Guidance Document on Risk Based Approach for Monitoring Quality at the Ports of Import

DRAFT GUIDANCE

This guidance document is for feedback purposes only. Comments suggestions, if any, may please be submitted to the office of Drugs Controller General India within thirty days

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

PREFACE

Import, manufacturing, sale and distribution of Drugs, Cosmetics and Medical Devices in India are regulated under Drugs and Cosmetics Act 1940 and Rules there under.

Imports of Drugs into India are required to be registered along with the manufacturing sites as per Chapter III of the Drugs and Cosmetics Act, 1940 and Part IV of the said rules. If the drug, falls within the definition of New Drug (Rule 2 w, under the Chapter I of the New Drugs and Clinical Trials Rules, 2019), the new drug approval is the pre-requisite for submission of application for Registration and import of drug.

Import of cosmetics into India is regulated through a system of registration by the CDSCO under the provisions of the Drugs and Cosmetics Act, 1940 and the Cosmetics Rules, 2020. Any article falling within the definition of cosmetic is required to be registered along with pack size, variants and manufacturing premises before its import into the country.

Import of Medical Devices and Diagnostics into India is regulated under Medical Devices Rules, 2017 and Import License is required to be obtained under the Medical Devices Rules, 2017.

The purpose of this guidance document is to provide guidance to the port officers to take appropriate decisions for monitoring quality at the port of import based on Risk Based approach.

INTRODUCTION

All the port offices of Central Drugs Standard Control Organization (CDSCO) are under the control of Drugs Controller General (India). CDSCO through the officers posted at the port, exercise control over Drugs, Cosmetics and Medical Devices which are imported / exported in the country. This control is exercised under Chapter III of the Drugs & Cosmetics Act. The port officers function in an advisory capacity to the Customs Authorities. Any action for contravention of Section 10 of the Drugs and Cosmetics Act is resorted to by advising the Commissioner of Customs to take action under Section 11 of Drugs & Cosmetics Act, read with relevant provisions of Customs Act 1962.

The monitoring of quality of the imported drugs, cosmetics and medical devices is of paramount importance to the public health. Each consignment by way of sampling for testing of imported consignment of Drugs/ Cosmetics/ Medical Devices in to the county shall be monitored forthwith for the quality which is indirectly monitoring the safety and efficacy. However, such monitoring for each consignment is practically not possible. Therefore, Risk base approach has been followed Worldwide for monitoring the quality and to take appropriate decision/action in case of quality failures.

This guidance document has been prepared for the Port Officer to implement Risk based approach at various levels for monitoring the quality of the imported consignments to provide high degree of assurance for the safety of public health.

RISK-BASED APPROACH FOR SAMPLING

Monitoring the quality at ports of entry is very important as it serves as a first-line intervention and has been shown to deter the trading of poor-quality drug, cosmetics and medical devices. This monitoring is based on the risks associated with manufacturing complexity, dosage form, stability (e.g., temperature sensitivity), safety/efficacy (e.g., narrow therapeutic window), demand (e.g., high-burden diseases), therapeutic indication (e.g., infectious diseases), or other factors.

Handling, storage, and transportation of samples

This guideline also recommends the use of a three tiered risk based approach for sampling which proposes that testing can occur at three levels: Desktop inspection and/or visual inspection; then through field-based tests (using the Minilab or other screening tools); and finally at the laboratory as required for complete testing.

Desktop and/ or Visual inspection (Tier 1)

The document verification at desktop may identify important characteristics related to product quality (registration status, expiry, shelf life, labelling and product packaging, etc.) or issues with the physical characteristics of the dosage form (presentation, colour, texture, and viscosity, etc.). Visual inspection, can be required at the point of sampling and can be used to identify falsified, unregistered, or incorrectly labelled medicines.

In some cases, the Port Officer may seek clarification with the applicant, proceed with other aspects of quality testing, or take other decisions based on the assessment.

In case some deviations are observed and if a determination cannot be made (e.g., deviations are not clearly discernable against expected product presentation), then the product should proceed to testing at **Tier 2.**

Sampling for primary testing (Tier 2)

Tier 2 involves reduced analytical testing of product quality especially identification/Assay w.r.t. suspicious drugs in a minilab or approved laboratories. Suspicious samples identified by visual inspection may undergo further screening using one or more advanced screening tests. This approach may further eliminate the need for additional testing.

