WRSA52-1



MEDOPHARM PRIVATE LIMITED **GUDUVANCHERY**

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No: WS 01:P01

WORKING STANDARD TEST PROTOCOL

AMORICICLIN

Effective date: 22/01/15 A.R. Number:

Title

AMOXICILLIN TRIHYDRATE BP

TRI HYDRATE

B.No / Lot: M 482415 Code number: WS01

Supplier:

Manufacturing date:

Working standard Name:

Expiry date:

Manufacturer:

DSM Sinochem

Janani phalmaleuticals.

Traceability of Reference standard:

Validity on 05/03/15 B. No:

| WORKING STANDARD TEST REPORT | | | |
|------------------------------|--|------------------------------|--|
| S. No | TEST | RESULT | LIMITS |
| 1. | Description | White Crystalline powder | White or almost white crystalline powder. |
| 2. | Identification Test A): Infra-red absorption | Complies | Concordant with reference spectrum of Amoxicillin trihydrate |
| 3 | Water | 12.71 y. | 11.5% to 14.5% |
| 4 | Related substances: Any impurity | O. 06 Y. | Not more than 1.0% |
| 5 | Assay (on anhydrous) | 99 • 40 % | 95.0%,to 102.0% |
| 6 | Declared purity (as is basis) | 86.77 %. | Not applicable |
| Remai | ks: The material is recommend | ded to use as the substitute | for the reference standard. |

Intended use: Assay, Identification, dissolution and related substan Storage: Q +5.0c

Store

in a cooling casenes

Validity period:

No of vials prepared: \$4

From: 07/03/15 To: 06/03/16

PREPARED BY

. CHECKED BY

Sign: Date:

Date: (07/02)

USAGE COPY APPROVAL:

MAS

MASTER COPY APPROVAL:

Date:

22/01/15

Sign: