

**भारत सरकार**  
केन्द्रीय औषध मानक नियन्त्रण संगठन  
(उत्तरीय खण्ड)  
(स्वास्थ्य सेवाओं का महानिदेशालय)  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
केन्द्रीय सरकार कार्यालय, भवन न.-प्रथम  
कमला नेहरू नगर, हापुर रोड,  
गाजियाबाद-२०१००२ (उ० प्र०)



**GOVERNMENT OF INDIA**  
**CENTRAL DRUGS STANDARD CONTROL**  
**ORGANISATION (NORTH ZONE)**  
(Directorate General of Health Services)  
**Ministry of Health & Family Welfare**  
C.G.O. Building No.-1, Kamla Nehru Nagar,  
Hapur Road, Ghaziabad-201002. (U.P.)

**'E-mail/Fax'**

Ref. No. NZ/EZ/BN/ 5330

Dated: 18<sup>th</sup> Nov 2013

To,  
All State Drug Controllers of North Zone

Uttar Pradesh / Punjab / Haryana / Rajasthan/  
NCT of Delhi / Chandigarh Administration / Himachal Pradesh,  
Jammu & Kashmir / Uttarakhand.

Subject:- Quinine Dihydrochloride Injection IP, Batch No. 22, D/M-12/2011, D/E-11/2014, M/s Superb Drugs Pvt. Ltd., 1/3/3D, Dum Dum Road, Kolkata-700002 declared as Not of Standard Quality-regarding.

Sir,

This office has been intimated by the Joint Drugs Controller (India), Central Drugs Standard Control Organisation, West Zone, Mumbai vide letter No. 24-2WZ-2013/5333 dated 22.10.2013 (copy enclosed) that a sample of Quinine Dihydrochloride Injection IP, Batch No. 22, D/M-12/2011, D/E-11/2014, M/s Superb Drugs Pvt. Ltd., 1/3/3D, Dum Dum Road, Kolkata has been declared as not of standard quality by the Govt. Analyst, Central Drugs Laboratory, Kolkata vide test report No. 32-9/2013-SS/DCA(W)-12/2885 dated 23.09.2013 for the reason that "the sample does not conform to IP due to the reason as stated under 'Description' and 'Particulate matter'

You are requested to alert your inspectorate to keep a strict vigil over movement of the subject cited drug and take appropriate action under the provision of Drugs and Cosmetics Act & Rules. Any action taken by your administration in the matter may please be communicated to this office at an early date.

This is for your information and further necessary action..

Yours faithfully,

Encl:- as stated above.

*(Signature)*  
(Dr. Ajay Sachan)  
Asstt. Drugs Controller (India)  
For Deputy Drugs Controller (India)

Copy for information to:-

- 5331 1. The Drugs Controller General (India), FDA Bhawan, Kotla Road, New Delhi.  
5332 2. The Joint Drugs Controller (India), CDSCO, West Zone, Mumbai w.r. to letter no. cited above.

**GOVERNMENT OF RAJASTHAN**  
**DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN,**  
**TILAK MARG, JAIPUR**

No. DC/D-1/Test/2013/ 539

Dated: 09.12.2013

Copy forwarded for necessary action to:-

1. Deputy Drugs Controller (India), CDSCO (North Zone), Kamla Nehru Nagar, Hapur Road, Ghaziabad (U.P.).
2. All Asstt. Drugs Controller of Rajasthan State.
3. All Drugs Control Officer of Rajasthan State.
4. Incharge Server Room Hqrs; you are requested to please upload this letter on Departmental website & E-mail.

Encl.: -3

*(Signature)*  
(Ashok Bhandari)  
Drugs Controller  
Rajasthan, Jaipur

# भारत सरकार

केन्द्रीय औषध मानक नियन्त्रण संगठन  
पश्चिम खण्ड

स्वास्थ्य सेवाओं का महानिदेशालय,  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
चौथा तल, झोनल एफ.डी.ए. भवन,  
जी.एम.एस.डी. कम्पाउंड, विलासी रोड,  
मुम्बई सेंट्रल, मुम्बई-400 008.



सत्यमेव जयते

# GOVERNMENT OF INDIA

CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION WEST ZONE

Directorate General of Health Services

Ministry of Health and Family Welfare

4<sup>th</sup> Floor, Zonal FDA Bhawan, GMSD Compound,

Bellasis Rd, Mumbai Central, Mumbai-400 008.

