterol Fumarate IP…6mcg	90.0 % to 125.0 % of the label claim.	96.8%
	Budesonide IP……400mcg	90.0 % to 125.0 % of the label claim.	101.1%
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~~ meets the specification of **ASTHACAN 400** and hence ~~is/is not~~ of standard quality.

Responsibility	PREPARED BY	CHECKED BY	APPROVED BY
Name	Lalita	Shashikant	U Hari Singh
Signature			
Date	24/12/2024	24/12/2024	24/12/2024

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