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: DEXPA	N PLUS CREAM IN LAMI TUBE		
GENERIC NAME	Dexpanthenol & Allantoin cream	PRODUCT CODE	401322
A.R. No.	1810F24001189	SAP BATCH	F240001407
BATCH NO.	B4FZ01	REPORT DATE	12.03.2024 19:05
MFG. DATE	Feb.24	TOTAL QTY. PACKED	47934 EA
EXP. DATE	Jan.26	ANALYTICAL QTY	198 EA
SAMPLED ON	04.03.2024	SAMPLED BY	Abhijeet S.
SPECIFICATION NO.	F0-300021143-00	QTY. SAMPLED	MS:03X30g, AS:20X30g, CS:20X30g, Custom:03X30g, SS:152X30g.
REGISTERED ON	05.03.2024 09:52	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	31 g	Not less than 30 g
4	pH	4.3	Between 3.0 and 7.0
5	Viscosity	16170 centi poise	6000 to 30000 centi poise
6	Uniformity of dosage units		
6.1	Uniformity of dosage units for Dexpanthenol	99.9 %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	98.9 %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	0.7	The Acceptance value (AV) should be less than or equal to 15.0
6.4	Acceptance value for Allantoin	0.7	The Acceptance value (AV) should be less than or equal to 15.0
7	Assay		
7.1	Each 100 mg of Cream	99.5 %w/w	Not less than 90.0 %w/w and not more

Remark(s): APPROVED (Sample conforms to above Specification) Comment(s): Approved.

Analysed By	Kiran.Patil	Checked By	Deepak.Kerkar	Approved	By	Tamilselvan.M
Analysed On	12.03.2024 17:40	Checked On	12.03.2024 18:54	Approved	On	12.03.2024 19:05
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PRODUCT NAME: DEXPAN	PLUS CREAM IN LAMI TUBE		
GENERIC NAME	Dexpanthenol & Allantoin cream	PRODUCT CODE	401322
A.R. No.	1810F24001189	SAP BATCH	F240001407
BATCH NO.	B4FZ01	REPORT DATE	12.03.2024 19:05
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REGISTERED ON	05.03.2024 09:52	DISPATCH QTY.	47736 EA

S. No.	TEST	RESULT	SPECIFICATION
	contains Dexpanthenol (5mg)		than 110.0 %w/w of the label claim
7.2	Each 100 mg of Cream contains Allantoin (0.5mg)	98.6 %w/w	Not less than 90.0 %w/w and not more than 110.0 %w/w of the label claim
3	Preservatives and antioxidants content		
8.1	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
3.2	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
3.3	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)	0.099 %w/w	Not less than 0.085 %w/w and not more than 0.115 %w/w
3.5	Each 100 mg Cream contains Butylated hydroxy anisole (0.01mg)	0.0096 %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

Remark(s): APPROVED (Sample conforms to above Specification) Comment(s): Approved.

Analysed By	Kiran.Patil	Checked By	Deepak.Kerkar	Approved By	Tamilselvan.M
Analysed On	12.03.2024 17:40	Checked On	12.03.2024 18:54	Approved On	12.03.2024 19:05

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GENERIC NAME	Dexpanthenol & Allantoin cream	PRODUCT CODE	401322
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REGISTERED ON	05.03.2024 09:52	DISPATCH QTY.	47736 EA

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

Remark(s): APPROVED (Sample conforms to above Specification) Comment(s): Approved.

Analysed By Kiran.Patil Checked By Deepak.Kerkar Approved By Tamilselvan.M 12.03.2024 17:40 Checked On 12.03.2024 18:54 12.03.2024 19:05 Analysed On Approved On Printed By: Tamilselvan.M Printed On: 12.03.2024 19:29 Copy No.: 1 Page No.: 3 of 3 Note: This document has been generated electronically with E-Signature. Format No.: F-QC-498-04