**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** | Abid Ali Shaik,  Drugs Inspector, Kurnool (Urban). |
| 2. | **Serial Number & date of Inspector’s memorandum** | 19/AUG/DI/KNL-Urban/2017, Dated: 29/08/2017 |
| 3. | **Number of sample** | 880/T/17 |
| 4. | **Date of Receipt** | 04/09/2017 |
| 5. | **Name of drugs purporting to be contained in the sample** | Pantacorn-40 Tab  (Pantoprazole Tablets I.P.) |
|  |  | **B.NO:** BT-675, **M.D:** 09/2016, **E.D**: 08/2018 |
|  |  | **Mfg. By:** Boffin Biotech Pvt. Ltd.  Vill Behral, Paonta Sahib,  Distt. Sirmour – 173025 (H.P.)  **Marketed by:** Bioshine Healthcare Pvt. Ltd.  (An ISO 9001:2008 Certified Co.)  34/428, Sector-3, Pratap Nagar Sanganer,  Jaipur – 302033(Rajasthan)  Email : bioshinehealthcare@gmail.com |
| 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:  Pantaprazole Sodium IP  Eq. to Pantoprazole 40 mg.  Excipients q.s.  Colour : Titanium Dioxide IP & Yellow oxide of iron |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTS DONE** | **FOUND** | **CLAIM** | **LIMITS** | **Complies/ Not Complies** |
| **Quantity Received** | 01x05x10Tablets | 1x5x10 Tablets | -- | -- |
| **Description** | Pale yellow coloured, circular, biconvex with one side score, coated and uniform tablets. | -- | -- | Complies |
| **Identification** | Positive for Pantoprazole  as per IP. | -- | -- | Complies |
| **Average Weight** | 0.1764 gm | -- | -- | -- |
| **Uniformity of Weight** | Complies as per I.P | -- | -- | Complies |
| **Test for Dissolution** | **Does not Complies**  as per I.P | -- | NLT 80% | **Not Complies** |
| **Assay for Pantoprazole**  **Ref: as per IP** | 37.26 mg | 40 mg | 36 - 44 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: 06/11/2017

GOVERNMENT ANALYST

To:

The Drugs Inspector, Kurnool (Urban), Kurnool Dist.

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: 880/T/2017**, **Date: 29/08/2017**.

**Sub**: Drugs and Cosmetics Act, 1940 and Rules Made there under – Analysis of Sample of Cefpodoxime Tablets IP, **B.NO:** BT-675, **M.D:** 09/2016, **E.D**: 05/2018. Manufactured by: Boffin Biotech Pvt. Ltd., Vill Behral, Paonta Sahib, Distt. Sirmour – 173025 (H.P.)

Marketed by: Bioshine Healthcare Pvt. Ltd. (An ISO 9001:2008 Certified Co.), 34/428, Sector-3, Pratap Nagar Sanganer, Jaipur – 302033 (Rajasthan),

Email: bioshinehealthcare@gmail.com

**Ref**: Sl. No. of Memorandum 19/AUG/DI/KNL-Urban/2017, Dated: 29/08/2017 of The Drugs Inspector, Kurnool (Urban), Kurnool Dist.

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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, Kurnool (Urban), Kurnool Dist.

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