



मुख्यालय, कर्मचारी राज्य बीमा निगम
HEADQUARTERS, EMPLOYEES' STATE INSURANCE CORPORATION
पंचदीप भवन, सी.आई.जी. मार्ग, नई दिल्ली-110002
PANCHDEEP BHAWAN: C.I.G. ROAD: NEW DELHI - 110 002
TelFax: 011-23234334, E-mail: dmc-rc@esic.nic.in



No. U-25/12/NSQ/2022-Med V | 653

दिनांक: 26.10.2022

सेवा में,

Director (Medical) Delhi / Director (Medical) Noida
Deans/Medical Superintendents - All ESIC Medical Colleges/Hospitals.
Directors, ESI Schemes - All states

NSQ/11/2022

विषय : परीक्षण पर दवा "Not of Standard Quality" की घोषणा के संबंध में

महोदया/महोदय,

It is hereby informed that the Drug as detailed below has been reported as "Not of Standard Quality", you are directed to **stop use of the batch of the following item immediately** which has been reported as "Not of Standard Quality": (copy enclosed)

NSQ Reported by	Name of the Firm	Item Name/ Brand Name	Instance of NSQ reported for Firm for year 2022	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date/	Reason of NSQ
MS, ESIC Model Hospital, Beltola, Guwahati, Assam-781022	USV Private Limited Plot No. 6 & 7E, HPSIDC Indl. Area, Baddi, Dist., Solan, Himachal Pradesh-173205	Mecobalamine + Lipoic Acid Cap Each cap to contain: Mecobalamine 0.5mg, Alpha Lipoic Acid 100mg (Cap Neuvesca)	First Instance	146 1388 8 RC valid upto 31.08.2021	28021831 04.2021 02.2023	The Government Analyst, RDTL, Guwahati-22 RDTL/Report/C/2 022-2023/A.N. 20897/3109 Dt.-03.08.2022	The sample is declared Not of Standard Quality for the reason stated under "Description" and for the Assay of "Alpha Lipoic Acid" Category 'B'

It is directed that action may be taken as per clause for 'Testing of Drugs-Quality Control' of Terms & Conditions of DG-ESIC RC. Replacement of supplies or cost of the material is to be recovered along with testing charges, if any, from the firm.

Action taken is to be maintained as record in respective user units.

यह चिकित्सा आयुक्त (Procurement) के अनुमोदन से जारी किया जाता है।

भवदीय,

संलग्नक: उपरोक्त अनुसार

(जय सिंह)

सहायक निदेशक (दर संविदा कक्ष)

Copy for information to: -

1. The State Drug Controller, Food & Drug Administration, Survey No. 341, 2nd Floor, Bandra Kurla Complex, Opposite RBI, Kala Nagar, Bandra East, Mumbai-400051, whogmp.mahafda@gmail.com with the request to take appropriate action on 'NSQ' reported for the above said batch under intimation to this office. (Copy of Test Report enclosed)
2. State Drug Controller, Controlling cum Licensing Authority, Baddi, Himachal Pradesh 173205 Email: sdclhp@gmail.com
3. M/s USV Private Limited, Arvind Vithhal Gandhi Chowk, B.S.D. Marg, Govandi, Mumbai-400088, Maharashtra, Email: manoj.sharma@usv.in
4. M/s USV Private Limited, Plot No. 6 & 7E, HPSIDC Indl. Area, Baddi, Dist., Solan, Himachal Pradesh-173205
5. Website Content Manager with request for uploading on ESIC website
6. Guard file

सहायक निदेशक (दर संविदा कक्ष)

भारत सरकार

स्वास्थ्य और परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय

केंद्रीय औषधि मानक नियंत्रण संगठन
सहायक औषधि नियंत्रक (भारत) का कार्यालय
उप-क्षेत्रीय कार्यालय,

क्षेत्रीय औषधि परीक्षण प्रयोगशाला परिसर,
छह माइल, पंजाबारी रोड, गुवाहाटी - 781022

दूरभाष: (0361)-2332628, फैक्स: (0361)-2330555
ईमेल: subzone.guwahati@cdsco.nic.in



GOVERNMENT OF INDIA

Ministry of Health and Family Welfare
Directorate General of Health Services

**CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION**

O/o the Assistant Drugs Controller (India)
Sub-Zonal office,

Regional Drugs Testing Laboratory campus,
Six Mile, Panjabari Road, Guwahati-781022

Tel: (0361)-2332628, Fax: (0361)-2330555
E-mail: subzone.guwahati@cdsco.nic.in

File No. CDSO-Guwahati/NSQ/AHIC/2022/ 2387

Date: 04.08.2022

Most Urgent: NSQ Drugs

To,
The Chief Medical Officer I/c.,
Medical Store, ESIC, Model Hospital,
Beltola, Guwahati - 781022

Subject: Methylcobalamin and Alpha Lipoic Acid Capsules (NEUVESCA); Batch No.: 28021831; Mfg. Date: 04/2021; Exp. Date: 02/2023; Manufactured by: M/s. USV Private Limited, Plot No. 6 & 7E, HPSIDC Indl. Area, Baddi, Dist.: Solan, Himachal Pradesh - 173205, declared "Not of Standard Quality" by Govt. Analyst, Regional Drugs Testing Laboratory, Guwahati- regarding.

