**FORM – 13**

**REPORT NO: 1942/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** | S. Jaya Ramudu  Drugs Inspector, Markapur. |
| 2. | **Serial Number & date of Inspector’s memorandum** | SA/37/DI/MKP/2017 Dated: 31/10/2017 |
| 3. | **Number of sample** | 1229/T/17 |
| 4. | **Date of Receipt** | 03/11/2017 |
| 5. | **Name of drugs purporting to be contained in the sample** | ULTRACET Tablets  (Acetaminophen and Tramadol Hydrochloride Tablets USP) |
|  |  | **B.NO:** N 548, **M.D:** 01/2017, **E.D**: 12/2018 |
|  |  | Made in India by: M/s Johnson & Johnson Private Limited, L.B.S Marg, Mulund (West),  Mumbai – 400 080.  Mfd. At: M/s Encore Healthcare Pvt. Ltd., Plot No. D-5,  M.I.D.C., Industrial Area, Paithan,  Aurangabad – 431 148. |
| 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 USP |
|  | **Composition** | Each film coated tablet contains:  Acetaminophen IP 325 mg  Tramadol Hydrochloride IP 37.5mg  Colour: Yellow Oxide of Iron  Tiatanium Dioxide IP |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTS DONE** | **FOUND** | **CLAIM** | **LIMITS** | **Complies/ Not Complies** |
| **Quantity Received** | 01x05X15 Tablets | 1x5x15 Tablets | -- | -- |
| **Description** | Pale yellow coloured, elongated, biconvex and coated tablets with brown coloured spots and a score on one side. | -- | -- | Complies |
| **Identification** | Positive for Acetaminophen as per USP | -- | -- | Complies |
| **Negative** for Tramadol Hydrochloride  **Does not complies as per USP** | -- | -- | **Not Complies** |
| **Average Weight** | 0.4828 gm | -- | -- | -- |
| **Uniformity of Weight** | Complies as per U.S.P | -- | -- | Complies |
| **Assay: Ref as per USP**  **Acetaminophen**  **Tramadol Hydrochloride** | 246.1mg  **NIL** | 325mg  37.5mg | 292.5 – 357.5mg  33.75 - 41.25mg | **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 to meet the Identification test for Tramadol Hydrochloride as per USP and**

**also fails to meet the label claim (assay) of Acetaminophen and Tramadol Hydrochloride as per USP"**

Date: 07/11/2017

GOVERNMENT ANALYST

To:

The Drugs Inspector, Markapur, Prakasam 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: 1229/T/2017**, **Date: 03/11/2017**.

**Sub**: Drugs and Cosmetics Act, 1940 and Rules Made there under – Analysis of Sample of

Acetaminophen and Tramadol Hydrochloride Tablets USP **Ultracet**, **B.NO:** N 548,

**M.D:** 01/2017, **E.D**: 12/2018. Made in India by: M/s Johnson & Johnson Private Limited, L.B.S Marg, Mulund (West), Mumbai – 400 080. and Mfd. At: M/s Encore Healthcare Pvt. Ltd., Plot No. D-5, M.I.D.C., Industrial Area, Paithan, Aurangabad – 431 148.

**Ref**: Sl. No. of Memorandum SA/37/DI/MKP/2017 Dated: 31/10/2017 of The Drugs Inspector, Markapur, Prakasam 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, Markapur, Prakasam District.

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