Alternatively, based on which screening tools are used and the tests performed, the Port officer may choose to send a portion of the passed samples for compendial testing (**Tier 3**) to confirm the results. Samples that fail field-based may be retested at the compendial level to confirm results.

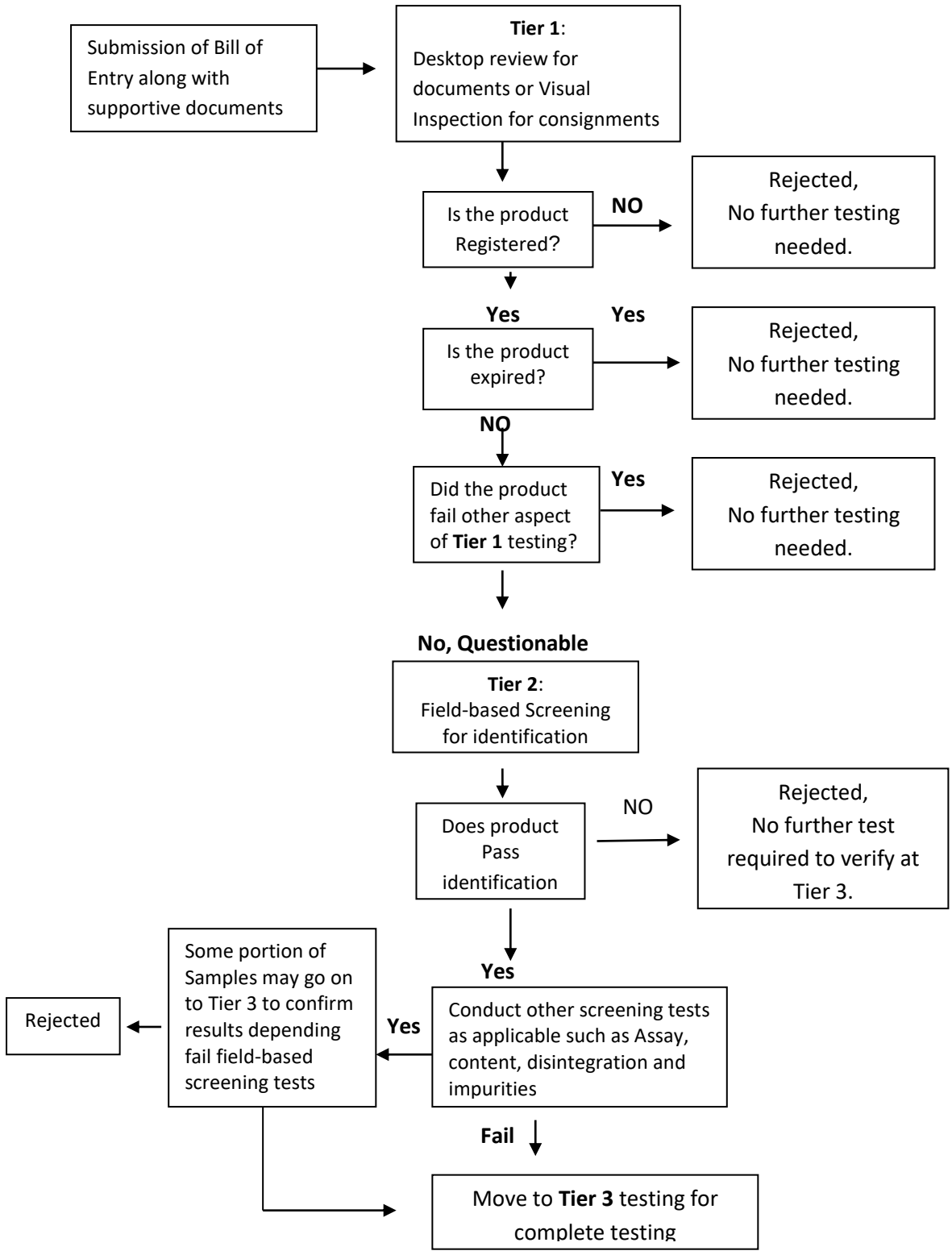
Sampling for Complete testing (Tier 3)

Compendial testing provides the most extensive information on product quality, but it is also the most complex, expensive, and time-consuming type of testing. Compendial testing should be carried out on suspected samples that fail field-based screening tests as well as, on the sample drawn, as per sampling plan mentioned under.

