

पश्चिम मध्य रेल

कार्यालय
मुख्य चिकित्सा निदेशक
जबलपुर,
दिनांक 28.07.2010

संख्या - पमरे/ एच क्यू/एच/एस/0512/अवमानक

चिकित्सा निदेशक/के.चिकि. जबलपुर

मुख्य चिकित्सा अधीक्षक- जबलपुर/भोपाल

Sub:- Sub-Standard quality of Tab Vitamin B.Complex (Prophylactic NFI), Batch No. IDBT 08/23 Mfg.date 11/2008, Exp. Date 10/2010 Mfgd. by M/s. Indian Drugs & Pharmaceuticals Ltd. Plot No. 27-30, Sector 6A, IIE, Sidcul, Ranipur, Haridwar -249403.

Ref:- CMS / JBP letter No. JBP/Med/S.8/ Drug Report dated 11.6.10.

As per above quoted letter of CMS / Kota, the Tab Vitamin B.Complex (Prophylactic NFI), Batch No. IDBT 08/23 Mfg.date 11/2008, Exp. Date 10/2010 Mfgd. by M/s. Indian Drugs & Pharmaceuticals Ltd. Plot No. 27-30, Sector 6A, IIE, Sidcul, Ranipur, Haridwar -249403 is **not of Standard Quality**; vide analytical report No.AR/COM/23/2010 dated 29.6.10 of Government Analyst, Assistant Director, Drugs control Laboratory, Maharashtra State, 341, Bandra Kurla Complex, Bandra (E), Mumbai- 400051.

If the above batch stock is available in your division the use of the same may please be stopped with immediate effect and full quantity of the item may be got replaced from the firms at their cost and payment should not be released till the full quantity of supply order is replaced and advised to this office.

An Analytical Report of the replaced stock supplied should also be obtained from the firm & also sample sent for Analysis.

✓ C/- DG(RHS) Railway Board, New Delhi for information please.

अ.ग.ग. 28/7/10
(डॉ. अ.ग.ग.)
कृते मुख्य चिकित्सा निदेशक
प.म. रेल, जबलपुर

Copy to :

CHIEF MEDICAL DIRECTORS :

Northern Railway, Baroda House, New Delhi.
Eastern Railway, Fairlie Place, Kolkata

Western Railway, Church Gate, Mumbai.
Southern Railway, Chennai.

Central Railway, CSTM, Mumbai.

North Eastern Railway, Gorakhpur. (UP)

North East Frontier Railway, Maligaon, (Assam)

North Central Railway, Allahabad, (UP)

East Central Railway, Hazipur, Bihar
South Central Railway, Rail Nilayam,
Secundrabad (AP)

East Coast Railway, Bhubaneshwar, Orissa
South Eastern Railway, Garden Reach, Kolkata.

South East Central Railway, Bilaspur C.G.)

North Western Railway, Jaipur, Rajsthan.

South Western Railway, Hubli, Karnataka.

- for information and necessary action please.

C/- M/s. Indian Drugs & Pharmaceuticals Ltd. Plot No. 27-30, Sector 6A, IIE, Sidcul, Ranipur, Haridwar -249403 to replace the material to the consignees immediately and balance quantity may be collected from our consignees and advice to this office accordingly. (copy of Analytical report is enclosed)

Authorized supplier M/s. Rama Medical Agencies, Shop No. 76, Dawa Bazar, Civic Center, Jabalpur - 482002 (M.P.) to replace the material to the consignees immediately and balance quantity may be collected from our consignees and advice to this office accordingly.

CMS / KTT for information and necessary action, with reference to his letter quoted as above.

मुख्य चिकित्सा निदेशक (रेलवे बोर्ड)
रेलवे बोर्ड
- 3 AUG 2010
क.र.सं./C.R. No.
अनुभाग आयरी सं.
Section Dy. No.
वर्गीकरण/Classification.

you were advised
to put all other
failure reports on []
why it hasn't been put up

Tel: 6592362-5
Fax: 6591959

No. AR/ COM/23/2010

Office Of the Assistant Director
Drugs Control Laboratory, M.S.
341, Bandra Kurla Complex,

Date : 29/06/2010

From
The Government Analyst,
Maharashtra State,
Mumbai - 400 051

To
SR DIVISIONAL MEDICAL OFFICER (STORE), OTHERS
KOTA, W.C.R., KOTA - , KOTA

Ref : Your Memo No COM/MD/170/2010/406
Date 21-FEB-10

Sir,

The report in triplicate is enclosed herewith on the following sample sent by you for analysis.

Particulars

Report No.

VITAMIN B COMPLEX TABLETS, PROPHYLACTIC NFI/

COM/23/2010

Further I have to request you to intimate to this Laboratory within 15 days of the receipt of this letter whether the remaining portion of this reported sample and records are required to be preserved in this Laboratory for Prosecution/investigation purpose or not.

