APEX HEALTHCARE LIMITED

METAPHARMACEUTICAL

N DE LOTE: 0240925

16/09/2025

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	BISACODYL	**Page No.**	01 of 01
Standard for Release	EP	**Drug Lic. No.**	G/25/1642

Batch No.:	BIAH0040525	**Batch Quantity**	385.350 Kgs.
Mfg. Date:	MAY-2025	**Date of Sampling**	26/05/25
Exp. Date:	APR-2030	**Date of Approval**	09/06/25
A.R. No.	FP/BI/013/25	**Dispatched Quantity**	5.000 Kgs.
CAS No.	603-50-9.		

Sr. No.	Tests	Acceptance Criteria	Test Result
1.	**Appearance**	White or almost white, crystalline powder.	White crystalline powder
2.	**Solubility**	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 %), It dissolves in dilute mineral acids.	Complies
3.	**Identification (By IR)**	Infrared spectrum of test sample should be concordant with the standard spectrum of Bisacodyl.	Complies
4.	**Acidity or Alkalinity**	NMT 0.4 mL of 0.01 M HCl is required to change the colour of the indicator to red.	Complies
5.	**Related Substances**	Impurity A: NMT 0.1 % Impurity B: NMT 0.1 % Impurity C: NMT 0.5 % Impurity E: NMT 0.5 % Impurity F: NMT 0.3 % Unspecified impurity: NMT 0.10 % Total impurities: NMT 1.0 %	ND ND 0.170 % BDL BDL BDL 0.17 %
6.	**Loss on Drying**	Maximum 0.5 %	0.18 %
7.	**Sulphated Ash**	Maximum 0.1 %	0.02 %
8.	**Assay (By Potentiometrically)**	98.0 % to 101.0 % w/w (Dried Substance)	100.02 %

Remarks: The Product Complies with respects to above tests and Prescribed Standard Specification as per EP 11.6.

Name	Mr. Pankaj Pateliya	Mr. Somnath Kokate	Mr. Samir Mehta
Designation-Dept.	Executive-QC	Sr. Executive-QC	Manager-QC
Sign. /Date	08/09/25	08/09/25	08/09/25
	Prepared by	**Reviewed by**	**Approved by**

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