



**HQRS. OFFICE**  
**EMPLOYEES' STATE INSURANCE CORPORATION**  
**PANCHDEEP BHAWAN: C.I.G. ROAD: NEW DELHI – 110 002**  
Tel/Fax: 011-23234334, E-mail: [dmc-rc@esic.nic.in](mailto:dmc-rc@esic.nic.in)  
(An ISO-9001:2008 Certified)

No.U-25/12/NSQ/2018-Med.V P-1

Dated: 04.07. 2019

To,

**Director(Medical)Delhi/ Noida**  
**Medical Superintendent-All ESIC Hospitals.**  
**The Director, ESI Scheme,All States.**

**Subject: DECLARATION OF DRUG 'NOT OF STANDARD QUALITY' ON TESTING**

Sir/Madam,

I am to inform you that the drug as detailed below is reported as "Not of Standard Quality" and directed to **stop the use of the following batch of item immediately** which has been reported as "Not of Standard Quality" :-

NSQ Reported By	Name of the Firm	Item Name/ Brand Name	R.C No. Item No. Page No.	Batch No. Date of Mfr. Date of Exp.	Report No. &Date	Name of Lab.
The Dean ESIC Medical College &Hospital, NH-3,NIT, Faridabad	M/s Synokem Pharmaceuticals Ltd	Misoprostol Tablets I.P 200 mcg (MST)	139A  563b  2 of 51	18SGET035  05/2018  04/2020	32-1/2019 -SS/DCA(N)-126/388 dtd 08/05/19	Govt. Analyst Central Drugs Laboratory Kolkata-16



It is also directed that action may be taken as per term and conditions of DGESIC R.C. clause 19 for "Testing of drugs- Quality Control". Replacement of the supplies or the Cost of the material is to be recovered along with Testing charges, if any, may also be recovered from the firm.

This issue with the approval of Competent Authority.

Yours Faithfully

  
Assistant Director (RC)

Copy for information to: -

1. The State Drug Controller, Drug Control Department,F-17,Karkardooma,Delhi-110032.with the request to take appropriate action on 'NSQ' reported for the above said batch item under intimation to this office. (Copy of test report is enclosed.)
2. M/s Synokem Pharmaceuticals Limited, Synokem House, 14/486, Sunder Vihar Outer Ring Road, Paschim Vihar, New Delhi-110087
3. WCM for uploading on ESIC website
4. Dr.  DMC - email - 
5. Guard file/Spare copy.
6. Hindi cell for translation.

  
Assistant Director (RC)

भारत सरकार

केन्द्रीय औषध मानकनियन्त्रण संगठन  
(उत्तरीय खण्ड)  
(स्वास्थ्य सेवाओंका महानिदेशकालय)  
स्वास्थ्य एवंपरिवारकल्याणमन्त्रालय  
केन्द्रीय प्रयोगशाला-दिल्ली  
एन. नं. 1/2019  
कमलमैदान, नया दिल्ली-110002 (एन. नं.)  
फ़ोन: 23387448, 23387449



भारत सरकार  
E-mail:cds@nic.gov.in

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

**"Registered Post/Fax"**

S&L No. 14/NZ/NSQ/SC/Synokem/18/2019

Date: 03/05/2019

To,  
Sh. Ripul (Pharmacist) / Dr. [Redacted] (Store Incharge)  
ESIC medical college and hospital,  
NH-3, NIT, Faridabad, Faridabad

**Subject:** - Testing of a sample of Misoprostol tablets IP 200 mcg MST, Batch No. 18SGE035, Mfg. Dt. May 2018 Exp. Dt. Apr. 2020, Mfg. by: M/s Synokem Pharmaceuticals Ltd, Plot No 35-36, Sector-5A, Integrated Industrial Estate (SIDCULI, Ranipur (BHEL), Haridwar-249403 declared as **Not of Standard Quality** - For necessary action - regarding.

**Reference:** Test Report in Form 13 issued by the Government Analyst, CDL, Kolkata, vide test report no. 32-1/2019-SS/DCA(N)-128/388 dated 08-05-2019 (Copy enclosed).

Sr/Madam,

The subject drug sample was drawn by the undersigned under Section 20 of the Drugs & Cosmetics Act, 1940 on 18-01-2019 from your hospital pharmacy and was sent to the Government Analyst for test/analysis. The sample was declared as **Not of Standard Quality** by the Government Analyst, Central Drugs Laboratory, Kolkata vide Test report cited as reference above, stating that **"the sample does not conform to I.P. with respect to Assay of Misoprostol"**.

As required under Section 25(2) of Drugs & Cosmetics Act, 1940, please send enclosed original of above mentioned Test Report.


Since the subject cited Drug has been declared as **Not of Standard Quality**, you are, therefore, required to disclose the name/address and other particulars of the person from whom, the said drug was obtained as required under Section 18-A of Drugs & Cosmetics Act 1940 and furnish the relevant documents (attested copies of bills/invoice etc.) as required under Section 18-B of the said Act to the undersigned within 7 days from the date of receipt of this letter.

f. d. o

You are advised to stop further usage of subject cited Not of Standard Quality drug with immediate effect.

This is for your information and necessary action in the matter.

Yours faithfully,

  
Drugs Inspector  
CDSCO, North Zone,  
Ghaziabad

Encl - Original test report no. 32-1/2019-S5/DCA(N)-126/388 dated 08-05-2019 of above cited batch.