**FORM – 13**

**REPORT NO: 1869/APDCL/2017**

**(See Rule-46)**

**DRUGS AND COSMETICS RULES, 1945**

**CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST**

**UNDER SECTION 25(1) OF DRUGS AND COSMETICS ACT, 1940**

|  |  |  |
| --- | --- | --- |
| 1. | **Name of the Inspector from whom received** | V. Keerthana,  Drugs Inspector, Tirupati (Rural). |
| 2. | **Serial Number & date of Inspector’s memorandum** | 280917/DI/TPT-R/2017, Dated: 21/09/2017 |
| 3. | **Number of sample** | 1044/T/17 |
| 4. | **Date of Receipt** | 25/09/2017 |
| 5. | **Name of drugs purporting to be contained in the sample** | Zenpod-200  (Cefpodoxime Tablets I.P.) |
|  |  | **B.NO:** QZP-160644, **M.D:** 06/2016, **E.D**: 05/2018 |
|  |  | Manufactured in India by: Preet Remedies Pvt. Ltd.,  At: Plot No.88-A, EPIP, Phase-II,  Thana, Baddi-173205(H.P.) |
| 6. | **Conditions of seals on the package** | SEALS INTACT AND IDENTICAL WITH THE SPECIMEN SEAL. |
| 7. | **Result of test or analysis with protocols of the test applied** | As per I.P-2014 |
|  | **Composition** | Each film coated tablet contains:  Cepodoxime Proxetil I.P.  Equivalent to Cefpodoxime 200 mg.  Colour : Ponceau 4R & Titanium Dioxide IP |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTS DONE** | **FOUND** | **CLAIM** | **LIMITS** | **Complies/ Not Complies** |
| **Quantity Received** | 01x04x10 Tablets | 1x4x10 Tablets | -- | -- |
| **Description** | Red coloured, elongated, biconvex, uniform tablets with a score on one side. | -- | -- | Complies |
| **Identification** | Positive for Cefpodoxime as per STP | -- | -- | Complies |
| **Average Weight** | 0.5942 gm | -- | -- | -- |
| **Uniformity of Weight** | Complies as per I.P | -- | -- | Complies |
| **Test for Dissolution** | **Does not Complies**  as per I.P | -- | NLT 70% | **Not Complies** |
| **Assay for Cefpodoxime**  **Ref: as per STP** | 198.44 mg | 200 mg | 180 – 220 mg | Complies |

In the opinion of the undersigned the sample referred to above is of **NOT OF STANDARD QUALITY** as defined in the Drugs and Cosmetics Act, 1940 and rules there under for the reasons given below:

**“The Sample fails to meet the Dissolution Test as per I.P-2014.”**

Date: 27 /10/2017 GOVERNMENT ANALYST

To:

The Drugs Inspector, Tirupati (Rural), Chittoor District.

Copy to The Director General, D&C, Drugs Control Administration, A.P., Guntur.

Copy to The Drugs Controller General (India), New Delhi.

**GOVERNMENT OF ANDHRA PRADESH**

**DRUGS CONTROL ADMINISTRATION**

**Laboratory No: 1044/T/2017**, **Date: 27/10/2017**.

**Sub**: Drugs and Cosmetics Act, 1940 and Rules Made there under – Analysis of Sample of Cefpodoxime Tablets IP, **B.NO:** QZP-160644, **M.D:** 06/2016, **E.D**: 05/2018. Manufactured by: Preet Remedies Pvt.Ltd., At: Plot No.88-A, EPIP, Phase-II, Thana, Baddi-173205(H.P.).

**Ref**: Sl. No. of Memorandum 280917/DI/TPT-R/2017, Dated: 21/09/2017 of The Drugs Inspector, Tirupati (Rural), Chittoor Dist.

-----------------

The sample received vide reference cited has been analysed and result of the same is enclosed.

GOVERNMENT ANALYST

To:

The Drugs Inspector, Tirupati (R), Chittoor Dist.

Copy to The Director General, D&C, Drugs Control Administration, A.P., Guntur.

Copy to The Drugs Controller General (India), New Delhi.