Central Drugs Testing Laboratory - Mumbai
CDSCO, DGHS, Ministry of Health & Family Welfare, Govt. Of India, Zonal FDA Bhawan,
Belasis Road, GMSD Compound Mumbai Central (India) - 400008
Fax : 022-23099240 Phone No.022-23002309, 022-23002138
Email:cdtlmumbai@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. Manoj Nilkant Gambhire ,Drugs Inspector West Zone -1 Mumbai CDSCO (West Zone-1) 4th Floor Zonal FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central,Mumbai-400008 (India)
2. **Serial No. and date of Inspector's memorandum** : 3-4/MG/CDTL-Mum/WZ/2025/999 , 26-AUG-2025
3. **Number of Sample** : LS/WZ/MG/2025/28
4. **Date of receipt** : 26-AUG-2025
5. **Names of drugs purporting to be contained in the sample** : Vildagliptin and Metformin Tablets IP

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/MUM/2025-26/0310	MUM/LS/2025-26/804	VMHT1315	05/2025 04/2027	NA	Unicure India Ltd, C-21, 22 & 23, Sector-3, Noida-201301, Distt. Gautam Budh Nagar (U. P.)

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**

Date of Testing : From 25-Nov-2025 To 15-Dec-2025

COMPOSITION : Each film coated tablet contains: Vildagliptin IP 50 mg
Metformin Hydrochloride IP 500 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Peach coloured oblong biconvex film coated tablet, scored on one side packed in alu blister strip supplied in paper carton.	NA
2	Identification	Gives positive tests for Vildagliptin and Metformin Hydrochloride	NA

3	Dissolution	Does not comply	NLT 80 % of labelled claim
	For Vildagliptin	Stage - S1 : (Unit 1: 36.15 %; Unit 2 : 39.44 %; Unit 3 : 35.12 %; Unit 4 : 38.30 %; Unit 5 : 41.61 %; Unit 6 : 39.89 %) None of the Unit is Q+5 %	NLT Q + 5 % (85 %)
		Stage -S2 : (Unit 1 : 34.2 %; Unit 2 : 30.8 %; Unit 3 : 33.8 %; Unit 4 : 32.5 %; Unit 5 : 30.8 %; Unit 6 : 36.5 %) (i) Average Drug Release of 12 units (S1+S2) : 35.8 % of claim (ii) All units less than 65.0 % of claim (Q-15 %)	Average NLT of 12 units (NLT Q-80 %) and no unit less than Q – 15 %
		Stage - S3 : (Unit 1: 32.8 %; Unit 2 : 32.4 %; Unit 3 : 28.8 %; Unit 4 : 35.8 %; Unit 5 : 31.1%; Unit 6 : 30.2 %; Unit 7 : 33.9 %; Unit 8 : 30.4 %; Unit 9 : 34.6 %; Unit 10 : 31.5 %; Unit 11: 34.2 %; Unit 12 : 34.5 %) (i) Average Drug Release of 24 units (S1+S2+S3) : 34.14 % of claim (ii) All 24 units less than 65.0 % of claim (Q-15 %) and 55.0 % of claim (Q-25 %)	Average of 24 units NLT Q- 80 % and NMT 2 units less than Q – 15 %, no unit less than Q – 25 %
	For Metformin Hydrochloride	Stage - S1 : (Unit 1 : 58.89 %; Unit 2 : 52.82 %; Unit 3 : 53.05 %; Unit 4 : 62.76 %; Unit 5 : 54.01 %; Unit 6 : 56.86 %) None of the Unit is Q+5%	NLT Q + 5 % (85 %)
		Stage -S2 : (Unit 1 : 54.6 %; Unit 2 : 58.5 %; Unit 3 : 60.4 %; Unit 4 : 55.9 %; Unit 5 : 64.9 %; Unit 6 : 55.8 %) (i) Average Drug Release of 12 units (S1+S2) : 57.37 % of claim (ii) All units less than 65.0 % of claim (Q-15 %)	Average NLT of 12 units (NLT Q-80 %) and no unit less than Q – 15 %
		Stage - S3 : (Unit 1 : 53.5 %; Unit 2 : 56.9 %; Unit 3 : 55.5 %; Unit 4 : 60.1 %; Unit 5 : 58.4 %; Unit 6 : 60.1 %; Unit 7 : 59.3 %; Unit 8 : 58.1 %; Unit 9 : 52.8 %; Unit 10 : 52.5 %; Unit 11 : 60.2 %; Unit 12 : 55.5 %) (i) Average Drug Release of 24 units (S1+S2+S3) : 56.90 % of claim (ii) All 24 units less than 65.0 % of claim (Q-15 %) (iii) Out of 24 units 03 units found less than 55.0 % of claim (Q-25 %)	Average of 24 units NLT Q- 80 % and NMT 2 units less than Q – 15 %, no unit less than Q – 25 %
4	Uniformity of weight	Complies	NA
5	Average weight	726.16 mg	NA

Assay

Sr.No	Ingredient Name	Found mg/ tablet	Claim mg/ tablet	% of claim	Limits	Procedure / Method
1	Vildagliptin	39.12	50.0	78.24	95.0 - 105.0 %	HPLC
2	Metformin Hydrochloride	496.83	500.0	99.366	95.0 - 105.0 %	HPLC

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 received does not conform to I.P. 2022 with respect to the test for "Dissolution" (Vildagliptin and Metformin Hydrochloride) and "Assay" of Vildagliptin .