Note: if a product fails a test at **Tier 2**, the same test should be performed at **Tier 3** using compendial methods before initiating tests for other quality attributes. If the result from **Tier 2** is confirmed at **Tier 3**, then no further testing is needed. If, on the other hand, conducting the same test using compendial methods does not confirm the result from **Tier 2** testing, it is recommended that the testing shall be considered as final for taking action.

Additionally, for products procured by the Govt. Agencies or similar Organization with sound quality assurance measures in place, sample can be collected using Tier 2 approach.

Figure 1. Guidance for visual and field-based screening (Tier 1 and 2)



Footnotes:

Tier 1: Desktop inspection or Visual inspection to include assessment of registration status, expiration date, labelling, batch number, scientific name, company logo, number of units per container, dosage form, strength, manufacturer's address, presence of a package insert, damage to packaging.

Tier 2: Field-based screening or Physical inspection may include assessment of a product's identity (ID) and other screening tests as identification, Assay and other screening tests.

Tier 3: complete compendia testing or laboratory testing.

PROCEDURE TO BE FOLLOWED FOR CLEARING BILL OF ENTRY AT PORT OFFICES OF CDSCO

a) **Filling and referral of Bill of entry**:

1. Bill of entry (B/E) filed by Importers at Custom through ICEGATE and referred to port offices of CDSCO for grant of NOC through ICEGATE.

b) **Examination of Bill of entry**:

1. Port officer of CDSCO in its dashboard after login in ICEGATE can see the referred Bill of entry and can examine the submitted documents.
2. The Port officer should examine B/E and should decide at this stage whether:-
   i. Labelling & marking need to be checked by the port officers and samples may be drawn (If the drug imported is in small container of 5 kg or less than the original container may be called for to check the markings/label)
   ii. When required Samples to be sent for testing / analysis to the Government / Approved testing lab.
   iii. The consignment may be recommended for release.

c) Inspection of Consignments and Drawing of Samples:

Inspection of consignment:

Visual inspection (Tier 1)

The document verification at desktop may identify important characteristics related to product quality (registration status, expiry, shelf life, labelling and product packaging, etc.) or issues with the physical characteristics of the dosage form (presentation, colour, texture, and viscosity, etc.). Testing at this level can be primarily performed in the field at the point of sampling and can be used to identify falsified, unregistered, or incorrectly labelled medicines.

If the product passes visual inspection or if a determination cannot be made (e.g., deviations are not clearly discernable against expected product presentation), then the product should proceed to testing at **Tier 2.**

Sampling for primary testing (Tier 2)

Level 2 involves analytical testing of product quality (for example, dual use item, n-1 intermediates, suspicious drugs and chemicals) using field-based screening technologies. Field-based screening technologies can identify potential product quality issues that may not be apparent at Tier 1 and can further reduce the number of samples that require compendial testing (**Tier** 3).

Sampling for Complete testing (Tier 3)

Intervention for inspection and sampling by port officers is only in the consignments where samples are required for testing as per defined risk based criteria issued by CDSCO vide order no. Import/Misc/89/2015-DC dated 07.03.2016**. (Annexure - 1).**

- Random sampling of any one consignment in six months or of any one consignment in sequential 10 consignments, whichever is earlier is to be done.
- Imported product & consignment, if from ICH countries (USA, EU, Australia, Japan, Canada) and being imported since last 5 years without any complaint/quality failure in testing of the samples drawn, the frequency of sampling is to be reduced to any one consignment in two years or to any one consignment in sequential 20 consignments, whichever is earlier.
- If the sample of any product has failed then, sampling has to be done on subsequent 5 consecutive consignments of the product.
- If the product is from a new source, it has to be sampled for testing.
- If the information/ evidences are received by Port officer of CDSCO/ Custom officer about doubtful quality of the product, it has to be sampled and tested.