If no reply is received within the above period it will be presumed that this sample is not required to be preserved in this Laboratory and such sample will be destroyed.

Your's faithfully,


SHRI A. M. RAVAL

GOVERNMENT ANALYST
DRUGS CONTROL LABORATORY, M.S.

No. AR/I(A)COM/23/201
MUMBAI - 51

Copy forwarded with compliment to:-

- 1.] The Joint Commissioner, Food and Drugs Administration, Maharashtra State.
1. HQ 2. BRJHAN MUMBAI 3. THANE 4. PUNE 5. NASIK 6. NAGPUR 7. AURANGABAD 8. AMRAVATI.
- 2.] The Drug Controller (India), Directorate General of Health Services, Nirman Bhavan, Phase-2, A-wing, Maulana Azad Road, New Delhi-11 for Information.


SHRI A. M. RAVAL

GOVERNMENT ANALYST
DRUGS CONTROL LABORATORY, M.S.

Drug Control Laboratory
Maharashtra State, Bandra (East), Mumbai - 400 051

FORM 13
[See Rule 46]
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST
(Under Section 25 (1) of the Drugs and Cosmetics Act, 1940.)

Page : 1 of 2

Report # : COM/23/2010

1. Name of the Inspector from whom received :

SR. DIVISIONAL MEDICAL OFFICER (KOTA), W.C.R., KOTA - , KOTA

2. Serial number and date of Inspector's memorandum :

COM/MD/170/2010/40 21/02/2010

3. Number of Sample :

3 x 10 TAB

4. Date of receipt :

26/02/2010

5. Name of drug purporting to be contained in the sample :

VITAMIN B COMPLEX TABLETS, PROPHYLACTIC NFI

6. Condition of seals on the package :

Intact and does not Tallies with the specimen impression of the seal received separately.

7. Results of tests or analysis with protocol of test applied :

Batch No. : IDBT-08/23
Mfg. Lic No. : 85/UALL/SC/P-2006

Mfg. Date : 01/11/2008
Exp. Date : 31/10/2010

Anamolies :

Observation on labelling :-

Container Label :

VITAMIN B COMPLEX TABLETS, PROPHYLACTIC NFI
VITAMIN B-COMPLEX TABLETS (PROPHYLACTIC) NFI
EACH UNCOATED TABLETS CONTAINS :
VITAMIN B1 MONONITRATE IP 2.0 MG
VITAMIN B2 IP 2.0 MG
VITAMIN B6 IP 0.5 MG
NIACINAMIDE IP 25.0 MG
CALCIUM PANTOTHENATE IP 1.0 MG
COLOUR : TARTRAZINE.
APPROPRIATE OVERAGES OF VITAMINS ADDED. HOSPITAL SUPPLY NOT
FOR SALE
FOR PROPHYLACTIC USE. KEEP IN A COOL DRY PLACE AWAY FROM LIGHT.

Manufactured by :

INDIAN DRUGS & PHARMACEUTICALS LTD.
Plot No. 27-30, Sec 6A, Side 1, Ranipet, Haridwar-249403

Description :

YELLOW COLOURED, CIRCULAR, FLAT UNCOATED TABLETS.

Report #: COM/23/2010

Identification : The sample gives identification test.

The sample complies for the following tests :-

DISINTEGRATION TIME

Assay :

INGREDIENT	FOUND	% OF LABELLED AMT.	LIMIT
VITAMIN B1	1.183mg / TABLET	59.15	90 -
VITAMIN B2	2.265mg / TABLET	113.25	90 -
VITAMIN B6	.287mg / TABLET	57.4	90 -
CALCIUM PANTOTHENATE	1.232mg / TABLET	123.2	90 -
NIACINAMIDE	30.68mg / TABLET	122.72	90 -


Additional Text : Method followed for vitamin B1 as per U.S.P.31 page no.184 under Thiamine assay and for vitamin B6 as per U.S.P.31 page no.3138 as given under pyridoxyn hydrochloride tablets.

In the opinion of the undersigned the sample referred to above is of NOT OF STANDARD QUALITY as defined in the Drugs and Cosmetics Act, 1940 and Rules thereunder for the reasons given below :-

CONTENT OF VITAMIN B1 MONONITRATE (i.e. 59.15 % of labelled amount) AND VITAMIN B6 (i.e. 57.38 % of labelled amount) IN THE SAMPLE ARE LESS THAN THE PERMISSIBLE LIMIT AS GIVEN IN THE PROTOCOL

In expressing the above opinion only the Test's and Assay's performed as given in the protocol are taken into consideration.

Date : 29/06/2010


SHRI. A. M. RAVAL
GOVERNMENT ANALYST (M.S)