



कर्मचारी राज्य बीमा निगम
(श्रम एवं 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
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in, ☎011-23604773, ✉ dmc-rc@esic.nic.in

No. U-25/12/NSQ/2023-Med V (E-178406)

दिनांक: 18.07.2023

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/2023

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

महोदय/महोदया,

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	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date/	Reason of NSQ
MS, ESIC Hospital, Rajaji Nagar, Bengaluru	M/s CMG Biotech Pvt Ltd 58, Industrial Area, Plot No 28/1/17, Industrial Area, Site IV, Sahibabad, Ghaziabad, (UP)- 201010 (Manufactured at : 58, Industrial Area, Phase III, Sansarpur Terrace, Dist. Kangra, HP	Acenocoumarol Tab/cap- Each tab/cap to contain: Acenocoumarol 1mg Cgtrom-1	150 72a 77	CT22231818 03/2023 02/2025	Central Drug Testing Laboratory, Kolkatta No: 32-13/2023- SS/DCA (B)-59/882 Dated:14.06.2023.	The sample is declared Not of Standard Quality for the reason stated under “Related Substances” Category ‘B’

It is also directed that action may be taken as per clause for ‘Testing of Drugs-Quality Control’ of Terms & Conditions of respective 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

सहायक निदेशक (दर संविदा कक्ष)

Copy for information to: -

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi 110002.
2. Office of the Director Health Services, Health and Family Welfare Directorate, SDA Complex, Kasumpti, Shimla-9 (HP) with the request to take appropriate action on NSQ reported for the above said batch under information to this office.
3. Office of the Assistant Commissioner (Drug) Food Safety & Administration, Govt of Uttar Pradesh with the request to take appropriate action on NSQ reported for the above said batch under information to this office
4. M/s Bajaj Healthcare Limited 602-606, 6th Floor, Bhoomi Velocity Infotech Park, Plot No: B-39, Road No. 23, Above ICICI Bank, Wagle Industrial Estate, Thane(W)-400604
5. Website Content Manager with request for uploading on ESIC website
6. Guard file

सहायक निदेशक (दर संविदा कक्ष)

Web - Upload

कर्मचारी राज्य बीमा निगम
(श्रम एवं रोजगार मंत्रालय, भारत सरकार)
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Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in, 011-23604773, dmsrc@esic.nic.in

File No.:e-U-25/12/NSQ/2022-MedV (E-12328)/391

Dated:

To,
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/09/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

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

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
M/s Central Medical Store, E.S.I. Scheme, D6 Dispensary Compound, Behind Pritampura School, Girdharnagar, Ahmedabad-Gujarat-380016	CMG Biotech Pvt. Ltd.	Betahistine hydrochloride/ Dihydrochloride Tab/Cap- Each Tab/Cap to contain: Betahistine hydrochloride/ Dihydrochloride 8mg Cghest-8	150 1539a 68	CT24250284A DOM:05-24 DOE:04-26	Government Analyst, Central Drug Testing Laboratory, Indore M.P.-452001 Report No. IND/LS/2025-26/92 dated 23-May-2025	The sample does not conform to IP standards with respect to "Assay for Ingredient Betahistine Dihydrochloride" (copy enclosed)

In context to above, it is directed to:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Initiate action as per clause for 'Testing of Drugs-Quality Control' of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.
4. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Faithfully,

Digitally signed by
Sanjiv Kochhar
Date: 18-07-2025
12:38:32
Dy. Medical Commissioner
(Rate Contract)

Copy for information to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi-110002 (dci@nic.in).
2. Central Drug Standard Control Organization, North Zone, C.G.O. Building-I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad, U.P.-2010024 (Email:- zghaziabad@cdsco.nic.in) with request to take appropriate action on NSQ reported for the above said batch under information to this office.
3. Office of Assistant Commissioner, Food & Drug Control Administration, C/o Food & Drug Laboratory, near Polytechnic, Vadodra-390002.
4. Office of Deputy Drugs Controller (I), Central Drugs Standard Control Organization, 2nd Floor, Air Cargo Complex, Old Airport Building, Bhargav Road, Near Rameshwar Char Rasta, Meghaninagar, Ahmedabad - 380016, Gujarat . (Email: ahmedabad@cdsco.nic.in, ahd.airport@cdsco.nic.in, hzr.seaport@cdsco.nic.in)
5. M/s CMG BIOTECH PVT. LTD., Plot No. 28/1/17, Industrial Area, Site-IV, Sahibabad, Ghaziabad, (UP)-201010.(Email: info@cmgbiotech.in)
6. Website Content Manager with request for uploading on ESIC website.
7. Guard file.



