

कर्मचारी राज्य बीमा निगम (श्रम एव रोजगार मंत्रालय,भारत सरकार) EMPLOYEES' STATE INSURANCE CORPORATION (Ministry of Labour & Employment, Govt. of India)



मुख्यालय/HEADQUARTERS' पंचदीप भवन, सी.आई.जी मार्ग, नई दिल्ली -110 002 PanchdeepBhawan, C.I.G. Marg, New Delhi-110002 <u>www.esic.gov.in</u>, 2501-23604773, C<u>dmc-rc@esic.nic.in</u>

U-25/12/NSQ/2023-MedV(E-178406)//39

दिनाँक: 08.04.2025

सेवा में, Director (Medical) Delhi / Director (Medical) Noida, Dean, All ESIC PGIMSR's, Medical & Dental Colleges Medical Superintendents - All ESIC Hospitals, Directors, ESI Scheme, All States

### NSQ/03/2025

## Subject: "Not of Standard Quality" on Testing - reg

विषय: "परीक्षण पर "मानक गुणवत्ता का नहीं" - संबंध में।

महोदय/महोदया,

It is hereby informed that the Drug/item, procured through GeM Portal, as detailed below has been reported as "Not of Standard Quality" as detailed below:

NSQ	Name of the	Item	RC No/	Batch	Sample	Reason of
Reported by	Pharmaceutic al Firm	Name/ Brand Name	Item No	No./ DOM/ DOE	no./Name of the Laboratory/ R eport No. & Date/	NSQ
Central Medical Store, E.S.I. Scheme, Gotri Road, Vadodara, Gujarat	M/s. Hindustan Antibiotics Ltd.	A REAL TO AN A REAL PROPERTY.	Procured through GeM	T24H009 08/2024 07/2026	sample no. 142/24 Food and Drug Laboratory- Vadodara R.No.: Q.1/3004/ 2025(E) dtd 26.03.25	"Dissolution" :- Not within IP 2022 Limit.

In context to above, it is directed to:

1. Stop use of the reported batch of the above mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).

2. Stop the payment for the above said batch of the respective item.

# Contd. to pre-page:

3. Incident to be raised on GeM Portal and penal action w.r.t. replacement/recovery/testing charges etc. to be taken as per Terms & Conditions of GeM.

This issues with the approval of Medical Commissioner (Procurement).

संलग्नः उपरोक्तानुसार

भवदीय,

Digitally signed by Sanjiv Kochhar Date: 16-04-2025 15:35:36 उप चिकित्सा आयुक्त(दर संविदा)

# 2 6 MAR 2025

Governn

page | of ||

From :

THE GOVERNMENT ANALYST, Food & Drugs Laboratory, Vadodara-390 002.

То,

N.M.Malani, Drugs Inspector, c/o Food & Drugs Laboratory, Nr. Polytechnic, Nizampura, Food & Drugs Control Administration, Vadodara.

Report No. : Q.1/ /2025(E). 2

#### FORM – 13 (See Rule 46 ) Certificate of test or analysis by Government Analyst under Section 25 (1) of the Drugs and Cosmetic s Act, 1940

- 1. Name of Inspector from whom received. :- N.M.Malani
- 2. Serial No. and date of Inspector's :- VAD/Regular/Emp- State Insurance /321064/GJ BDL .dt 23/10/24 Memorandum.

3.	Number of Sample.	:-	1 x 5 x 10 Tab.
4.	Date of receipt.	:-	22/11/24

- 5. Name of drugs purporting to be contained in the sample :- Vitamin C Tablets IP 500mg Mfg. by :Hindustan Antibiotics ltd, At B-1/11,B-2/1, MIDC, Industrial area, Butibori, Nagpur, Maharashtra.
- 6. Condition of seals on the packet or on portion of samples or container :-Seals were intact & Identical with the specimen impression of the seal received separately from the Drugs Inspector.
- 7. Results of test or analysis with protocols of test or analysis applied :- Is attached. In the opinion of the undersigned the sample referred to above

Is of standard quality as defined in the Drugs and 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 for the reasons given below :-The Sample does not conforms to the Standards laid down for Ascorbic Acid Tablets in IP 2022 in respect of Dissolution.

6



Date : Pjp 4473832/

/2	025/SEC-MED 5-ESICHQ						
	, 30	04 • • • • • • • • • • • • • • • • •					
	REPORT NO. : Q-1/	/2025 ( E ). SAMPLE NO.:142/24					
		"Vitamin C Tablets IP 500mg"					
	Results of the tests or analysis with protocols of test or analysis applied :-						
	Outer label :- Container label :-	Nil. Vitamin C Tablets IP 500 mg. Each Uncoated tablet Contains Ascorbic Acid IP 500 mg. ExcipientsQ.S. Approved color used, Approved flavored are used. Storage : store protected from light and moisture. Govt. Supply Not for sale. Mfg. Lic. No. : MH/102465A Batch. No. : T24H009 Mfg. dt. : 08/2024					
		Exp. dt : 07/2026 Mfg. in by : Hindustan Antibiotics Ltd, At: B-1/11, B-2/1, MIDC, Industrial area, Butibori, Nagpur -441108.					
	For the following tests an followed.	d methods given in IP 2022 under Ascorbic Acid Tablets page 4040 are					
	Description	:- Yellow Coloured, Circular flat tablets, Scored on one side.					
	Content	:- 10 Tablets per strip. (5 Strips).					
	Identification	:- Complies with the tests for Identification.					
	Average weight of Tablet	:- 0.6796 gm					

Average weight of Tablet :-0.6796 gm

Uniformity of Weight :-Within IP 2022 Limit.

Dissolution Not Within IP 2022 Limit. :-

Assayed for Ascorbic acid Content :-

Ascorbic acid : 522.71 mg per average weight of tablet. (i.e. 104.54 percent of the claim made)  $(C_6H_6O_6)$ 

[ IP 2022 limits :- Ascorbic Acid tablets contain not less than 95 percent and not more than 115.0 percent of the stated amount of Ascorbic Acid  $C_6H_6O_6$ .] KGS

	0	NO'	1.01
	KIL .	al star	120
	(P.J.Parmar)	<b>k</b>	12
	Government Analyst.		13
page if OI		that E	1 south
End of the Report		1. * 11	1 2 2
Disclaimer : This report refers only to a particular sample su	bmitted for testing . Labo	oratory is not	essa.
involved in sampling, Address : Food & Drugs Laboratory,	Near Polytechnic, Niza	mpura, Vadod	ara.

Generated from eOffice by RAMESH KUMAR SAINI, PHA-MED5-RKS, PHARMACIST, Employees State Insurance Corporation (ESIC) on 08/04/2025 03:43 pm