(***Note: The above said Risk Based Criteria is applicable to drugs other than Human and Veterinary vaccines, which falls under high risk category. However, 100% samples are to be sent for testing for the items like Vaccines, Blood products, Critical Diagnostic Kits, Condoms and Re-Import case.***)

Batch testing is being carried out at port offices of CDSCO only for the High Risk IVD reagents/kits (HIV, HBsAg, HCV and Blood Grouping reagents). Samples of imported consignment (100%) is drawn and sent to the Director-NIB, Noida for testing and release the consignments only after having complied with the prescribed specifications

Other Medical devices are required to be sampled randomly and also on the basis of any complaint or quality failure.

In case of re-import of drugs and cosmetics of Indian origin by the manufacturer / exporter due to certain reasons, samples may be drawn for complete test including specific test in which the consignment was reported to have failed and release the goods thereafter if found to be standard.

Further, the following points may also be considered for inspection and sampling:

1. There are no proper labels/markings or no markings on the containers or the markings are illegible.
2. Drugs imported from a supplier/manufacturer have been reported to be not of standard quality/spurious etc at this port or any other port in India.
3. The price of the drug imported is abnormally low as compared with the previous imports.
4. Customs HS number on the invoice is not tallying with the declared item HS number.
5. On request from the Customs etc. based on certain information.
6. In case of import of suspicious sample intimation has to be given to DCG(I) within one hours and permission granted within 24 Hours.

Note: When sampling is to be done in case of expensive drugs, the minimum quantity required for test may be drawn and the duplicate and the unutilized sample may be returned to the importer later if everything is in order.

d) Procedure for drawing of samples

1. Samples are drawn in duplicate.
2. Quantity required for test has been specified by the Director, CDL/CRI/CDTL/NIB/NIV/ NARI/NICD/IVRI etc. from time to time.
3. Samples are drawn as far as possible under the direct supervision of a technical representative of the port office. Also, sampling should invariably be carried out in the presence of the importer‘s representative.
4. In case of drugs requiring special precautions due to their hygroscopic, thermo labile nature etc., samples to be drawn invariably under proper conditions.
5. If the drug is sterile, the importers should be asked to make arrangement for drawing of samples under sterile conditions.
6. If the manufacturer premise is located outside the city, Govt. approved private testing laboratories facilities to be utilized and the technical staff from the port offices may be deputed to supervise the drawing of samples.
7. Usually $\sqrt{n}+1$ number of samples may be drawn, where ‘ n’ is number of containers / batches as per requirements.

e) Dispatch of Samples

1. It is responsibility of the Port Officer to ensure that all samples intended for test, are sent to laboratory as early as possible.
2. The first part of the sample (original) is for test, the second part (Duplicate) is to be retained in the Port Office.
3. Samples drawn from bulk containers to be sent to the laboratories with a code number in order to maintain secrecy. Only the name of the drug shall be mentioned.
4. Port officer should ensure that the seal of the samples should remain intact at required temperature / cold chain shall be maintained during the transportation.

f) Testing of samples

Several mini drug testing laboratories has been established at port offices. Apart from thses Mini Drug Testing Laboratories at Port Offices, the samples may also be got tested at the following drug testing laboratories depending on the nature of imported items /consignments drawn by the Port offices of CDSCO.

- Central Drugs Laboratory, Kolkata,
- Central Drugs Laboratory, Kasauli,
- Central Drug Testing Laboratory, Mumbai,
- Central Drug Testing Laboratory, Chennai,
- Central Drug Testing Laboratory, Hyderabad
- Central Drug Testing Laboratory, Indore
- Regional Drug Testing Laboratory, Chandigarh,
- Regional Drug Testing Laboratory, Guwahati,
- Indian Pharmacopoeial Commission (IPC), Ghaziabad,
- Indian Veterinary Research Institute, Izzatnagar,
- National Institute of Biologicals, NOIDA,
- Homeopathic Pharmacopoeial Laboratory, Ghaziabad
- Any other private drug testing laboratories approved by the Licensing authority under the Drugs and Cosmetics Act and Rules made there under, which are available across the Country in the vicinity of port offices.

The following criteria to be followed for sending of samples to the laboratory for testing purpose.

1. Any bulk drug/formulation imported for the first time to be sent to CDL/CDTL/RDTL.

2. Any bulk drug/formulation on routine to be sent to CDL/CDTL/RDTL/ Functional Minilab or any Government Approved Private Testing Laboratory.