Tel: 022-23002215 /23002279

Fax : 022-23002271

211  
TO

CDSCO

Ref. No.: 24-2/WZ-2013/5333

Date: 22 OCT 2013

To

The Dy. Drugs Controller (I) of East Zone /Ahmedabad Zone/ South Zone /Hyderabad Zone/Sub  
Zone Bangalore, North Zone.

Subject: "Quinine Dihydrochloride Injection I.P Batch No: 22, D/M:12/2011, D/E :11/2014,  
M/s. Superb Drugs Pvt Ltd, 1/3/3D, Dum Dum Road, Kolkata-700002 declared as  
"Not of Standard Quality"- for necessary action-Reg.

Ref : Test Report in Form-13 issued by Govt. Analyst, Central Drug Laboratory, Kolkata  
Vide letter No: 32-9/2013-SS/DCA(W)-12/2885 dated: 23/09/2013.(copy enclosed).

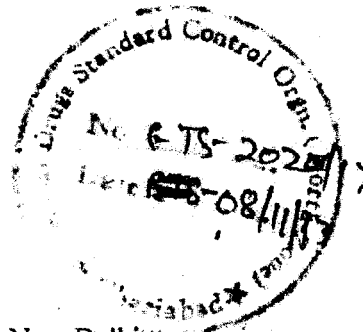
Sir,

The subject sample drawn by Drugs Inspector of this office under Section 23 of Drugs & Cosmetics,  
declared as "Not of Standard Quality" by the Govt. Analyst, Central Drug Laboratory, Kolkata vide  
reference cited above, as the sample does not conform to I.P. due to the reason as stated under 'Description  
& Particulate matter'.

Therefore, you are hereby requested to alert drugs inspector under your control on movement of subject  
batch of drugs and take necessary action (under intimation to this office), and shall also intimate to the State  
authorities under your jurisdiction for appropriate action as per the provisions of Drugs & Cosmetics Act  
Rules.

Yours faithfully,

(DR. V. G. SOMANI)  
JOINT DRUGS CONTROLLER (INDIA)  
CDSCO, WEST ZONE, MUMBAI



Copy to:

1. The Drug Controller General (India), New Delhi.
2. The Drugs Controller, Food & Drugs Adm. Chattisgarh- 492001.
3. The Director, Dir of Food & Drugs Adm., Goa- 403001
4. The Commissioner, Food & Drugs Admin, Guajrat- 382010
5. The Drugs Controller, Food & Drugs Admin. MP, Bhopal- 462001
6. The Joint Commissioner, Food & Drugs Admin., Mumbai-400051



पत्र : " बायोस्टैनलेब , कलकत्ता"  
 Gram: " Biostanlab, Calcutta "  
 दूरभाष : } 2229-9541 ( निदेशक / Director )  
 Phone: } 2229-9021 ( कार्यालय / Office )

सी० डी० एल०-7 / CDL-7

रजिस्टर्ड  
Registered

भारत सरकार  
Government of India  
केन्द्रीय औषध प्रयोगशाला के निदेशक का कार्यालय  
OFFICE OF THE DIRECTOR, CENTRAL DRUGS LABORATORY  
3, कीड स्ट्रीट, कलकत्ता - 700 016  
3, Kyd Street, Calcutta - 700 016

सं० ..... दिनांक , कलकत्ता  
No 32-9/2013-SS/DCA (W) - 12/2885

.....2013.....  
Dated, Calcutta, the...23-9-2013

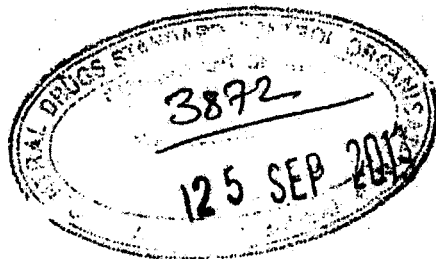
विषय : का परीक्षण.....  
SUBJECT: Testing of... : Quinine Dihydrochloride Injection I.P.

ज्ञापन / MEMORANDUM

आपके त्वरीक ..... के ज्ञापन सं० ..... दिनांक ..... के संदर्भ में ।  
Reference your Memo No. : 17/WZ-2013/1538 dt. 20-03-2013

औषध नियमों के फ़ॉर्म 13 पर रिपोर्ट की तिन प्रतियाँ संलग्न हैं । कृपया फावती भेजें ।  
The report in triplicate is sent herewith in form-13 of Drug Rules. Please acknowledge receipt.

