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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 USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/050


Revision No.:
00

Effective Date
17/09/2021

Review Date
16/09/2024

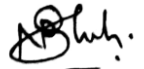
Change Control No.

NA

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Date: 14/09/2021

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Date: 15/09/2021

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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: 60.06 gm/mol.****8.0 CATEGORY: Antifungal (topical).****9.0 STORAGE: Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.****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: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	Urea occurs as colorless to white, crystals or crystalline powder. It is odorless, and has a cooling, saline taste.
2.	Solubility	It is very soluble in water.
3.	Identification A Spectroscopic Identification Tests ,Infrared Spectroscopy Identification B The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	To Pass test To Pass test
4.	Assay % (Dried basis)	98.0 % - 102.0 %
5.	Residue on Ignition	Max. 0.1 %
6.	Organic Impurities	Disregard any impurity peaks less than 0.05%.
7.	Alcohol-Insoluble Matter	Max. 0.04 %
8.	Sterility Tests	Where the label states that Urea is sterile, it meets the requirements.
9.	Bacterial Endotoxins Test	Max. 0.003 USP Endotoxin Units/mg of urea
10.		

REVISION HISTORY:

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

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