

FORM 13
(See rule 46)

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



1. Name of Inspector from whom received : Lalruatdika varte,
Drugs Inspector,
Office of the Chief Medical Officer,
Kolasib, Mizoram – 796 082
2. Serial No. and date of Inspector's Memorandum : KLB/24/2022/DRUGS
Dated Kolasib, the 23rd September, 2022
3. Number of Sample : Nil.
4. Date of Receipt : 06/10/2022
5. Name of Drugs purporting to be contained in the sample :

Name of the Drugs	Batch No.	Mfg. Date	Exp. Date	Mfd. By:-
KOOCAL-500 Tablets (Calcium with Vitamin D Tablets IP)	TG21-2565	10/2021	03/2023	M/s Athens Life Sciences, Mauza Rampur Jattan, Nahan Road, Kala Amb, Distt. Sirmour, H.P. – 173 030

6. Condition of seals on the packet or on portion of sample or container : Seals were intact and identical with
the specimen impression of the seal
received from the Drugs Inspector.
7. Result of test or analysis with protocols of test or analysis applied : Please see below :

Method: I.P. 2018

Description : White, elongated and bi-convex shaped, one side scored, film coated tablets in
blister pack.

Identification : Gives positive test for Calcium and Vitamin D₃.

Average weight of Tablet : 1.44601 g

Uniformity of weight : Complies.

Dissolution : Complies.
{Individual percent release of entire six units under test at "S1" found above D+5%,
where "D" is 70% specified in the individual monograph. (Release found from min.
84.5% to max. 94.8%)}
{Average release of Calcium: 89.1% of claim ; (Limit: Not less than 70% of claim)}

Assay

Content of	Found/Tablet	Claim/Tablet	% of Claim	Limit (%) of Claim
Calcium Carbonate eq. to Elemental Calcium	500.94 mg	500.0 mg	100.2	90.0-110.0
Vitamin D ₃	21.12 I.U	250 I.U	8.44	Not less than 90

Date of Testing: 18/10/2022, 15/11/2022, 29/11/2022 & 05/12/2022 to 06/12/2022

No. RDTL/Report/S/2022-2023/A.N.23137/ 7654-7656


Date: 08/12/2022

In the opinion of the undersigned the sample referred to above is **Not of Standard Quality** as defined in the Drugs
& Cosmetics Act, 1940, and rules thereunder for the reasons given below:

The sample does not conform to I.P. with respect to the test for Assay of "Vitamin D₃"

Dated: 08/12/2022

Report in red coloured paper indicates that the sample is "Not of Standard Quality".


(Arun Kumar Das)
Government Analyst
RDTL, Guwahati
Arun Kumar Das
Government Analyst
R.D.T.L., Guwahati-22