FORM 13
 (See rule 46)

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

1. Name of Inspector from whom received : Mrs. Neha Sharma ,Drugs Inspector
 Mrs. Neha Sharma
 Ahmedabad Zone Central Drugs Standard Control
 Organization, 2nd Floor, Air Cargo Complex, Old Airport
 Building, Bhargav Road, Near Rameshwar Char Rasta,
 Meghaninagar, Ahmedabad - 380016, Gujarat (India) -
 0
2. Serial No. and date of Inspector's memorandum : CDSCO/AHD/ SS/2025/NSH/15/934 , 20-MAR-2025
3. Number of Sample : CDSCO/AHD/ SS/2025/NSH/15
4. Date of receipt : 24-MAR-2025
5. Names of drugs purporting to be contained in the sample : Betahistine Dihydrochloride Tablets IP (CGHEST-8)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/IND/2024-25/0183	IND/LS/2025-26/92	CT24250284A	05/2024 04/2026	Not mentioned	CMG BIOTECH PVT. LTD., (Unit-II) Plot No. 58, Phase III, Industrial Area, Sansarpur Terrace HP- 176501

6. Condition of seals on : Seals were intact & identical to the
 [the packet or on portion of sample or container] specimen impression of the seal received
 from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below
 Date of Testing : From 15-May-2025 To 23-May-2025

COMPOSITION : Each uncoated tablet contains
 Betahistine Dihydrochloride IP 8 mg

Protocol Applied : Betahistine Tablets (IP 2022)

Sr No.	Test Name	Result	Limits
1	Description	Off white, round, biconvex, uncoated tablets, having brown and light brown spots on both surfaces (mottled appearance), supplied in aluminium foil blister pack.	NA
2	Identification	Gives positive test for Betahistine Hydrochloride	NA
3	Dissolution	Complies with I.P. Average drug release- 96.60% of claim	NLT 80 % of claim
4	Related substances	Test not done due to non-availability of impurities.	NA
5	Uniformity of content	Complies with I.P.	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Betahistine Dihydrochloride	7.69 mg/ tablet	8 mg/ tablet	96.125	95 % to 105 %	I.P 2022

In the opinion of the undersigned the sample referred to above 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 is not of standard quality for the reasons stated under description.

Date: 23-MAY-2025

Turjya Ray.
GOVERNMENT ANALYST

तुर्ज्या रे / Turjya Ray
सरकारी विश्लेषक / Government Analyst
केंद्रीय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory
भारत सरकार / Govt. of India
सीडीएससीओ क्वॉर, सीपीओ क्वॉर / CDSCO Bhowan, GPO Square
एबी रोड, इंदौर (एमपी)-452001 / AB Road, Indore (M.P.)-452001

----- END OF REPORT -----





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



मुख्यालय/HEADQUARTERS
पंचदीप भवन, सी.आइ.जी. मार्ग, नई दिल्ली -110 002
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in, 011-23604773, dmc-rc@esic.nic.in

File No.:e-U-25/12/NSQ/2022-MedV(E-12328) | 403 Dated:

To,
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/10/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

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

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
Medical college and Hospital & PGIMSR, Kalaburagi, Karnataka-585106	Glenmark Pharmaceuticals Limited	Clotrimazole + Lignocaine Ear Drop- Each Bottle to contain: Clotrimazole 1%, Lignocaine Hydrochloride 2% Candid	149 551 42	Batch No.-11231684 DOM:09-23 DOE:08-26	Government Analyst, Karnataka MR No. 1577-BLR-25-26/PS-7459 Dated 19-07-2025	The sample has been declared as Not of Standard Quality as it does not conform to the label claim with respect to "Assay for Clotrimazole" Category-"B" (copy enclosed)

In context to above, it is directed to:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Initiate action as per clause for "Testing of Drugs-Quality Control" of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.

Contd. to pre page:

4. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Faithfully,

Digitally signed by

Sanjiv Kochhar

Date: 26-07-2025

10:39:26

Dy. Medical Commissioner
(Rate Contract)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi-110002 (dci@nic.in).
2. State Drug Controller (Karnataka), Drug Control Department, Palace Road, Bengaluru-560001 (Email-dc.dcd-ka@nic.in).
3. 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)
4. State Drug Controller, Controlling cum Licensing Authority, Baddi, himachal Pradesh-173205 (Email-sdc4hp@gmail.com) with request to take appropriate action on NSQ reported for the above said batch (copy of test report enclosed).
5. M/s Glenmark Pharmaceuticals Limited, Glenmark House, B.D.Sawant Marg, Chakala, Andheri East, Mumbai - 400099 (Email: govt.tenders@glenmarkpharma.com).
6. M/s Glenmark Pharmaceuticals Limited (Unit-III, Village- nattanwara, P.O.- Rajpura, Nalagarh, Distt. Solan (H.P.)-174101 (Email- complianceofficer@glenmarkpharma.com)
7. Website Content Manager with request for uploading on ESIC website.
8. Guard file.



