Central Drugs Testing Laboratory, Indore
CDSCO Bhawan GPO Square, Residency Area A. B Road Indore(MP)-452001
Phone No.
Email:cdtl.indore@cdsco.nic.in

FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. **Name of Inspector from whom received** : Mr. LOKESH CHOURE ,Drugs Inspector
   Mr. LOKESH CHOURE
   SUBZONAL OFFICE (Indore) Indore (India) - 452001
2. **Serial No. and date of Inspector's memorandum** : LS/SZI/LC/2024/016/198 , 28-FEB-2024
3. **Number of Sampie** : LS/SZI/LC/2024/016
4. **Date of receipt** : 28-FEB-2024
5. **Names of drugs purporting to be contained in the sample** : Atorvastatin Tablets I.P. 20 mg

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/NA/2023-24/41184	IND/LS/2023-24/6	5202323	01-Nov-2023	31-Oct-2025	KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LIMITED, Plot No.14, II Phase,Peenya,Bengaluru-560058

6. **Condition of seals on** [the packet or on portion of sample or container] : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. **Result of test or analysis with protocols or test or analysis applied** : **Please see below**

SR. No. 110
Date 22.03.2024
Rishi

Date of Testing : From 05-Mar-2024 To 22-Mar-2024

COMPOSITION : Atorvastatin Calcium IP eq. to Atorvastatin 20 mg
Excipients q.s.

Protocol Applied : As per IP

Sr No.	Test Name	Result	Limits
1	Description	Green coloured, round Shaped , biconvax film coated tablets supplied in aluminium foil blister pack.	NA
2	Identification	Gives positive results for Atorvastatin calcium .	NA
3	Uniformity of weight	Complies	NA
4	Test for Dissolution	Does not comply. Average drug release is 37.09 % of claim .	NLT 70 % of Claim
5	Related Substances	Complies	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Atorvastatin Calcium equivalent to Atorvastatin	19.5 mg/ tablet	20 mg/ tablet	97.5	90 % to 110 %	As per IP

In the opinion of the undersigned the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The Sample does not conform to IP with respect to the test for Dissolution.

GOVERNMENT ANALYST

Date: 22-MAR-2024

अरिजित साहा / Arijit Saha
सरकारी विश्लेषक Government Analyst
केंद्रीय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory
भारत सरकार / Govt. of India
सीडीएससीओ भवन, जीपीओ स्क्वायर, CDSCO Bhawan, GPO Square
एबी रोड, इंदौर (एमपी)-452001 AB Road, Indore (M.P.)-452001

---------- END OF REPORT ----------

भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
केन्द्रीय औषधि मानक नियंत्रण संगठन
उप-खंड इंदौर
कार्यालय उप औषधि नियंत्रक (भारत),
सीडीएससीओ भवन, जीपीओ चौराहा, रेजीडेंसी क्षेत्र,
ए.बी. रोड इंदौर - ४५२००१
ई-मेल: indoresubzone@cdsco.nic.in
0731-2707966

सत्यमेव जयते

CDSCO

ISO 9001:2015 Cer

GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
SUB ZONE
O/o The Deputy Drugs Controller (India),
CDSCO BHAWAN
GPO square, Residency Area
A.B. Road, Indore -452001
Email: indoresubzone@cdsco.nic.in
Ph. No. 0731-2707966

Registered Post

Ref.: No. SZI/2024/LC/NSQ/Atovastatin Tablets/ Karnataka/006/283 Date: 26/03/2024

To

Dr. Uday Kumar Chourasia,
Chief Medical Officer, Drug Store,
Employee State Insurance Corporation ESIC, Model Hospital,
ODC, Nanda Nagar, Indore, Madhya Pradesh-452011

Subject: - The Drug sample no. LS/SZI/LC/2024/016 of Drug Atorvastatin Tablets I.P. 20 mg, Batch No. 5202323, D/M: 11/2023, D/E: 10/2025, manufactured by : KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LIMITED, Plot No.14, II Phase, Peenya, Bengaluru-560058 declared as "Not of Standard Quality"- For necessary action -Regarding.

Reference: Test Report in Form 13 issued by Government Analyst, Central Drugs Testing Laboratory (CDTL), Indore vide Test Report No. IND/LS/2023-24/6, Dated 22.03.2024 (Copy Enclosed).

Sir,

The subject drugs sample was drawn by the undersigned under section 23 of the Drugs & Cosmetics Act, 1940 on 28.02.2024 from Drug Store, Employee State Insurance Corporation ESIC, Model Hospital, ODC, Nanda Nagar, Indore, Madhya Pradesh-452011 and was sent to the Government Analyst for test and analysis at CDTL, Indore. The sample was declared as **"Not of Standard Quality"** by the Government Analyst, Central Drugs Testing Laboratory, Indore vide reference cited above that **"The sample does not confirm to IP with respect to the test for Dissolution."**

As required under Section 25(2) of Drugs & Cosmetics Act 1940, please find enclosed original copy of above mentioned Test Report.

Since the subject cited Drug has been declared as **Not of Standard Quality,** you are, therefore, required to disclose the name/address and other particulars of the firm/person from whom, the said drug was obtained as required under Section 18-A of Drugs & Cosmetics Act 1940 and furnish the relevant documents (attested copies of bills/invoice etc.) as required under Section 18-B of the said Act to the undersigned within 7 days from the date of receipt of this letter.

To, Payram for Urgent action.
3647
30/03/2024.

You are directed to stop further usage of subject cited **Not of Standard Quality** dru with immediate effect.

This is for your information and necessary action in the matter.

Yours faithfully

Loresh Choure
Drugs Inspecto
CDSCO Sub Zone Indor

Encl: -

Original copy of test report bearing test report no IND/LS/2023-24/6, Dated 23.202 of subject cited batch.

Copy to:

1. KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS LIMITED, Plot No.14, I Phase, Peenya, Bengaluru-560058
2. The Deputy Drugs Controller (India), CDSCO Sub Zone Indore, CDSCO BHAWA GPO square, Residency Area, A.B. Road, Indore -452001