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Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Urea EP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/050


Revision No.:
00

Effective Date
17/09/2021

Review Date
16/09/2024


Change Control No.

NA

Prepared By: 

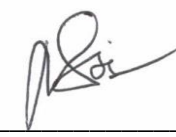
Date: 14/09/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 15/09/2021

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Approved By: 

Date: 16/09/2021

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1.0 SAMPLING LEVEL :

As mentioned in the “Sampling procedure” SOP.

2.0 SAMPLING METHOD TO BE FOLLOWED:

100% sampling to be done from each container.

3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED :

100 gm

4.0 EXPIRY :

Five years from the Date of Manufacturing.

5.0 CAS No: 57-13-6**6.0 MOLECULAR FORMULA: CH₄N₂O****7.0 MOLECULAR WEIGHT: 60.1 gm/mol.****8.0 CATEGORY: Antifungal (topical).****9.0 STORAGE: Store protected from light and moisture.****10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :**

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.**UNCONTROLLED COPY****Format No. QC/017/F/01-00****Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS

REF: EP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder or transparent crystals, slightly hygroscopic.
2.	Solubility	Very soluble in water, soluble in ethanol (96 %), practically insoluble in methylene chloride.
3.	Identification A Melting point: 132 °C to 135 °C.	To Pass test
	Identification B Infrared absorption Spectrophotometry	To Pass test
	Identification C Comparison urea CRS	To Pass test
	Identification D A white, crystalline precipitate is formed.	To Pass test
	Identification D A reddish-violet colour is produced	To Pass test
4.	Appearance of Solution	The solution is clear and colorless
5.	Alkalinity	To Pass test
6.	Biuret	Max. 0.1 %
7.	Aluminium	Max. 500 ppm
8.	Loss on drying	Max. 1.0 %
9.	Sulfated ash	Max. 0.1 %
10.	Assay (dried basis)	98.5 % - 101.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	17/09/2021	First Issuance	N A

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