कर्मचारी राज्य बीमा निगम
(श्रम एवं 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
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in ☎011-23604773, ✉dmgrc@esic.nic.in

File No.:U-25/12/NSQ/2021-MedV(E-1119) / Dated: 1446

To
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/11/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

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

NSQ Reported by	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
ESIC Medical College, Gulbarga, Karnataka	Swiss Parenterals Limited	Sodium Bicarbonate Inj- Each Amp to contain: Sodium Bicarbonate 7.5%, 10ml Amp	152 1326 36	240115A DOM:01-24 DOE:12-25	Government Analyst, Karnataka MR No.2830-BLR-25-26/PH -5967 dated 25.08.2025	The sample has been declared as Not of Standard Quality as it does not conform to IP Standards with respect to Test for Sterility

In context to above, it is directed to:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Initiate action as per relevant clause of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC 152.

Contd. to pre page:

4. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Faithfully,

Digitally signed by

Sanjiv Kochhar

Date: 03-09-2025

18:54:58

Dy. Medical Commissioner
(Rate Contract)

Copy for information to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (dci@nic.in).
2. Office of Assistant Commissioner, Food & Drug Control Administration , C/o Food & Drug Laboratory , near Polytechnic , Vadodra-390002.
3. Office of Deputy Drug Controller (I), Central Drug Standard Control Organization , 2nd floor, Air Cargo Complex, Old Airport Building , Bhargav Road, Near Rameshwar Char Rasta , Meghaninagar, Ahmeddabad-380016, Gujarat.(Email-ahmedabad@cdsco.nic.in,ahd.airport@cdsco.nic.in, hzr.seaport@cdsco.nic.in)
4. State Drug Controller (Karnataka), Drug Control Department, Palace Road, Bengaluru-560001 (Email-dc.dcd-ka@nic.in) with the request to take appropriate action on NSQ reported for the above said batch under information to this office (copy of test report enclosed).
5. M/s SWISS PARENTERALS LTD ,808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad -382220, Gujarat, INDIA.
6. M/s SWISS PARENTERALS LTD ,62, 6th Floor, Corporate Road, Prahalad Nagar, Ahmedabad-380 015, Gujarat.(Email-bd2@swiss.in)
7. Website Content Manager with request for uploading on ESIC website.
8. Guard file.

Email**RCCell****Fwd: Not of standard quality report of Inj Sodium bicarbonate**

From : DMC RC <dmc-rc@esic.nic.in>
Subject : Fwd: Not of standard quality report of Inj Sodium bicarbonate
To : RCCell <rc-hqrs@esic.gov.in>
Cc : PS KUMAR <ps.kumar@esic.nic.in>
Reply To : DMC RC <dmc-rc@esic.nic.in>

Thu, Aug 28, 2025 11:01 AM

 1 attachment

महोदय/महोदया,

उपरोक्त विषयांतर्गत आपके सादर सूचनार्थ एवं आवश्यक कार्रवाई हेतु संलग्नक प्रेषित है।

Please find herein attachment for your kind information & necessary action.

धन्यवाद,

उप चिकित्सा आयुक्त (आर सी व पीसी, शाखा ५)

क रा बी निगम मुख्यालय

VOIP No. 10011026

From: "ESIC Medical College Gulbarga Karnataka" <deanmc-gb.kar@esic.nic.in>
To: "ms esic-list" <ms.esic-list@ismgr.nic.in>, "dean esic-list" <dean.esic-list@ismgr.nic.in>, ms-esic@esic.nic.in, rc-hqrs@esic.nic.in, "DMC RC" <dmc-rc@esic.gov.in>, "DMC RC" <dmc-rc@esic.nic.in>, "Medical CommissionerSouth Zone" <mc-southzone@esic.gov.in>
Cc: "Thanneru Sujathamma" <thanneru.sujathamma@esic.nic.in>, "MSOBranch" <msomch-gb.kar@esic.gov.in>
Sent: Thursday, August 28, 2025 9:36:44 AM
Subject: Not of standard quality report of Inj Sodium bicarbonate

Sir/Madam,

Please find the attachment.

