**REPORT NO: 1852 /APDCL/2017**

**FORM – 13**

**(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** | 300917/DI/TPT-R/2017, Dated: 21/09/2017 |
| 3. | **Number of sample** | 1046/T/17 |
| 4. | **Date of Receipt** | 25/09/2017 |
| 5. | **Name of drugs purporting to be contained in the sample** | Clavogard-375  (Amoxycillin and Potassium Clavulanate Tablets IP)) |
|  |  | **B.NO:** BT161033, **M.D:** 12/2016, **E.D:** 05/2018 |
|  |  | Manufactured by: Theon Pharmaceuticals Ltd,  Vill. Saini Majra, Tehsil Nalagarh, Distt. Solan (H.P)-174 101. |
| 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  Each film coated tablet contains  Amoxycillin Trihydrate IP eq. to Amoxycillin 250 mg  Potassium Clavulanate Diluted IP eq. to  Clavulanic Acid 125 mg Excipients q.s.  Colour: Titanium Dioxide IP |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTS DONE** | **FOUND** | **CLAIM** | **LIMITS** | **Complies/ Not Complies** |
| **Quantity Received** | 1x7x6 Tablets | 1x7x6 Tablets | -- | -- |
| **Description** | White, elongated, biconvex, coated, uniform tablets with score on one side. | -- | -- | Complies |
| **Identification** | Positive for  Amoxycillin and Clavulanic Acid as per I.P | -- | -- | Complies |
| **Average Weight** | 0.9462gm | -- | -- | -- |
| **Uniformity of Weight** | Complies as per I.P | -- | -- | Complies |
| **Test for Dissolution** | **Does not Complies** for Amoxycillin as per I.P | -- | NLT 85% | **Not Complies** |
| **Does not Complies** for Clavulanic Acid as per I.P | -- | NLT 80% | **Not Complies** |
| **Assay for Amoxycillin**  **Assay for Clavulanic Acid**  **Ref: as per IP** | 208.16 mg  82.29 mg | 250 mg  125 mg | 225 – 300 mg  112.5 – 150 mg | **Not Complies**  **Not 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 in Dissloution Test and Label Claim (Assay) for Amoxycillin and Clavulanic Acid**

**as per I.P-2014.”**

Date: /10/2017 GOVERNMENT ANALYST

To:

The Drugs Inspector, Tirupati (Rural).

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

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