Note : Other tests could not be done due to technical reason.

ए. एस. परांजपे / A. S. PARANJPE
वरिष्ठ वैज्ञानिक सहायक एवं सरकारी विश्लेषक
SENIOR SCIENTIFIC ASSISTANT & GOVT. ANALYST
केंद्रीय औषध परीक्षण प्रयोगशाला
CENTRAL DRUGS TESTING LABORATORY
मुंबई / MUMBAI
GOVERNMENT ANALYST

Date: 18-DEC-2025

Report in the red colored paper indicates the sample is not of standard quality.

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

भारत सरकार
केन्द्रीय औषध मानक नियन्त्रण संगठन
पश्चिम खण्ड
स्वास्थ्य सेवा महानिदेषालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
चौथा तल, झोनल एफ.डी.ए. भवन
जी.एम.एस.डी. कम्पाउंड, बेलासीस रोड
मुम्बई सेन्ट्रल, मुम्बई–400008
ISO 9001:2015 Certified

सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
WEST ZONE
Directorate General of Health Services
Ministry of Health and Family Welfare
4th Floor, Zonal FDA Bhawan, GMSD Compound
Bellasis Rd, Mumbai Central, Mumbai-400 008
Tel: (+91-22) 2300 2215, 2300 2279
Fax : (+91-22) 2300 2271
Email: wzmumbai@cdsco.nic.in

By Regd./Speed Post

F. No.: 4-1/WZ-2025/MG/**1793** **Date**: 22.12.2025

To

Mr. Datir R. B. (Pharmacist)
Maharashtra Employees State Insurance Society Hosp.
Road No. 33, Wagle estate, Thane (W)- 400604,
Maharashtra
Ph No: 9890593464
Email Id: rahul1pharma@gmail.com

Subject: Drug reported as **Not of Standard Quality** Drug: Vildagliptin and Metformin Tablets IP, B. No. VMHT1315, D/M: 05/2025, D/E: 04/2027, Mfg by M/s Unicure India Ltd,C-21, 22 & 23, Sector-3, Noida-201301, Distt. Gautam Budh Nagar (U.P)- regarding.

Sir,

The subject drug sample was drawn by undersigned Drugs Inspector of this office from your premises i.e. M/s Maharashtra Employees State Insurance Society Hosp., Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra on 25.08.2025 under section 23 of the Drugs & Cosmetics Act, 1940 and Rules made thereunder and was sent for test and analysis at Central Drugs Testing Laboratories (CDTL), Mumbai.

The subject drug has been declared as "**Not of Standard Quality"** by Government Analyst, Central Drugs Testing Laboratory, Mumbai vide test report No. MUM/LS/2025-26/804 dated 18.12.2025 in Form 13 as **the sample does not conform to I.P. 2022 with respect to test for "Dissolution" (Vildagliptin and Metformin Hydrochloride) and "Assay" of Vildagliptin**. A original copy of test report enclosed herewith.

As per Section 18 a(i) of the Drugs & Cosmetics Act,1940, no person shall himself or by any other person on his behalf manufacture for sale (or for distribution), or sell or stock or exhibit (or offer) for sale, or distribute any drug which is not of standard quality.

You are required to disclose the name/address and other particulars of the person/firm from whom subject drug was obtained as required under Section 18-A of the Drugs and Cosmetics Act 1940 and furnish the relevant documents as required under Section 18-B of the Drugs and Cosmetics Act 1940. Further, you are requested not to use subject batch of the Drug and recall the same in the greater public interest.

You are also required to submit the following information along with certified copies of the requisite documents as required under section 22(1)(cca) of the Drugs & Cosmetics Act,1940.

1. The quantity of the subject drug procured and used.
2. The source from whom subject Drug was obtained with relevant copies of documents, purchase invoice etc.
3. Further, directed not to use subject batch of the Drug and recall the same in the public interest and intimate the hold/recall the stock (if any) to this office.

A copy of original report of Government analyst, Central Drugs Testing Laboratories (CDTL), Mumbai in Form 13 is enclosed herewith as required under section 25(2) of the Drugs & Cosmetics Act, 1940.

You are required to furnish the aforesaid information within 7 days for taking further action in this regard.

You are requested to acknowledge the receipt.

Thank You,

MANOJ NILKANT GAMBHIRE

Digitally signed by MANOJ NILKANT GAMBHIRE
Date: 2025.12.22 13:43:05 +05'30'

(Dr. Manoj Nilkant Gambhire)
Drugs Inspector
CDSCO, West Zone, Mumbai

Enclosure: Copy of Government Analyst report No. MUM/LS/2025-26/804 dated 18.12.2025 in Form 13

Copy:

1) The Medical superintendent, Maharashtra Employees State Insurance Society Hosp. Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra - **For giving necessary directions to stop further use of subject NSQ batch of the Drugs & its recall**
2) M/s Unicure India Ltd,C-21, 22 & 23, Sector-3, Noida-201301, Distt. Gautam Budh Nagar (U.P)- To stop further sale & distribution of subject NSQ Drug & for its immediate recall
3) Deputy Drugs Controller (I), CDSCO (WZ), Mumbai