सादर With Regards,

डॉ. एस वी क्षीरसागर, Dr. S V Kshirsagar

डीन, Dean

ईएसआई निगम, ESI Corporation

मेडिकल कॉलेज और अस्पताल और पीजीआईएमएसआर, Medical college and Hospital & PGIMSR

कलबुर्गी, कर्नाटक 585106, Kalaburagi, Karnataka, 585106

चल दूरभाष: 08472 265546

 **signedpdfnew (6).pdf**
145 KB

**Form-13**

(See Rule-46)



MR No.2830-BLR-25-26/PH -5967

**Certificate of test or analysis by Government Analyst Under Section 25(1) of the
Drugs and Cosmetics Act,1940**

- Name of Inspector from whom received: Karunadevi,Assistant Drugs Controller
**OFFICE OF THE ASST DRUGS CONTROLLER,CA:4/1 SyNo:17,Ground Floor,MSK Compound,
Kalaburgi Circle-ADC2,Kalaburgi-585103**
- Serial No of Inspectors Memorandum : **GL2/REG/CMS/110201/KA-B01** and Date **19-05-2025**
- Number of Sample : **110201**
- Date of Receipt : **07-07-2025**
- Name of drugs purporting to be contained in the sample: **Sodium Bicarbonate Injection IP 7.5%w/v**
Batch No: 240115A **Date Of Mfg.:01/2024** **Date of Exp: 12/2025**
Quantity: 1x10x10ml ampoules. **Mfg Lic.No. G/28/1078**
**Mfg. by: SWISS PARENTERALS LTD ,808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad -
382220, Gujarat, INDIA.**

6. Condition of seals on the package: **Intact & Tally with Specimen Seal**7. Result of test or analysis with protocols of test or analysis applied:**IP 2022.**

In the opinion of the undersigned the sample referred to above **is not of standard quality as defined in the
Drugs and Cosmetics Act,1940 and rules thereunder for the reasons given below**

RESULTS

DESCRIPTION: Clear, colorless solution in sealed, transparent glass ampoules, in an ampoule tray, packed in a sealed polythene cover.

IDENTIFICATION : Answers to the test for Sodium salts and Bicarbonates.

pH:	PASSES THE TEST	Found	8.45	IP Limits	7.0 to 8.5
EXTRACTABLE VOLUME:	PASSES THE TEST				
BACTERIAL ENDOTOXIN TEST:	PASSES THE TEST				
STERILITY:	DOES NOT PASS THE TEST				

Assay For	Found	IP Limits
Sodium Bicarbonate	7.64%w/v	7.05%w/v to 7.95%w/v

Reason for declaring Sample as Not of Standard Quality:

The sample has been declared as Not of Standard Quality as it does not conform to IP Standards with respect to Test for Sterility.

Dated:25/08/2025

(Manjula G.)

Government Analyst, Karnataka

Note:'Manufacturer's Address on the sample label is stated as "SWISS PARENTERALS LTD., 808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad - 382220, Gujarat, INDIA." whereas, the same is stated as "SWISS PHARMACEUTICALS LTD., 808, 809 & 810, KERALA INDUSTRIAL ESTATE, GDC NR BAVTA. DIST AHMEDABAD - 382220" in the Form-18 sent by the ADC.'



Form-13

(See Rule-46)



MR No.2830-BLR-25-26/PH -5967

Certificate of test or analysis by Government Analyst Under Section 25(1) of the Drugs and Cosmetics Act,1940

1. Name of Inspector from whom received: **Karunadevi,Assistant Drugs Controller
OFFICE OF THE ASST DRUGS CONTROLLER,CA:4/1 SyNo:17,Ground Floor,MSK Compound,
Kalaburgi Circle-ADC2,Kalaburgi-585103**
2. Serial No of Inspectors Memorandum : **GL2/REG/CMS/110201/KA-B01** and Date **19-05-2025**
3. Number of Sample : **110201**
4. Date of Receipt : **07-07-2025**
5. Name of drugs purporting to be contained in the sample: **Sodium Bicarbonate Injection IP 7.5%w/v**
Batch No: 240115A Date Of Mfg.:01/2024 Date of Exp: 12/2025
 Quantity: **1x10x10ml ampoules.** Mfg Lic.No. **G/28/1078**
 Mfg. by: **SWISS PARENTERALS LTD ,808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad -
382220, Gujarat, INDIA.**
6. Condition of seals on the package: **Intact & Tally with Specimen Seal**
7. Result of test or analysis with protocols of test or analysis applied:**IP 2022.**
 In the opinion of the undersigned the sample referred to above **is not of standard quality as defined in the Drugs
and Cosmetics Act,1940 and rules thereunder for the reasons given below**

RESULTS

DESCRIPTION: Clear, colorless solution in sealed, transparent glass ampoules, in an ampoule tray, packed in a sealed polythene cover.

