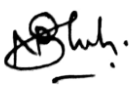



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ACPL/FP/SP/050**Revision No.:**
00**Effective Date**
17/09/2021**Review Date**
16/09/2024**Change Control No.**

NA

Prepared By: Date: 14/09/2021Name : Pankaj Patel
(QC Officer / Designee)Reviewed By: Date: 15/09/2021Name : Nilesh Shah
(Unit Head / Designee)Approved By: Date: 16/09/2021Name : Naresh Solanki
(QA/QC In Charge / Designee)**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  17/09/2021

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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: Containers—Well-closed containers.

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.

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TEST PARAMETERS AND SPECIFICATIONS

REF: JP

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, freely soluble in boiling ethanol (95%)
3.	Identification (1) A reddish purple color develops Identification (2) A white, crystalline precipitate is formed.	To Pass test To Pass test
4.	Melting point	132.5 °C to 134.5 °C
5.	Chloride	Max. 70 ppm
6.	Sulfate	Max. 100 ppm
7.	Heavy metals	Max. 20 ppm
8.	Ethanol-insoluble substances	The mass of the residue is not more than 2.0 mg
9.	Residue on ignition	Max. 0.1 %
10.	Assay % (Dried basis)	Min. 99.0 %

REVISION HISTORY:

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

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