

राजस्थान सरकार
औषधि नियंत्रण संगठन, स्वास्थ्य भवन, तिलक मार्ग,
जयपुर, राजस्थान

क्रमांक:-डीसी/डी-4/पी-36(चुरु)/2017/224

दिनांक:-14/9/2017

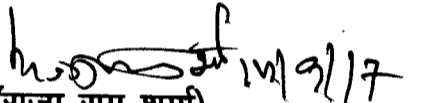
समस्त सहायक औषधि नियंत्रक
राजस्थान

विषय:- 1. Not of Standard Quality drug, sample no. NZ/SMP/NS/A-070-2016-17 of Zinc Sulfate Dispersible Tablets I. P. B. No. T0286, M/D 05-2016, E/D 04-2018, Mfd. By M/s Quest Laboratories Pvt. Ltd. Plot No.45, Sector-III, Pithampur Distt. Dhar-454775, M. P. .regarding. 2. Testing of a drug sample of Germicide Gargle Povidone Iodine 1% w/v B. No. EPM6001AL, M/D 06-2016, E/D 11-2017, Mfd. By M/s Hindustan Laboratories Plot No. 5-9, Survey no. 38/2, Aliyali, Palghar-(W), Dist-Palghar - 401404(M.S.) India, declared as Not of Standard Quality-Regarding

संदर्भ:-Assistant Drugs Controller (India) Ghaziabad Vide Letter No. 429 Dated: 13-07-2017., 1446 Dated:13-07-2017 के संदर्भ में।

उपरोक्त विषयान्तर्गत प्राप्त संदर्भित पत्रमय संलग्नको की छायाप्रतियां इस पत्र के साथ संलग्न कर आपको आवश्यक कार्यवाही हेतु प्रेषित हैं।

संलग्न:- उपरोक्तानुसार -3


(राजा राम शर्मा)
औषधि नियंत्रक
राज0 जयपुर

क्रमांक:-डीसी/डी-4/पी-36(चुरु)/2017/224

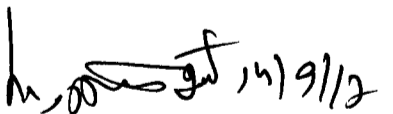
दिनांक:-14/9/2017

प्रतिलिपि:-

1. औषधि नियंत्रक-प्रथम, राजस्थान, जयपुर। संलग्न-3

2. प्रभारी कम्प्यूटर सर्वर रूम मुख्यालय को भेजकर लेख हैं कि उक्त पत्रमय संलग्नकों को विभाग की वेबसाइट पर लगाने की शीघ्र व्यवस्था करें। संलग्न-3

3. रक्षित पत्रावली।


(राजा राम शर्मा)
औषधि नियंत्रक
राज0 जयपुर

भारत सरकार
केन्द्रीय औषध मानक नियन्त्रण संगठन
(उत्तरीय खण्ड)
(स्वास्थ्य सेवाओं का महानिदेशालय)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
केन्द्रीय सरकार कार्यालय, भवन नं-प्रथम
कमला कौशिक नगर, हावड़ा रोड,
गान्धियाबाद-207002 (उ.प्र.)



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

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JUL 2017

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"Registered Post/Fax/E-mail"

Ref. No. NZ/SMP/DK2/A-51/Pov-I-gargle/Hindustan/2017/1446 Dated: 13-7-17

To,

1. The Drugs Controller, Drugs Licensing & Controlling Authority, 9 Jagat Narayan Road, Lucknow, UP
2. The Drug Controller, Controlling cum Licensing Authority, Himachal Pradesh, Health & Family Welfare Department, Nagar Panchayat Bhawan, Near SDO's Office, Sector-1, Dehra Dun - 248001
3. The Assistant Drug Controller, C/o the Regional Licensing Authority, Drugs Control Administration, Himachal Pradesh, CMO's Office Complex, Solan - 173202 (H.P.)
4. The Drugs Controller, State Drugs Controller cum Licensing Authority, Food and Drug Administration, Haryana, SCO No. 94, Sector-5, Faridkot, Punjab
5. The Drugs Controller, Drugs Control Organisation, Swasthya Bhawan, Jaipur (Rajasthan)
6. The Drug Controller, Bahadrabad Road, Dehradun, Uttarakhand-248001
7. The Drug Controller, Drugs & Food Control Administration, Patoli Magotrian, Jammu & Kashmir, Jammu - 180001
8. The Drug Control Department, 4th Floor, 17, Karkarduma, Shadara, Delhi - 110 003
9. The State Drug Controller, Food & Drug Administration Punjab, Fatiwar Kalyan Bhawan, Sector-34 A, Chandigarh (Punjab)

Subject: - Testing of a drug sample of Benzalkonium Chloride Povidone Iodine 1% w/v Batch No. EPM6001AL, Mfg. No. 06/2016, Exp. Date 07/2017, Mfg. By: M/s. Hindustan Laboratories, Plot No. 5-A, Sector-1, Alyah, Palghar (W), Dist. Palghar-401404 (M.S.) India, declared as Not of Standard Quality regarding.

