

Enforc-11017(11)/3/2023-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi-110002

Date: 13th Sep, 2023

To,

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

Subject: - Approval of NABL Accredited Private Testing Laboratory for Testing of Cough Syrup to be exported by the Manufacturer/Authorize person of Manufacturer/Exporter -reg.

Ref:- 1. Notification no: 06/2023 dated 22nd May 2023, Ministry of Commerce & Industry, Govt. of India.
2. D.O. Letter No. X-11035/40/2023-DRS dated 23.05.2023 JS (R), MoHFW, Govt. of India
3. Directorate Letter. No. DCGI/MISC/2023/09 dated 26.05.2023.

Sir,

Further to this Directorates Letter vide File No. DCGI/MISC/2023/09 dated 26.05.2023, it has been decided with the approval of Ministry of Health & Family Welfare to include the following 03 NABL Accredited Private Testing Laboratories for Testing of Cough Syrup to be exported by the Manufacturers/Authorize person of Manufacturer/Exporter apart from 14 NABL Accredited Government Laboratories. The details of the 03 Laboratories are as follows:

1. Bee Pharmo Labs Pvt. Ltd Thane, C-2 Hatkesh Udyog Nagar, Mira Bhayander Road, Mira Road (East), thane-401107, Maharashtra.
2. Oasis Test House, 24-A, B Sardar Patel, industrial Estate, Narol, Ahmedabad-382407, Gujarat.
3. Shriram Institute for Industrial Research (A Unit of Shriram Scientific and Industrial Research Foundation), 19-University Road, New Delhi-110007.

The List of NABL Accredited Central Drugs Testing Laboratories and State Drug Testing Laboratories which are involved in testing of cough syrup are listed below:

Details of NABL Accredited Central Drugs Testing Laboratories

State	Location
Uttar Pradesh.	Indian Pharmacopoeia Commission (IPC), Raj Nagar, Ghaziabad
West Bengal	Central Drugs Laboratory (CDL), Kolkata,
Tamil Nadu	Central Drugs Testing Laboratory (CDTL), Chennai
Maharashtra	Central Drugs Testing Laboratory (CDTL), Mumbai
Telangana	Central Drugs Testing Laboratory (CDTL), Hyderabad
Chandigarh	Regional Drugs Testing Laboratory (RDTL)
Assam	Regional Drugs Testing Laboratory (RDTL), Guwahati

Details of NABL Accredited State Drugs Testing Laboratories:

State	Location
Gujarat	Food and Drugs Laboratory, Near Polytechnic, Opp. M.S. University, Nizampura, Vadodara
Jammu & Kashmir	Combined Food & Drug Testing Laboratory, Patoli Mangotrian, Jammu
Karnataka	Drug Testing Laboratory, Drug Control Department. Palace Road, Bengaluru
Kerala	Drug Testing Laboratory, Red Cross Road, Vanchiyoar, Thiruvananthapuram
Madhya Pradesh	Food and Drugs Administration, IDGAH HILLS, Bhopal, Madhya Pradesh
Maharashtra	Drug Administration Laboratory Mumbai, Bandra Kurla Complex, Bandra East, Mumbai
Uttarakhand	STATE FOOD AND DRUG TESTING Laboratory OLD, J.L.N Govt. Hospital Campus, Near Indira Chowk, Kichha Road Rudrapur

The pre-requisite/requirements for submission of samples by the manufacturer/exporter to one of the above mentioned laboratories remains same as mentioned in Directorate letter vide No. DCGI/MISC/2023/09 dated 26.05.2023 and the same is reproduced below.

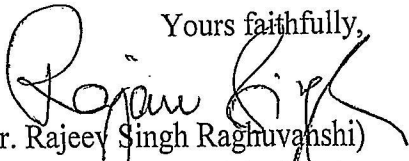
1. Covering letter from the manufacturer/exporter on letter head addressed to concerned laboratory.
2. Manufacturing license of the product for export purpose.
3. Export order
4. Representative sample from the export consignment.
5. Thrice the quantity required for performing complete analysis of the sample as per their STP
6. Qualitative composition of product including excipients.
7. Certificate of analysis by the manufacturer of the particular batch, product specification and method of analysis (Spec./STP).

8. Reference/working standard and Placebo as applicable.

In view of above, all State Licensing Authorities/CDSCO Zonal, Sub-Zonal Offices and all Indian Drug Manufacturer Associations are once again requested to note the above information/requirements for export of cough syrup.

Encl:

1. Directorate Lr. No. DCGI/MISC/2023/09
dated 26.05.2023

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.
7. Bee Pharmo Labs Pvt. Ltd Thane, C-2 Hatkesh Udyog Nagar, Mira Bhayander Road, Mira Road (East), thane-401107, Maharashtra.
8. Oasis Test House, 24-A, B Sardar Patel, industrial Estate, Narol, Ahmedabad-382407, Gujarat.
9. Shriram Institute for Industrial Research (A Unit of Shriram Scientific and Industrial Research Foundation), 19-University Road, New Delhi-110007.

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.