3. The following products to be forwarded to CDL/CRI Kasauli:

    a. Sera
    b. Solution of serum proteins intended for injection.
    c. Vaccines.
    d. Toxins.
    e. Antigens.
    f. Anti-toxins.
    g. Sterilized surgical ligature and sterilised surgical suture.
    h. Bacteriophages:,

    Note-The samples of Oral Polio Vaccine is also send at Pasture Institute of India, Conoor, Enterovirus Research Center (ICMR), Haffkine Institute Compound parel Mumbai and NIB Noida

4. The following products to be forwarded to NIB Noida:

    a. Blood grouping reagents.
    b. Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus.
    c. Blood products-
        - Human Albumin;
        - Human Normal Immunoglobulin (intramuscular and intravenous);
        - Human Coagulation Factor VIII;
        - Human Coagulation Factor IX;
        - Plasma Protein Fractionation;
        - Fibrin Sealant Kit;
        - Anti Inhibitor Coagulation complex.
    d. Recombinant products such as-
        - Recombinant insulin and insulin analogue;
        - r-erythropoietin (EPO);
        - r-Granulocyte Colony stimulating Factor (G-CSF).
    e. Biochemical kits
        - Glucose Test Strips;

- Fully Automated analyzer based glucose reagents.]

f. Enzymes and Harmons such as
   - Streptokinase (Natural and Recombinant)
   - Human Chorionic Gonadotropins (HCG)
   - Human Menopausal Gonadotropins(HMG)

g. Bacterial Vaccines Such as Bacillus Calmette Guerin (BCG)

h. Viral Vaccine

i. Live Attenuated Measles Vaccine

j. Live Attenuated Rubella Vaccine

k. Cell culture Rabies Vaccine

5. Veterinary Vaccines/Sera/Toxoids/Diagnostic Antigen for Veterinary use 100% to IVRI, Izzatnagar

6. Haemorrhagic Septicaemia Vaccine and Ranikhet Disease Vaccine samples to be sent to Chaudhary Charan Singh National Institute of Animal Health, Baghpat, UP.

7. 100% blood products for HIV and Hepatitis testing to NIV / NARI, PUNE or CMC Vellore or NICD, Delhi etc. depending on the area of import.

8. Sample of VDRL antigen 100% to be sent for testing at the Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta

9. Homoeopathic medicines to Homeopathic Pharmacopeial laboratories (HPL) , Ghaziabad

10. Medical Devices are to be sent for test as directed by the DCG (I).

11. Drug intermediates to be cleared as per batch test certificate or sometimes to be tested to establish the identity of the goods in local CDTL or Private Labs.

12. No samples should be drawn from the consignments imported for the purpose of registration only.

13. The following laboratory have been notified for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory:

    - **The National Institute of Biologicals, Noida**- In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent.

- **The Central Drugs Testing laboratory, Chennai** – Condoms.
- **The Central Drugs Laboratory, Kolkata** - Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant.
- **The Regional Drugs Testing Laboratory (RDTL), Guwahati** - Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae.
- **The Central Drugs Testing Laboratory, Mumbai** - Intra Uterine Devices (IUD) and Falope Rings.

Note: Testing of the imported consignments are also to be undertaken on any other laboratory which is notified /approved for the purpose time to time.

g) Release of consignments on Letter of Guarantee(L/G)

1. Pending testing report, to avoid demurrage if the importer gives an undertaking (Rule 40 (1)) in writing not to dispose of the drugs without the consent of Customs Commissioner etc., the goods can be released on L/G for test (on Stamp Paper) as per attached Proforma. **(Annexure-2).**
2. Drugs requiring cold storage such as sera, vaccines, may be released forthwith conditionally on L/G for test etc., for proper storage pending the completion of the formalities as per attached Proforma. (**Annexure-3**).
3. If there are any labeling defects and importer desire torectify the defects at their place, they may be allowed to be clear the consignment on L/G for rectification of labeling and/or test. as per attached Proforma**. (Annexure-4)**

Note:

- **Goods on L/G should not be permitted to be taken outof the city of import unless otherwise directed by theDDC(I) of the concerned Zone as a special case.**
- **Drugs should not be released on L/G for producing Registration Certificate or Drug Import License unless otherwise directed by the DDC (I) of the concerned Zone.**

h) Procedure to be followed on receipt of Test Reports

1. If the goods on test by the laboratory are found to be of standard quality and are labelled as prescribed, they may be released.