IDENTIFICATION : Answers to the test for Sodium salts and Bicarbonates.

pH:	PASSES THE TEST	Found	8.45	IP Limits	7.0 to 8.5
EXTRACTABLE VOLUME:	PASSES THE TEST				
BACTERIAL ENDOTOXIN TEST:	PASSES THE TEST				
STERILITY:	DOES NOT PASS THE TEST				

<u>Assay For</u>	<u>Found</u>	<u>IP Limits</u>
Sodium Bicarbonate	7.64%w/v	7.05%w/v to 7.95%w/v

Reason for declaring Sample as Not of Standard Quality:

The sample has been declared as Not of Standard Quality as it does not conform to IP Standards with respect to Test for Sterility.

Dated:25/08/2025

CC: DC Karnataka

(Manjula G.)

Government Analyst, Karnataka

Note:'Manufacturer's Address on the sample label is stated as "SWISS PARENTERALS LTD., 808,809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Dist: Ahmedabad - 382220, Gujarat, INDIA." whereas, the same is stated as "SWISS PHARMACEUTICALS LTD., 808, 809 & 810, KERALA INDUSTRIAL ESTATE, GDC NR BAVTA. DIST AHMEDABAD - 382220" in the Form-18 sent by the ADC.'



File No.:U-25/12/NSQ/2021-MedV(E-1119)/489 Dated:

To,
**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/12/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

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

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
Medical Superintendent MH-ESIS Society Hospital, Thane-400604	Morepen Laboratories Ltd.	Rabeprazole Tab/Cap / Gastro Resistant Tab/Cap - Each Tab/Cap / Gastro Resistant Tab/Cap to contain: Rabeprazole 20 mg Rabidoc 20	149 567b 62	Batch No.- F4L0950 DOM:12-24 DOE:11-26	Senior Scientific Assistant & Govt. Analyst, Central Drugs Testing Laboratory - Mumbai MUM/LS/2025-26/454 dated 14.08.2025	The sample does not conform to 1.P. 2022 with respect to test for " Dissolution " (copy enclosed).

In context to above, it is directed to:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Stop placement of purchase order for said NSQ item no. 567b in RC 149.
4. Initiate action as per relevant clause of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC 149.

Contd. to pre page:

5.. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Sincerely,

Digitally signed by
Sanjiv Kochhar
Date: 16-09-2025
16:44:35

Dy. Medical Commissioner
(Rate Contract)

Copy for information to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (dci@nic.in).
2. Central Drugs Standard Control organization, West Zone , DGHS, Ministry of Health & Family Welfare, 4th Floor, Zonal FDA Bhawan, GMSD Compound , Bellasis Rd., Mumbai-400008 (Email-wzmumbai@cdsco.nic.in)
3. The State Drug Controller , Controlling cum Licensing Authority , Baddi, Himachal Pradesh, -173205 (Email-sdc4hp@gmail.com)
4. Morepen Laboratories Limited, 2nd Floor, Tower - C, DLF Cyber Park, Udyog Vihar - III, Sector - 20, Gurugram (Email- yadvinder.singh@morepen.com, institution@morepen.com).
5. M/s Morepen Laboratories ltd, Unit V, Plot 12C, Sector-2, Parwanoo, Distt-Solan, H.P.-173220 (Email- plants@morepen.com)
6. Website Content Manager with request for uploading on ESIC website.
7. Guard file.



**Government of
Maharashtra**

**Maharashtra Employees State Insurance Society Hospital,
Thane**

(An Autonomous Body of Govt. of Maharashtra registered under Reg. No. GBBSD 488/2019 & F-75443 (M) and Approved by Govt. of India vide letter dt. 25-10-2019)

Office of the Medical Superintendent

Road No. 33, Wagale Estate, Thane 400604

Phone No. 022 20810612/ 20810622

Email: thane.esis@gmail.com

No.TGH/MH-ESIS/Med.Store/ Tab. Rabeprazole Not standard quality/ **6561-63** /2025/Date: **20 AUG 2025**

To,

The Director General,
Employees' State Insurance Corporation (ESIC),
New Delhi.

Subject: Intimation Regarding "Not of Standard Quality" Drug Sample
– Rabeprazole 20 mg (Rabidoc-20 Tablet) – Batch No. F4L0950

Respected Sir,

This is to bring to your kind notice that the Drug Inspector, CDSCO (West Zone), Mumbai has drawn a sample of **Tab. Rabeprazole Gastro-resistant Tablet IP 20 mg (Rabidoc-20 Tablet)** manufactured by **Morepen Laboratories Ltd., Batch No. F4L0950, Expiry Date: November 2026** from **MH-ESI Society Hospital, Thane.**

As per the laboratory test report received from CDSCO, the said sample has been declared "**Not of Standard Quality (NSQ)**".

