DRUGS CONTROL ADMINISTRATION
Government of Telangana

Circular.Rc.No.1737/JD/Misc/2023

Dated: 14 .07.2023

Sub: DCA – Procedure for submission of cough syrups to be exported by the manufacturer/authorized person of manufacturer/exporter directly to any of the Central/NABL State accredited Laboratories for testing purpose – Regarding.

Ref:
1. Letter dt: 25.05.2023 in File.No.DCGI/MISC/2023/09 of the Drugs Controller General (India) & Central Licensing Authority, CDSCO, New Delhi
2. Notification No.06/2023, dt: 22.05.2023 of Ministry of Commerce & Industry, Government of India

-x-x-x-

With reference to the letter 1st cited, you are hereby directed to adhere to the procedure indicated in the said letter scrupulously regarding submission of cough syrups to be exported by you to the central drug testing laboratory, Hyderabad for testing purpose.

You are further directed to submit a copy of the test report received by you in this regard for every batch of cough syrup meant for export without fail.

14/7/23

JOINT DIRECTOR (I/C)
LICENSING AUTHORITY

To
The cough syrup manufacturers located in Telangana enlisted in the Annexure

Copy to:
All the Drugs Inspectors concerned to ensure strict adherence of the manufacturers to the procedure indicated in the enclosed letter and monitor regarding submission of test reports to directorate.

Copy submitted to:
The DCG(I), CDSCO, New Delhi for information
The DDC(I), CDSCO, Hyderabad for information
The Director, CDTL, CDSCO, Hyderabad with a request to forward test reports of cough syrups to this office for information.

File No: DCGI/MISC/2023/09
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi-110002

Date: 25th, May, 2023

To,
All State Drug Controllers/UTs
All CDSCO Zonal, Sub-Zonal, Port offices,
All Indian Drug manufacturers Associations

Subject: - Procedure for submission of cough syrups to be exported by the manufacturer/authorised person of manufacturer/exporter directly to any of the Central/NABL State accredited laboratories for testing purpose-reg.

Ref:- 1. Notification no. 06/2023 dated 22nd May, 2023
2. D.O. Letter No.X-11035/40/2023-DRS dated 23.05.2023

Sir,

Ministry of Commerce & Industry, Government of India vide Notification no. 06/2023 dated 22nd May, 2023 shall be permitting export of cough syrups, subject to the export sample being tested and production of Certificate of Analysis (CoA) issued by any of the Central Government Laboratories and any NABL accredited State Drug Testing Laboratory. Accordingly, Joint Secretary (R) MoH&FW, Government of India issued D.O. letter No. X.11035/04/2023-DRS on dated 23rd May, 2023 to all State Drug Controllers to actively engage with the manufacturer/export houses and relevant associations to ensure that this process goes smoothly.

In order to facilitate the process of testing of cough syrups at the said laboratories the following are the pre-requisite/requirements for submission of samples by the manufacturer directly to the nearby NABL accredited State / Central laboratories as mentioned in the notification issued by the Department of Commerce (**Ref.1**):

1. Covering letter from the manufacturer/exporter on letter head addressed to concerned laboratory.
2. Manufacturing license of the product for export purpose.
3. Export order
4. Representative sample from the export consignment.
5. Thrice the quantity required for performing complete analysis of the sample.
6. Qualitative composition of product including excipients.
7. Certificate of analysis by the manufacturer of the particular batch and method of analysis (STP).
8. Reference/working standard (with traceability certificate) and Placebo as applicable.

In view of above, all State Licensing Authorities/CDSCO Zonal, Sub-Zonal Offices and all Indian Drug Manufacturer Association are requested to percolate the above requirements to all concerned who intend to export cough syrups.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licensing Authority

Copy to:

1. The Drugs Controller for the State of Gujarat/Karnataka/Kerala/Madhya Pradesh/Maharashtra/Jammu & Kashmir and Uttarakhand,
2. All Directors of NABL accredited State Laboratories of Gujarat/Karnataka/Kerala/Madhya Pradesh/Maharashtra/Jammu & Kashmir and Uttarakhand,
3. Secretary-cum-Scientific Director, IPC, Ghaziabad,
4. Head of laboratories of CDL, Kolkata,
5. Head of laboratories of CDTL, Chennai, Mumbai and Hyderabad,
6. Head of laboratories of RDTL, Guwahati, Chandigarh.

} With a request to test DEG/EG in all samples even if it is not part of the mfr. specifications along with other test parameters and issue the test report as per the format enclosed.

LETTER HEAD OF THE LABORATORY CONCERNED

REPORT NO:

Certificate of test or analysis by the Drugs Testing Laboratory, ...

Certified that the sample bearing number :

Name of the product:

Purporting to be sample of /**Mfd. By** :

Batch No. :
Qty Received :

Mfg. Date :
Exp. Date :

Received on : Covering Letter No.
Received From Manufacturer/Exporter Name :

Has been tested/analysed and that the result of such test/analysis is stated below.

Test Parameter	Result of Analysis	Limits/Specification
Description		
Identification		
XX		
YY		
Assay		
DEG		**0.1%**
EG		**0.1%**

In the opinion of the undersigned, the sample referred to above is of **STANDARD QUALITY/Not of Standard Quality** as per the test specification for the reasons given below:-

Date:

(Government Analyst /Director)

Terms & Conditions:- This result relates only to the item tested. The test report shall not be reproduced either in full or in part without written approval of the laboratory.

END OF REPORT

ANNEXURE

1. HITECH PHARMACEUTICALS PRIVATE LIMITED,
   134-B, S.V. CO-OP INDUSTRIAL ESTATE, BOLLARAM(V), JINNARAM(M), SANGAREDDY(DIST.) TELANGANA

2. SAIN MEDICAMENTS PVT. LTD.,
   P-2/4, IDA, UPPAL, HYDERABAD-500 039, TELANGANA

3. YELURI FORMULATIONS PRIVATE LIMITED,
   H.NO 16-124, SY NO.296/7/6, IDA BOLLARAM, SANGAREDDY DISTRICT, TELANGANA STATE, INDIA – Loan Licence at PLOT NO 134-B, SV CO.OP INDUSTRIAL ESTATE, IDA BOLLARAM, C/O M/s.HI-TECH PHARMACEUTICALS PVT LTD