Encl:3 (Form-13)



सरकारी विश्लेषक एवं  
निदेशक , केन्द्रीय औषध प्रयोगशाला

*(Signature)*  
(Dr. Nandita Saha)  
सरकारी विश्लेषक / Government Analyst  
Central Drugs Laboratory

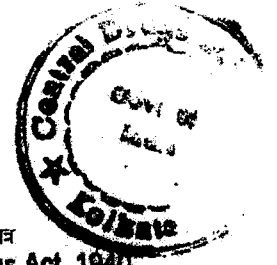
सेवा में / To:

Pravin Jagtap, Drugs Inspector,  
CDSCO, West Zone,  
4<sup>th</sup> Floor, FDA Bhawan, GMSD Compound,  
Bellasis Road, Opp. Hotel Sahil,  
Mumbai Central, Mumbai - 400 008.

*(Signature)*  
20/9/13

CENTRAL DRUGS LABORATORY  
Govt. of India  
3, Kyd Street, Calcutta

फॉर्म संख्या - 13 / FORM NO -13  
कोओ प्रो-8 / CDL-8  
(नियम 46 देखिये) / (See Rule 46)



औषध अधिनियम, 1940 की धारा 25(1) के अन्तर्गत के विश्लेषक द्वारा जांच या विश्लेषक करने का प्रमाण-पत्र  
Certificate of Test or Analysis by Government Analyst under Section 25 (1) of the Drugs Act, 1940

1. निरीक्षक का नाम जिससे प्राप्त हुआ  
Name of the Inspector from whom received : Pravin Jagtap, Drugs Inspector, CDSCO, West Zone, Mumbai - 400 008.
2. निरीक्षक के ज्ञापन की क्रम संख्या व तारीख  
Serial No. and date of Inspector's memorandum : 17/MZ-2013/1538 dt 20-03-2013
3. नमूने की संख्या  
Sample No. : PJ/WF/12-13/080  
4. प्रति की तारीख  
4. Date of receipt : 17-04-2013
5. उस औषध का नाम जो नमूने में मिली है  
Name of drug purporting to be contained in the sample : Quinine Dihydrochloride Injection I.P., Batch No : 22, D/M: 12/2011, D/E: 11/2014, M/s. Superb Drugs Pvt. Ltd., 1/3/3D, Dum Dum Road, Kolkata - 700 002.
6. पैकेट अथवा नमूने के हिस्से पर अथवा पात्र पर मूहर की स्थिति  
Condition of seal on the packet or on portion of sample or container : Intact and Identical with Specimen.
7. जांच अथवा विश्लेषण का परिणाम, किये गये परीक्षणों की प्रामाणिकता सहित  
Result of test or analysis with protocols of tests applied :  
मेरे विचार में उक्त नमूना निम्नलिखित कारणों से औषध अधिनियम, 1940 और तत्समीन नियमों में यथापरिभाषित नामक कोटि का है / नहीं है :  
In the opinion of the undersigned the sample referred to above is not of standard quality as defined in drugs Act, 1940 and rules there under, for reasons given below:-  
Date of Testing : 21-05-2013 to 26-07-2013

**Method : I.P.**

Description	: Pale yellow coloured liquid containing particles, observed with unaided eye in normal daylight supplied in colourless glass ampoule, packed in paper carton.		
Identification	: Gives positive test for Quinine Dihydrochloride.		
pH	: 1.66 (Limit : 1.5 to 3.0)		
Extractable volume	: 2.01 ml/ampoule (Claim : 2.0 ml/ampoule)		
Particulate matter	: Does not comply with I.P.		
Sterility	: Complies with I.P.		
Assay	Found/ 2ml	Claim / 2ml	Limit
Quinine Dihydrochloride	303.075 mg (= 101.025% of label claim)	300 mg	95.0% to 105.0% of label claim
Remarks	<b>Reason for declaring the sample as not of standard quality</b> : The sample does not conform to I.P. due to the reason as stated under 'Description & Particulate matter'.		

संख्या / No. 32-9/2013-SS/DCA(W) - 12/2885  
तारीख / Dated: 23-9-2013

(Dr. Nandita Saha)  
सरकारी विश्लेषक / Government Analyst

1. प्रतिलिपि, औषध नियंत्रक, भारत, स्वास्थ्य सेवा महानिदेशालय, नई दिल्ली - 110 011 को सुचनाई प्रेषित ।  
Copy to : The Drugs Controller General (I), Dte. General of Health Services, FDA Bhawan, Kotla Road, Near Mata Sundari College, I.T.O., New Delhi - 110 002, for information.

Central Drugs Laboratory  
Govt. of India  
4, Arad Street, Kolkata-1

(Dr. Nandita Saha)  
सरकारी विश्लेषक / Government Analyst  
Central Drugs Laboratory

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