In this regard, we are enclosing herewith a copy of the **test report and related documents** for your kind perusal and necessary action at your level.

Enclosures:

1. Copy of CDSCO Test Report
2. Copy of Covering Letter from CDSCO

We request you to kindly take note of the same and issue further directions as deemed appropriate.

With regards,

Dr. V K. Naik
Medical Superintendent
MH-ESI Society Hospital, Thane

Copy to:

1. Commissioner, MH-ESI Society, Mumbai
2. M/s Morepen Laboratories Ltd



By Regd./Speed Post

F. No.: 4-1/WZ-2025/MG/981

Date: 22.08.2025

To

Mr. Datir R. B. (Pharmacist)
Maharashtra Employees State Insurance Society Hosp.
Road No. 33, Wagle estate, Thane (W)- 400604,
Maharashtra
Ph No: 9890593464
Email Id: rahul1pharma@gmail.com

Subject: Drug reported as **Not of Standard Quality** Drug: Rabeprazole Gastro-resistant Tablets IP 20 mg (Rabidoc-20 Tablets), B. No. F4L0950, D/M: DEC-2024, D/E: NOV-2026, Mfg by M/s Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Parwarnoo, Dist.- Soaln HP - 173220- regarding.

Sir,

The subject drug sample was drawn by undersigned Drugs Inspector of this office from your premises i.e. M/s Maharashtra Employees State Insurance Society Hosp., Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra on 26.06.2025 under section 23 of the Drugs & Cosmetics Act, 1940 and Rules made thereunder and was sent for test and analysis at Central Drugs Testing Laboratories (CDTL), Mumbai.

The subject drug has been declared as **"Not of Standard Quality"** by Government Analyst, Central Drugs Testing Laboratory, Mumbai vide test report No. MUM/LS/2025-26/454 dated 14.08.2025 in Form 13 as **the sample does not conform to I.P. 2022 with respect to test for "Dissolution"**. A original copy of test report enclosed herewith.

As per Section 18 a(i) of the Drugs & Cosmetics Act, 1940, no person shall himself or by any other person on his behalf manufacture for sale (or for distribution), or sell or stock or exhibit (or offer) for sale, or distribute any drug which is not of standard quality.

You are required to disclose the name/address and other particulars of the person/firm from whom subject drug was obtained as required under Section 18-A of the Drugs and Cosmetics Act 1940 and furnish the relevant documents as required under Section 18-B of the Drugs and Cosmetics Act 1940. Further, you are requested not to use subject batch of the Drug and recall the same in the greater public interest.

You are also required to submit the following information along with certified copies of the requisite documents as required under section 22(1)(cca) of the Drugs & Cosmetics Act, 1940.

1. The quantity of the subject drug procured and used.
2. The source from whom subject Drug was obtained with relevant copies of documents, purchase invoice etc.
3. Further, directed not to use subject batch of the Drug and recall the same in the public interest and intimate the hold/recall the stock (if any) to this office.

A copy of original report of Government analyst, Central Drugs Testing Laboratories (CDTL), Mumbai in Form 13 is enclosed herewith as required under section 25(2) of the Drugs & Cosmetics Act, 1940.

You are required to furnish the aforesaid information within 7 days for taking further action in this regard.

You are requested to acknowledge the receipt.

Thank You,

MANOJ
NILKANT
GAMBHIRE

Digitally signed by
MANOJ NILKANT
GAMBHIRE
Date: 2025.08.22
17:12:18 +05'30'

(Dr. Manoj Nilkant Gambhire)
Drugs Inspector
CDSCO, West Zone, Mumbai

Enclosure: Copy of Government Analyst report No. MUM/LS/2025-26/454 dated 14.08.2025 in Form 13

Copy:

- 1) The Medical superintendent, Maharashtra Employees State Insurance Society Hosp. Road No. 33, Wagle estate, Thane (W)- 400604, Maharashtra - **For giving necessary directions to stop further use of subject NSQ batch of the Drugs & its recall**
- 2) M/s Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Parwarnoo, Dist.- Soaln HP - 173220
- 3) Deputy Drugs Controller (I), CDSCO (WZ), Mumbai



FORM 13
(See rule 46)