2. If the goods, on test, are declared to be not of standard quality, the Customs Commissioner is required to be informed along with two copies of the test Report. The Proforma of the communication for action under Rule 41(1) used is given in **Annexure-5.** Intimation about such imports is made to the Deputy Drugs Controller (India) with copies to the other Port Offices. The Proforma used for such communication is given in **Annexure-6**.

3. On the basis of the advice of the Port Officers, the Customs will issue a show Cause memo to the firm concerned. Proforma of show Cause memo generally used is given in **Annexure-7**. On the basis of the firm‘s reply the case will be finally adjudicated after ascertaining views of the Port Officers.

4. In case the importers appeal for a retest by submitting sufficient evidence like manufacturer‘s protocols of test on the items in question, the case should be referred to the Deputy Drugs Controller (India) for orders along with comments of the Port Officer. If the Deputy Drugs Controller (India) so directs, a fresh sample shall be drawn, should be sent for retest to the laboratory. Test report so received should be sent to the Deputy Drugs Controller (India). The orders passed by the Deputy Drugs Controller (India) on the basis of such retest are final.

5. Where the defect is such, that the importers undertake to recondition the goods up to the required standard, they must submit along with their appeal -

6. The method that will be adopted for re-processing of Bulk Drugs.

7. A declaration to the effect that in the event after the reconditioning failing to comply with the prescribed standards of the quality, the material to be surrendered for destruction.

8. If the Deputy Drugs Controller (India) agrees to the party‘s request for re-processing, the importers must be asked to execute a Letter of Guarantee to the Commissioner of Customs to that effect (**Annexure-2)**.

9. In case of grossly substandard / spurious / adulterated drugs, Commissioner of customs is to be informed stating that the import of these goods constitutes an offence u/s.10 (bb) etc. of Drugs & Cosmetics Act, read with Section 11 ibid read with 11 (k) of the Customs Act 1962 and liable for absolute confiscation u/s. 111 (d) and shall punishable u/s. 135 and prosecution can be launched u/s. 137 of Customs Act 1962 by the Customs Authority under intimation to DDC(I). A proforma used for such communication is given in **(Annexure-8).**

10. In case of not of standard quality, other than those mentioned in point 9 above, the importers may be given the option to reship the goods to the

country of origin if they so desire or forfeit them to the Central Government for destruction.

11. It is very important to preserve the integrity of each sample from the collection sites to the location where quality testing will occur which can affect the results.

- The excessive mechanical vibration during transportation of the samples should be avoided and the sample shall be stored in original container, where available, and labelled accordingly with the relevant details. These should be stored away from sunlight and excessive humidity.
- Samples that are light or heat sensitive may require special handling, transportation, and storage conditions.

Annexure-1

Import / Misc/89/2015-DC

Directorate General of Health Services

Central Drugs Standard Control Organisation

(Import & Registration Division)

FDA Bhawan, NewDelhi.

Dated 07 MAR 2016

Order

In light of bringing ease in regulatory clearance without compromising the quality issues on the consignment entering into the Indian market, it has been decided to have 'Risk based criteria for sampling of imported consignment under Drugs and Cosmetics Rules, 1945', the details of which is appended below:

1. Random sampling of any one consignment in six months or of any one consignment in sequential 10 consignments, whichever is earlier is to be done.
2. Imported product & consignment, if from ICH countries (USA, EU, Australia, Japan, Canada) and being imported since last 5 years without any complaint/quality failure in testing of the samples drawn, the frequency of sampling is to be reduced to any one consignment in two years or to any one consignment in sequential 20 consignments, whichever is earlier.
3. If the sample of any product has failed then, sampling has to be done on subsequent 5 consecutive consignments of the product.
4. If the product is from a new source, it has to be sampled for testing.
5. If the information/ evidences are received by Port officer of CDSCO/ Custom officer about doubtful quality of the product, it has to be sampled and tested.

You are hereby directed to adhere with above criteria and submit performance based report quarterly.

