

FORM 13

[See Rule 46]

Certificate of Analysis by Government Analyst under section 25(1) of the Drugs & Cosmetics Act, 1940..

1. Name of the Drug Inspector from whom received: Amit Mahajan, DCO: Samba(Bari Brahmana)
2. Serial No. and date of Inspector's memorandum: DIJ/Z-IV/S/02-26/19; Dated: 21.02.2026
3. Number of Sample: 1X05X10 Tabs.
4. Date of receipt: 23.02.2026
5. Name of drug purporting to be contained in the sample: Vildagliptin and Metformin Hydrochloride IP
6. Condition of seals on the packet or on portion of sample or container:-The seals are intact and inconformity with specimen impression used by the Inspector on memo received separately .
7. Result of test or analysis with protocols of test or analysis applied.

Labelling

Rx

Vildagliptin 50mg and Metformin 1000mg Tablets
Vilgllp-M 1000

ESI SUPPLY
NOT FOR SALE

Composition:

Each uncoated tablet contains:

Vildagliptin.....50mg
Metformin Hydrochloride IP.....1000mg

B.No.: EVMT-2607
M.D.: JAN.2026
E.D.: DEC.2027
M. L. No.: TN00002453

Mfd. By: HEAL Heal(India)Laboratories Pvt. Ltd. 197/1, Periyapalayam Road, Manjankaranai Chennai 601102, Tamil Nadu.

For the general standard, method given in the IP-2022 under the monograph 'Tablets' has been followed:

1. Description: Blister pack of 10's containing white, oblong shaped, biconvex, uncoated tablets with bisecting impression on one side and smooth surface on the other side.
2. Average weight of tablet: 1.212g
3. Uniformity of weight: Complies [Limit: $\pm 5\%$]
4. Disintegration test: 12 minutes 53 seconds (IP Limit: NMT 15 minutes)
5. ASSAY:

I) Vildagliptin [As per IP-2022]

The content of Vildagliptin in the given tablets of average weight 1.212g is found to be 48.60mg viz. 97.21% of the label claim.

II) Metformin Hydrochloride IP [As per IP-2022]

The content of Metformin Hydrochloride in the given tablets of average weight 1.212g is found to be 983.9mg viz 98.59% of the label claim.

[Limit: 90-110 %]

In the opinion of the undersigned the sample referred to above is of standard quality as defined in the Drugs & Cosmetics Act, 1940 and rules there under _____ is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and rules there under reason given below:-

NOTE: The sample passes for the tests applied as above for the sample portion received. However, the sample is found misbranded as "Vildagliptin" in composition have not been shown official as per IP 2022.

NO: CFBLM/2025-26/1748
Dated: 26/02/2026

Handwritten Signature
Government Analyst
Smt. MONIKA PAROITA
R. Pharma
Government Analyst
J&KUT