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

1. Name of Inspector from whom received : Mr. Manoj Nilkant Gambhire ,Drugs Inspector
West Zone -1 Mumbai CDSCO (West Zone-1) 4th Floor
Zonal FDA Bhawan, GMSD Compound, Belasis Road,
Mumbai Central, Mumbai-400008 (India)
2. Serial No. and date of Inspector's memorandum : 3-4/MG/CDTL-Mum/WZ/2025/596 , 26-JUN-2025
3. Number of Sample : LSWZ/MG/2025/21
4. Date of receipt : 27-JUN-2025
5. Names of drugs purporting to be contained in the sample : Rabeprazole Gastro-resistant Tablets IP 20 mg
(Rabidoc-20 Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. &	Marketed By	Mfg. By
LSD/MUM/2025-26/0180	MUM/LS/2025-26/454	F4L0950		NA	Morepen Laboratories Ltd., Unit V, Plot 12C Sector -2, Panwaroo, Dist. - Soaln HP - 173220.

6. Condition of seals on (the packet or on portion of sample or container) : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or tests applied : Please refer below
 Date of Testing : From 25-Jul-2025 To 12-Aug-2025

COMPOSITION : Each enteric coated tablet contains:
 Rabeprazole Sodium IP 20 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Peach coloured, circular, biconvex, enteric coated tablet, packed in alu-alu blister strip supplied in paper carton.	NA
2	Identification	Gives positive test for Rabeprazole Sodium	NA
3	Dissolution	Acid stage : Complies Buffer stage : Does not comply	
	S1	Release of each individual unit obtained is as follows: Unit 1 : 66.76 %, Unit 2 : 62.88 %, Unit 3 : 66.09 %, Unit 4 : 63.93 %, Unit 5 : 65.97 %, Unit 6 : 67.21 % All units less than; 70 % of label claim : - Limit 75 % of label claim	Each unit is not less than Q + 5 (i.e. 75 %) Q is 70 %

	S2	Release of each individual unit obtained is as follows: Unit 1 : 65.95 %, Unit 2 : 66.10 %, Unit 3 : 64.90 %, Unit 4 : 62.28 %, Unit 5 : 66.75 %, Unit 6 : 62.70 % Average Drug release of 12 units (S1 + S2) is 65.13 % of label claim :- Limit NLT 70 % of label claim	Average of 12 units (S1 + S2) is equal or greater than 70 % (Q) and no unit is less than 55 % of claim (Q - 15 %)
	S3	Release of each individual unit obtained is as follows: Unit 1 : 70.89 %, Unit 2 : 73.46 %, Unit 3 : 63.80 %, Unit 4 : 67.83 %, Unit 5 : 65.56 %, Unit 6 : 69.21 %, Unit 7 : 63.29 %, Unit 8 : 54.26 %, Unit 9 : 61.62 %, Unit 10 : 57.43 %, Unit 11 : 57.83 %, Unit 12 : 56.33 % of label claim Average of 24 units : 63.46 %	Average of 24 units (S1 + S2 + S3) = NLT 70 %
4	Uniformity of content	Complies	NA
5	Average weight	151.08 mg	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Rabeprazole Sodium	18.98 mg/ tab	20.0 mg/ tab	94.9	90.0 to 110.0 % of label claim	I.P. 2022

In the opinion of the undersigned the sample referred to above 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 conform to I.P. 2022 with respect to test for "Dissolution".

Signature
14/08/25
एस. ए. नवरत्ने / S. A. NAVARATNE
वरिष्ठ वैज्ञानिक सहायक एवं सरकारी विश्लेषक
SENIOR SCIENTIFIC ASSISTANT & GOVT. ANALYST
केंद्रीय औषधि परीक्षण प्रयोगशाला
CENTRAL DRUGS TESTING LABORATORY
मुंबई / MUMBAI

Date: 14-AUG-2025

GOVERNMENT ANALYST

Report in the red colored paper indicates the sample is not of standard quality.

----- END OF REPORT -----

INDIAN DRUGS STANDARD CONTROL ORGANIZATION





कर्मचारी राज्य बीमा निगम
(श्रम एवं 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
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in, ☎011-23604773, ✉dmc-rc@esic.nic.in

File No.: U-25/12/NSQ/2021-MedV (E-1119) | Web -Upload

500

To,
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/14/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

It is hereby informed that the Drug/item has been reported as "Not of Standard Quality". The details of the drug reported NSQ is given below:

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
Maharashtra ESIS Hospital, Nasik- Mumbai-422002	Med Manor Organics Pvt Ltd,	Serratiopeptidase Tab/Cap- Each Tab/Cap Contain: Serratiopeptidase 5 mg (10,000 Units Of Serratiopeptidase)	149 1107	Batch No.- ISP 122 DOM:05-25 DOE:04-27	Junior Scientific Assistant & Govt. Central Drugs Testing Laboratory - Mumbai MUM/LS/2025-26/508 dated 19.09.2025	The sample does not conform to 1.P. 2022 with respect to Assay of "Serratiopeptidase".(copy enclosed).

