

Encube Ethicals Pvt.Ltd. , Plot. No.:C-1, Madkaim Industrial Estate,
Madkaim, Post : Mardol Ponda, Goa 403 404



**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

PRODUCT NAME: DEXPAN PLUS CREAM IN LAMI TUBE

GENERIC NAME	Dexpanthenol & Allantoin cream	PRODUCT CODE	401322
A.R. No.	1810F23004658	SAP BATCH	F230005184
BATCH NO.	B3FZ02	REPORT DATE	25.10.2023 17:40
MFG. DATE	Oct.23	TOTAL QTY. PACKED	47782 EA
EXP. DATE	Sep.25	ANALYTICAL QTY	46 EA
SAMPLED ON	17.10.2023	SAMPLED BY	Vishal P.
SPECIFICATION NO.	F0-300021143-00	QTY. SAMPLED	AS:20X30g, MS:03X30g, CS:20X30g, Custom:03X30g
REGISTERED ON	21.10.2023 16:34	DISPATCH QTY.	47736 EA

S.No.	TEST	RESULT	SPECIFICATION
1	Description	White homogeneous cream free from visible extraneous matter	White to off white homogeneous cream free from visible extraneous matter
2	Identification	The retention time of the major peaks due to Dexpanthenol, Allantoin, methylhydroxy benzoate, propylhydroxy benzoate, phenoxyethanol, butylated hydroxy toluene and butylated hydroxy anisole in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation under assay.	The retention time of the major peaks due to Dexpanthenol, Allantoin, methylhydroxy benzoate, propylhydroxy benzoate, phenoxyethanol, butylated hydroxy toluene and butylated hydroxy anisole in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation under assay.
3	Average net content	30 g	Not less than 30 g
4	pH	4.1	Between 3.0 and 7.0
5	Viscosity	12770 centi poise	6000 to 30000 centi poise
6	Uniformity of dosage units		
6.1	Uniformity of dosage units for Dexpanthenol	102.5 %w/w	Not less than 90.0 %w/w and not more than 110.0 %w/w of the label claim
6.2	Uniformity of dosage units for Allantoin	100.1 %w/w	Not less than 90.0 %w/w and not more than 110.0 %w/w of the label claim
6.3	Acceptance value for Dexpanthenol	1.7	The Acceptance value (AV) should be less than or equal to 15.0
6.4	Acceptance value for Allantoin	0.8	The Acceptance value (AV) should be less than or equal to 15.0
7	Assay		
7.1	Each 100 mg of Cream contains Dexpanthenol	102.0 %w/w	Not less than 90.0 %w/w and not more than 110.0 %w/w of the label claim

Remark(s): APPROVED (Sample conforms to above Specification)

Comment(s): Approved

Analysed By	Sanjyoti.S Kumbhar	Checked By	Deepak.Kerkar	Approved By	Vijaykumar.Mane
Analysed On	25.10.2023 16:11	Checked On	25.10.2023 17:24	Approved On	25.10.2023 17:40

Printed By: Sourabh.Nagap Printed On: 25.10.2023 18:24

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APPROVED



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S. No.	TEST	RESULT	SPECIFICATION
7.2	(5mg) Each 100 mg of Cream contains Allantoin (0.5mg)	99.5 %w/w	Not less than 90.0 %w/w and not more than 110.0 %w/w of the label claim
8.1	Preservatives and antioxidants content Each 100 mg Cream contains Phenoxyethanol (0.3mg)	0.299 %w/w	Not less than 0.255 %w/w and not more than 0.345 %w/w
8.2	Each 100 mg Cream contains Methylhydroxy benzoate (0.2mg)	0.20 %w/w	Not less than 0.17 %w/w and not more than 0.23 %w/w
8.3	Each 100 mg Cream contains Propylhydroxy benzoate (0.02mg)	0.020 %w/w	Not less than 0.017 %w/w and not more than 0.023 %w/w
8.4	Each 100 mg Cream contains Butylated hydroxy toluene (0.1mg)	0.098 %w/w	Not less than 0.085 %w/w and not more than 0.115 %w/w
8.5	Each 100 mg Cream contains Butylated hydroxy anisole (0.01mg)	0.0089 %w/w	Not less than 0.0085 and not more than 0.0115 %w/w
9	Microbial enumeration tests and tests for specified micro organisms		
9.1	Total aerobic microbial count	Less than 10 cfu/gm	Not more than 100 cfu/gm
9.2	Total combined yeasts and moulds	Less than 10 cfu/gm	Not more than 10 cfu/gm
9.3	Pathogens		
9.3.1	Staphylococcus aureus	Absent per 1 g	Shall be absent per 1g
9.3.2	P. aeruginosa	Absent per 1 g	Shall be absent per 1g
9.3.3	Salmonella	Absent per 10 g	Shall be absent per 10g

Remark(s): APPROVED (Sample conforms to above Specification)

Comment(s): Approved

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S.No.	TEST	RESULT	SPECIFICATION
984	Escherichia coli	Absent per 1 g	Shall be absent per 1g
985	Bile tolerant gram negative bacteria	Absent per 1 g	Shall be absent per 1g

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