(Dr. G.N.Singh)
Drugs Controller General (India)

To
All Zonal/Subzonal/Port offices of CDSCO

Copy for information to:
Sh. S.P.Sahu – Customs Commissioner (Single Window)

Annexure -2

The President of India Date :

Through the Collector of Customs,

LETTER OF GUARANTEE

(Vide Provision to Rule 40 of the Drugs and Cosmetic Rules, 1945)

1. Bill of Entry No. Date.
2. I.G.M. No. Lines No. Date.
3. Steamer Name /Flight Name S.S. / Flight Name No. Date
4. Description of goods.
5. Marks and Numbers.
6. Packing and Quantity.
7. Country of Origin.
8. C.I.F. Value Rs.
9. Name & Address of Supplier
10. Name & Address of Manufacturer

LETTER OF UNDERTAKING FOR TEST

In consideration of the Collector of Customs or any Officer on his behalf having permitting to clear the above goods not withstanding his decision to detain the same goods under the above mentioned Rule 40 of the Drugs and Cosmetics Rules 1945 on having reason to doubt whether the above mentioned goods comply with the provisions of Chapter III of the Drugs & Cosmetics Act 1940 and rules there under.

We hereby undertake :-

1. That we shall arrange for inspection of the goods as soon as they arrive in the go-down and follow the instructions of representative of the O/o. Assistant Drugs Controller (I), with regard to drawing of samples for test, rectification of labelling defects etc., if any.
2. That we shall not dispose of the said goods without the consent of the Collector of Customs or any Officer on his behalf in writing.
3. That we shall return the said goods in whole or in part as the Collector of Customs or any officer on his behalf may direct within ten days of receipt of a notice from the Collector of Customs or any officer on his behalf to return the goods.
4. That we shall reship or surrender the said goods within two months of the receipt of any order to that effect from the Collector of Customs or any officer in his behalf.
5. That we shall forthwith pay such fine and / or penalty and be liable for such punishment as the collector of Customs or any Officer on his behalf or magistrate may impose under Section II of the drugs & Cosmetics Act, 1940 as read with the relevant provisions of the Customs Act, 1962 and Under Section 13 of the Drugs & Cosmetics Act, 1940.

Any amount due under this bond may be recovered in the manner laid down in the subsection of the Section 142 of the Customs Act, 1962 without prejudice to any other mode or recovery.

The undertakings referred to above is given in view of rule 40 of the drugs and Cosmetics Rules 1945. The goods will be stored in our

Go-down at: _

Signature of the Importer

WITNESS:

(1)

(2)

ACCEPTED ON BEHALF OF THE PRESIDENT OF INDIA.

Annexure – 3

The President of India Date :

Through the Collector of Customs,

LETTER OF GUARANTEE (Direct Delivery)

(Vide Provision to Rule 40 of the Drugs and Cosmetic Rules, 1945)

1. Bill of Entry No. Date.
2. I.G.M. No. Lines No. Date.
3. Steamer Name /Flight Name S.S. / Flight Name No. Date
4. Description of goods.
5. Marks and Numbers.
6. Packing and Quantity.
7. Country of Origin.
8. C.I.F. Value Rs.
9. Name & Address of Supplier
10. Name & Address of Manufacturer

LETTER OF UNDERTAKING FOR TEST

In consideration of the Collector of Customs or any officer on his behalf having permitting to clear the above goods no with standing his decision to detain the same goods under the above mentioned Rule 40 of the Drugs and Cosmetics Rules 1945 on having reason to doubt whether the above mentioned goods comply with the provisions of Chapter III of the Drugs and Cosmetics Act 1940 and the Rules there under.

We hereby undertake:

1. That we shall arrange for inspection of the goods as soon as they arrive in our go-down by a representative of Asst. Drugs Controller (India) and obey his instructions as regards drawing samples under proper conditions and rectification of labelling defects if any etc
2. That we shall not dispose of the said goods without the consent of the Collector of Customs or any officer on his behalf in writing.
3. That we shall return the said goods in whole or in part us the Collector of Customs or any officer on his behalf nay direct within ten days of receipt of a notice from the Collector of Customs or any officer on his behalf to return the goods.
4. That we shall reship or surrender the said goods within two months of the receipt of any order to that effect from the Collector of Customs or any Officer on his behalf.
5. That we shall forthwith pay such fine and /or penalty and be liable for such Punishment as the collector of Customs or any Officer on his behalf or Magistrate may impose under Section II of the Drugs and Cosmetics Act, 1940 as red with the relevant provisions of the customs Act, 1962 and under Section 13 of the Drugs and Cosmetics Act, 1940.