In context to above, it is directed to:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Stop placement of purchase order for said NSQ item no. 1107 in RC 149 (which is under extension till 30.09.2025).
4. Initiate action as per relevant clause of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC 149.

Contd. to pre page:

5. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Sincerely,

Digitally signed by
Sanjiv Kochhar
Date: 25-09-2025
15:02:17

Dy. Medical Commissioner
(Rate Contract)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (dci@nic.in).
2. CDSCO, Zonal office, Hyderabad , CDSCO BHAVAN, Beside T.B. & Demonstration Centre, S.R. Nagar, Hyderabad-500038,TG (ddchderabad@gmail.com , cdscohyd@gmail.com).
3. Assistant Drugs Controller (I), CDSCO, Sub Zonal Office, The Survey of India, Survey Chowk Campus, Plot No. 68, 17 EC Road, Dehradun - 248001, Uttarakhand (Email-cdscorishikesh@gmail.com).
4. Med Manor Organics Pvt. Ltd.,16-11-477/45, Sri, Krishna Nilyam, Dilsukh Nagar, Hyderabad - 500036 (Email:yoqendra.mishra@medmanor.in, ganesh.jayraman@medmanor.in).
5. Med Manor Organics Pvt Ltd, Unit-II, KH,143/7, Village Raipur Pargana-Bhagvanpur, Tehsil-Roorkee, Distt.-Haridwar (Email-info@medmanor.in).
6. Website Content Manager with request for uploading on ESIC website.
7. Guard file



FORM 13
(See rule 46)

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

1. Name of Inspector from whom received : Mr. Swapnil Ramesh Patil ,Drugs Inspector
West Zone -1 Mumbai CDSCO (West Zone-1) 4th Floor
Zonal FDA Bhawan, GMSD Compound, Bellasis Road,
Mumbai Central, Mumbai-400008 (India)
2. Serial No. and date of Inspector's memorandum : 3-2/WZ-2025/SP/624 , 30-JUN-2025
3. Number of Sample : LS/WZ/SP/2025/140
4. Date of receipt : 03-JUL-2025
5. Names of drugs purporting to be contained in the sample : Serratiopeptidase Tablets IP 5 mg (SPADE Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/MUM/2025-26/0201	MUM/LS/2025-26/508	ISP 122	MAY.2025 APR.2027	NA	Med Manor Organics Pvt. Ltd. Unit-II, Kh. No.143M/7, Village- Raipur Pagwana Bhagwanpur, Tehsil- Roorkee, Dist. Haridwar, Uttarakhand- 247 661.

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] specimen impression of the seal received
from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 14-Jul-2025 To 15-Sep-2025

COMPOSITION : Each enteric coated tablet is purported to contain Serratiopeptidase I.P. 5 mg.
(Equivalent to 10000 Units of Activity)

Protocol Applied : I.P. 2022

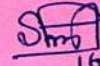
Sr No.	Test Name	Result	Limits
1	Description	White, circular, biconvex , enteric coated tablet in blister strip and supplied in paper carton.	NA
2	Identification	Gives positive test for Serratiopeptidase activity	NA
3	Disintegration (Acid stage)	Complies	No tablet shows signs of cracks till 2 hours
4	Disintegration (Buffer stage)	Complies (31 mins 30 secs)	NMT 60 mins
5	Average weight	104.52 mg	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Serratiopeptidase	1.208 mg/ tablet (2416.33 units/ tablet)	5.0 mg/ tablet (10,000 units/ tablet)	24.16	Not less than 90 % of claim	I.P. 2022

In the opinion of the undersigned the sample referred to above **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 received does not conform to the I.P. 2022 with respect to Assay of "Serratiopeptidase".



16/09/25

एस. के. सिंह / S. K. SINGH
कनिष्ठ वैज्ञानिक सहायक एवं सरकारी विश्लेषक
JUNIOR SCIENTIFIC ASSISTANT & GOVT. ANALYST
केन्द्रीय औषधि परीक्षण प्रयोगशाला
CENTRAL DRUGS TESTING LABORATORY
मुंबई / MUMBAI

Date: 16-SEP-2025

GOVERNMENT ANALYST

Report in the red colored paper indicates the sample is not of standard quality.

----- END OF REPORT -----