Reference: - Test report in Form 13 vide No. RDTL/Report/C/2022-2023/A.N. 20897/3109 dt. 03.08.2022 of the Govt. Analyst, Regional Drugs Testing Laboratory, Guwahati.

Sir,

This is with reference to the subject cited above and brings to your kind notice that the subject batch of drug was drawn under the provision of Section 23 of Drugs and Cosmetics Act, 1940 by the undersigned from your premises on 31.12.2021 and forwarded for test/analysis to the Government Analyst, Regional Drugs Testing Laboratory, Six Mile, Guwahati.

After test/analysis, the subject sample is declared "Not of Standard Quality" in Form 13 for the reasons stated under "Description" and for the Assay of "Alpha Lipoic Acid" vide test report no. RDTL/Report/C/2022-2023/A.N. 20897/3109 dt. 03.08.2022 of the Govt. Analyst, Regional Drugs Testing Laboratory, Guwahati.

As per the provision of Section 25 (2) of Drugs and Cosmetics Act, 1940, one copy of the original test report in Form 13 is being forwarded to you.

As the subject batch of drug is declared "Not of Standard Quality", as defined in the said Act 1940, therefore, you are requested under Section 18A & Section 24 of Drugs and Cosmetics Act 1940 to disclose the name, address and other particulars of the person from whom you acquired the subject batch of drug along with invoice & the place where the subject batch of drug has been manufactured, respectively.

Further you are also requested to keep a sealed portion of above sample along with original Form 17 & Form 17A issued to you in safe and secure custody till the disposal of the matter or further official direction in the matter.

It is requested to provide the requisite information on top priority please.

This is for your kind information and necessary action.

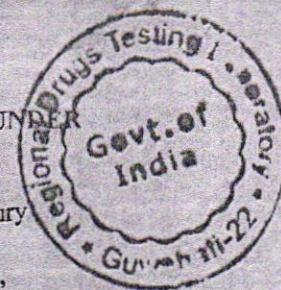
Yours faithfully,

Encl: One original test report in Form 13:

(Abu Hanif Imran Choudhury)

Drugs Inspector
Abu Hanif Imran Choudhury
Drugs Inspector
CDSCO Sub-Zone
DGHS, MoH & FW, Govt. of India
Six Mile, Panjabari Road
Guwahati-78

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 : Sh. Abu Hanif Imran Choudhury
Drugs Inspector
C.D.S.C.O., Sub-Zonal Office,
Regional Drugs Testing Laboratory Campus,
Six Mile, Panjabari Road, Guwahati- 781022.
2. Serial No. and date of Inspector's Memorandum : CDSCO-Guwahati/Sampling/AHIC/2021/2414
Date: 31.12.2021
3. Number of Sample : 60/AH/LS/GSZ/2021-22
4. Date of Receipt : 31/12/2021
5. Name of Drugs purporting to be contained in the sample :

Name of the Drug	Batch No.	Mfg. Date	Exp. Date	Mfd. By
Methylcobalamin and Alpha Lipoic Acid Capsules	28021831	04/2021	02/2023	USV Private Limited Plot No. 6 & 7E, HPSIDC Indl. Area, Baddi, Dist.: Solan, Himachal Pradesh- 173205

6. 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
7. Result of test or analysis with protocols of test or analysis applied :

Description : Red and yellow coloured pellets, sticky, clubbed together as wild mass in red coloured capsule having printed "USV" and "NEUVESCA" of each half of the capsule shells in blister strip.

Identification : Gives positive test for Methylcobalamin and Alpha Lipoic Acid.

Average filled content : 0.4332 gm.

Uniformity of weight : Passes the test. (Method I.P.)

Assay					
Content of	Found mg/Cap	Claim mg/Cap	% of Claim	Limit (% of Claim)	Method
Methylcobalamin	0.76	0.50	152.0	N.L.T. 90.0	H.P.L.C. Ref. Manufacturer's Specification
Alpha Lipoic Acid	39.14	100.0	39.1	N.L.T. 90.0	-do-

Date of Testing: 01/08/2022, 02/08/2022

No. RDTL/Report/C/2022-2023/A.N. 20897/3109

Date: 03/08/2022

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 is declared Not of Standard Quality for the reason stated under "Description" and for the Assay of "Alpha Lipoic Acid".

Dated: 03/08/2022

Report in red colored paper indicates the sample is Not of Standard Quality.