Reference: Test Report in Annex-2 issued by the Government Analyst, Regional Drug Testing Laboratory, Chandigarh, vide Memorandum No. LSD/SDTL/0219/17-18 dated 30/06/2017 (Copy enclosed).

Sir/Madam,

The subject Drug sample was drawn by the Drugs Inspector of this office under Section 23 of Drugs & Cosmetics Act, 1940, declared as Not of Standard Quality by the Government Analyst, Regional Drug Testing Laboratory, Chandigarh, vide reference cited above for the reason that "the sample does not conform to claim as per Test & Result in respect to the Assay of Povidone Iodine calculated as available iodine".

Therefore, you are requested to alert Drugs Inspectors under your control on movement of subject batch of drug and take necessary action under intimation to this office.

Yours faithfully,

(Signature)
(Dr. Ajay Sachan)
Asst. Drugs Controller (India)
for Deputy Drugs Controller (India)

Encl: Test Report No. Reg No. LSD/RDTL/1529/16-17 dt 01/05/2017.

Copy to:

- 1430 > The Drugs Controller General (India), New Delhi
- 1431 > The Dy. Drugs Controller (India) of West Zone
- 1431 > The Dy. Drugs Controller (India) of East Zone
- 1431 > The Dy. Drugs Controller (India) of South Zone
- 1431 > The Dy. Drugs Controller (India) Zonal office Hyderabad
- 1431 > The Dy. Drugs Controller (India) Zonal office Ahmedabad
- 1431 > The Dy. Drugs Controller (India) of Sub-Zone office Bangalore
- 1431 > The Asst. Drugs Controller (India) of Sub-Zone office Jaipur
- 1431 > The Asst. Drugs Controller (India) of Sub-Zone office Chandigarh
- 1431 > The Dy. Drugs Controller (India) of Zone office Bhopal
- 1431 > All Dts. CDDOs, Zonal offices, Ahmedabad

You are hereby requested to intimate the State Authorities under your jurisdiction for appropriate action as per provision of Drug and Cosmetics Act 1940 and Rules 1945.

Therefore, you are requested to alert Drugs Inspectors under your control on movement of subject batch of drug and take necessary action under intimation to this office.

Yours faithfully,

(Dr. Ajay Sachan)
Asst. Drugs Controller (India)
for Deputy Drugs Controller (India)

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- 1431 > The Dy. Drugs Controller (India) of Central Zone, Hyderabad
- 1431 > The Dy. Drugs Controller (India) of Central Zone, Ahmedabad
- 1431 > The Dy. Drugs Controller (India) of South Zone, Bangalore
- 1431 > The Asst. Drugs Controller (India) of South Zone, Chennai
- 1431 > The Asst. Drugs Controller (India) of South Zone, Chandigarh
- 1431 > The Dy. Drugs Controller (India) of West Zone, Delhi
- 1431 > All Dis. CDSCO, New Delhi, Government

You are hereby requested to intimate the State Authorities under your jurisdiction for appropriate action as per provision of Drugs and Cosmetics Act 1940 and Rules 1945.

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 : Dinesh Kumar-2, Drugs Inspector (India), CDSCO (North Zone)
CGO, Building No.1, First Floor,
Kamla Nehru Nagar
Ghaziabad, (UP), 201002

2. Serial No. and date of Inspector's Memorandum : NZ/SMP/DK2/A/2017/304 dated :- 05/05/17

3. Number of Sample : NZ/SMP/DK2/A-51/2017

4. Date of receipt : 11/05/17

5. Name of drugs purporting to be contained in the sample : (GERMICIDE GARGLE POVIDONE IODINE 1% W/V)

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 the Drug Inspector

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

Reg. No : LSD/RDTL/0210/17-18 B.No : EPM6001AL D/Mfg : Jun./2016 D/Exp : Nov./2017 Mfd. By : HINDUSTAN LABORATORIES,
Plot No.5-9, Survey No. 33/2,
Aiyali Palghar-(W) Dist. Palghar, 401404 (M.S)

COMPOSITION : Povidone Iodine IP 1% w/v
(available Iodine 0.1% w/v)

Result & Protocols : As per Patent and Proprietary

Description : Brown liquid filled in transparent plastic bottle.

Identification : Positive for Iodine.

Nominal Volume : 50.00ml

Uniformity of filled volume : Not done due to insufficient sample quantity.

Weight/ml : 1.0208gm

ASSAY

Content of	Obtained	Claim	Obtained	Limits	Protocol
Povidone Iodine calculated as Available Iodine	0.060%w/v	0.100%w/v	60.00%	90% to 110%	RDTL-STP-P05

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 claim as per Patent & Proprietary in respect to the Assay of Povidone Iodine calculated as Available Iodine.

Dated :- 30/06/17

End Of Report
Page 1 of 1



GOVERNMENT ANALYST