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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 BP

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: 

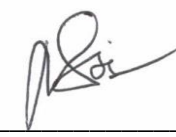
Date: 14/09/2021

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: BP

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 per cent), 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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