**FORM – 13**

**REPORT NO: 1940/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** | P.Mangamma,  Drugs Inspector, Guntur (Urban). |
| 2. | **Serial Number & date of Inspector’s memorandum** | 171106/DI/GNT (U), Dated: 02/11/2017 |
| 3. | **Number of sample** | 1228/T/17 |
| 4. | **Date of Receipt** | 03/11/2017 |
| 5. | **Name of drugs purporting to be contained in the sample** | Chymoral forte Tablets |
|  |  | **B.NO:** WBA96049, **M.D:** 03/2016, **E.D**: 02/2018 |
|  |  | Manufactured in India by: Windlas Biotech Limited, Plant-2, Khasra No.141 to 143&145,  Mohebawala Indl.Area, Dehradun-248 110, India. |
| 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 enteric coated tablet contains:  1,00,000 Armour Units of Enzymatic Activity. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTS DONE** | **FOUND** | **CLAIM** | **LIMITS** | **Complies/ Not Complies** |
| **Quantity Received** | 01x03x20 Tablets | 1x3x20 Tablets | -- | -- |
| **Description** | Red coloured,circular, biconvex tablets with improper coating. | -- | -- | Complies |
| **Identification** | Negative for Chymotrypsin as no peak was observed at 281mm as per E.P | -- | -- | **Not Complies** |
| **Average Weight** | 0.3435 gm | -- | -- | -- |
| **Disintegartion Test** | **Does not Complies**  as per I.P | -- | -- | **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 the Identification test as per E.P and also fails in Disintegration test as per IP.”**

Date: 07/11/2017 GOVERNMENT ANALYST

To:

The Drugs Inspector, Guntur (Urban), Guntur 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: 1228/T/2017**, **Date: 03/11/2017**.

**Sub**: Drugs and Cosmetics Act, 1940 and Rules Made there under – Analysis of Sample of Cefpodoxime Tablets IP, **B.NO:** WBA96049, **M.D:** 03/2016, **E.D**: 02/2018. Manufactured by: Windlas Biotech Limited, Plant-2, Khasra No.141 to 143&145, Mohebawala Indl.Area, Dehradun- 248 110, India.

**Ref**: Sl. No. of Memorandum 171106/DI/GNT (U), Dated: 02/11/2017 of The Drugs Inspector, Guntur (Urban), Guntur District.

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

GOVERNMENT ANALYST

To:

The Drugs Inspector, Guntur (Urban), Guntur District.

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