FORM 13

(See rule 46)

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

Name of Inspector from whom received 1.

: Mrs. C. Ramdinmawii

Assistant Director (Food & Drugs) C.M.O Office, Champhai - 796321

Mizoram.

Serial No. and date of Inspector's Memorandum 2.

294/22

Date:27.09.2022

3. Number of Sample

Nil

13/10/2022

4. Date of Receipt 5.

Name of Drugs purporting to be contained in the sample

Name of the Drug

B. No.

Mfg. Date

Exp. Date

Mfd. By

KOOCAL-500 Tablets (Calcium with Vitamin D

TG21-2346 09/2021

02/2023

M/s Athens Life Sciences

Tablets IP)

Mauza Rampur Jattan, Nahan Road, Kala Amb, Distt. Sirmour, H.P.-173030

Condition of seals on the packet or on portion of sample or container : Seals were intact and identical to the

specimen impression of the seal received

from the Drugs Inspector

Result of test or analysis with protocols of test or analysis applied

Method: I.P. 2018

Description Identification White, elongated, bi-convex, one side scored, film coated tablets in blister pack. Gives positive test for Calcium but does not give positive test for Vitamin D₃.

Average weight Uniformity of weight

1.5627 g. Complies I.P.

Dissolution

Complies for Calcium.

(Average Release of Calcium: 82.48% 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	517.5 mg	500.0 mg	103.5	90.0-110.0
Vitamin D ₃	Nil	250 111		Not less than 90.0%

Date of Testing: 02/11/2022 to 03/11/2022, 15/11/2022 to 18/11/2022 & 30/11/2022 to 01/12/2022

No. RDTL/Report/S/2022-2023/A.N.23199/ 7479 - 748/

Date: 02/12/2022

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.

Remarks: The sample does not conform to I.P. with respect to the test for 'Identification and Assay' of "Vitamin D3".

Dated: 02/12/2022

(Dilip Kr. Sarkar) **Government Analyst** RDTL, Guwahati Dilip Kr. Sarkar Government Analyst R.D.T.L., Guwahati-22