(Amar Jyoti Chamuah)
Government Analyst
RDTL, Guwahati
Amar Jyoti Chamuah
Government Analyst
R.D.T.L., Guwahati-22

भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
केंद्रीय औषधि मानक नियंत्रण संगठन
सहायक औषधि नियंत्रक (भारत) का कार्यालय
उप-क्षेत्रीय कार्यालय,
क्षेत्रीय औषधि परीक्षण प्रयोगशाला परिसर,
छह माइल, पंजाबारी रोड, गुवाहाटी -781022
दूरभाष: (0361)-2332628, फैक्स: (0361)-2330555
ईमेल: subzone.guwahati@cdsco.nic.in



GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services
**CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION**
O/o the Assistant Drugs Controller (India)
Sub-Zonal office,
Regional Drugs Testing Laboratory campus,
Six Mile, Panjabari Road, Guwahati-781022
Tel: (0361)-2332628, Fax: (0361)-2330555
E-mail: subzone.guwahati@cdsco.nic.in

File No. CDSO-Guwahati/NSQ/AHIC/2022/

Date: 04.08.2022
(Email copy only)

To,
2416 i. The Drugs Controller, Assam
12411 ii. The Asstt. Drugs Controller & Licensing
Authority, Arunachal Pradesh
2412 iii. The Drugs Controller, Manipur

2413 iv. The Asstt. Drugs Controller & Licensing
Authority, Meghalaya
2414 v. The Drugs Controller, Mizoram
2415 vi. The Drugs Controller, Nagaland
2416 vii. The Drugs Controller, Tripura

Subject: - Methylcobalamine and Alpha Lipoic Acid Capsules, Batch No. 28021831, Mfg. Date: 04/2021, Exp. Date: 02/2023, Manufactured by M/s. USV Private Limited, Plot No. 6 and 7 E, HPSIDC Industrial area, Baddi, Dist. Solan, Himachal Pradesh-173025 declared "Not of Standard Quality" by the Govt. Analyst, RDTL, Guwahati- regarding.

Reference: - Test report in Form 13 vide no. RDTL/Report/C/2022-2023/A.N.20897/3109 dt. 03.08.2022 of the Govt. Analyst, Regional Drugs Testing Laboratory. Guwahati received to this office on 04.08.2022.

Sir,

This is with reference to the subject cited above and bring to your kind notice that the subject batch of drug was drawn by the Drugs Inspector of this office from the premises of Medical Store, ESIC Model Hospital, Beltola, Guwahati-781022 on 31.12.2021 under the provision of Section 23 of Drugs and Cosmetics Act, 1940 and forwarded to the Government Analyst, Regional Drugs Testing Laboratory (RDTL), Six Mile, Guwahati for the purpose of test/analysis.

After test/analysis, the subject batch of drug is declared "**Not of Standard Quality**" for the reason stated under "Description" and for the Assay of "Alpha Lipoic Acid" vide test report no. RDTL/Report/C/2022-2023/A.N.20897/3109 dt. 03.08.2022 of the Govt. Analyst, Regional Drugs Testing Laboratory, Guwahati (copy of test report is enclosed herewith for your ready reference).

Therefore, you are requested to alert the Inspectorate staffs under your jurisdiction on movement of subject batch of drug, if any movement of such drug is reported, necessary action may kindly be taken in the matter and copy of action taken in the matter if any may be forwarded to this office.

This is for your kind information and necessary action.

Yours faithfully,

(Shiv Kumar)

Assistant Drugs Controller (India)

Copy to:

- 2417 1. The Drugs Controller General (India), CDSCO, FDA Bhawan, New Delhi.
- 2418 2. The Deputy Drugs Controller (I), CDSCO, West Zone, Mumbai.
- 2419 3. The Deputy Drugs Controller (I), CDSCO, North Zone, Ghaziabad.
- 2420 4. The Deputy Drugs Controller (I), CDSCO, South Zone, Chennai.
- 2421 5. The Deputy Drugs Controller (I), CDSCO, East Zone, Kolkata.
- 2422 6. The Deputy Drugs Controller (I), CDSCO, Zonal Office, Hyderabad.
- 2423 7. The Deputy Drugs Controller (I), CDSCO, Zonal Office, Ahmedabad.
- 2424 8. The Deputy Drugs Controller (I), CDSCO, Sub-Zone Office, Bangalore.
- 2425 9. The Deputy Drugs Controller (I), CDSCO, Sub-Zone Office, Baddi.
- 2426 10. The Deputy Drugs Controller (I), CDSCO, Sub-Zone Office, Indore.
- 2427 11. The Assistant Drugs Controller (I), CDSCO, Sub-Zone Office, Jammu.P
- 2428 12. The Assistant Drugs Controller (I), CDSCO, Sub-Zone Office, Goa.
- 2429 13. The Assistant Drugs Controller (I), CDSCO, Sub-Zone Office, Varanasi.
- 2430 14. The Chief Medical Officer, Medical Store, ESIC Model Hospital, Beltola-781022.
- 2431 15. M/s. USV Private Limited, Plot No. 6 and 7 E, HPSIDC Industrial area, Baddi, HP-173025