Any amount due under this bond may be recovered in the, manner laid down in subsection of the Section 142 of the Customs Act, 1962 without prejudice to any other mode of recovery.

The undertakings referred to above is given in view of Rule 40 of the Drugs and Cosmetics Rules, 1945. The goods will be stored in our

Go-down at ……

Signature of Importers

WITNESS:

(1)

(2)

ACCEPTED ON BEHALF OF THE PRESIDENT OF INDIA.

Annexure – 4

The President of India Date :

Through the Collector of Customs, Custom House

LETTER OF GUARANTEE

(Vide Provision to Rule 40 & 96 of the Drugs and Cosmetic Rules, 1945)

1. Bill of Entry No. Date.
2. I.G.M. No. Lines No. Date.
3. Steamer Name /Flight Name S.S. / Flight Name No. Date
4. Description of goods.
5. Marks and Numbers.
6. Packing and Quantity.
7. Country of Origin.
8. C.I.F. Value Rs.
9. Name & Address of Supplier
10. Name & Address of Manufacturer

LETTER OF GUARANTEE FOR LABELING

In consideration of the Collector of Customs or any officer on his behalf having permitting to clear the goods mentioned above, although the same have contravened the following provisions of the Drugs & Cosmetics Act, 1940 and the Rules there under, namely Rules 40 & 96

We hereby undertake:

1. That we shall label the goods mentioned above as required under the above rules within a month or such extended period as the Collector of Customs or any officer on his behalf may allow.
2. That we shall not dispose of the said goods without the consent of the Collector of Customs or anyofficer on his behalf in writing.
3. That we shall return the said goods in whole or in part us the Collector of Customs or any officer on his behalf nay direct within ten days of receipt of a notice from the Collector of Customs or any officer on his behalf to return the goods.
4. That we shall reship or surrender the said goods within two months of the receipt of any order to that effect from the Collector of Customs or any Officer on his behalf.
5. That we shall forthwith pay such fine and /or penalty and be liable for such Punishment as the collector of Customs or any Officer on his behalf or Magistrate may impose under Section II of the Drugs and Cosmetics Act, 1940 as red with the relevant provisions of the customs Act, 1962 and under Section 13 of the Drugs and Cosmetics Act, 1940.

Any amount due under this bond may be recovered in the, manner laid down in subsection of theSection 142 of the Customs Act, 1962 without prejudice to any other mode of recovery.

The undertakings referred to above is given in view of Rule 40 & 96 of the Drugs and Cosmetics Rules,1945. The goods will be stored in our

Go-down at ……

Signature of Importers.

WITNESS:

(1)

(2)

ACCEPTED ON BEHALF OF THEPRESIDENT OF INDIA.

Annexure – 5

File No.

Office of the Assistant Drugs Controller (India)

Mumbai / Kolkata / Chennai / Delhi/

Ahmadabad / Hyderabad/Cochin

Date:

1. Name and address of the Importer.
2. Name and address of the Manufacturer.
3. Description of Goods.
4. Quantity Imported
5. C.I.F. Value
6. Bill of Entry No Date :
7. I.G.M. No. Line No. Date:
8. Steamer Name / S.S. / Flight Name No. Date:

The Sample drawn from the above consignment and forwarded for test to the Director, Central Drugs Laboratory, Kolkata /Central Research Institute, Kasauli / NIB Noida / NARI –NIV Pune / IVRI –Izzat Nagar, CDTL, Mumbai, Chennai, Chandigarh has since reported to be "NOT OF STANDARD QUALITY" as defined in the Drugs and Cosmetics Act, 1940 and the Rules there under for the reasons given below:-

"The Sample does not conform to…….. in respect of.....(state the reasons)"

Reasons:

1)

2)

As such the import of the subject drug is prohibited under Section 10 (a) of the Drugs and Cosmetics Act and the goods are liable to absolute confiscation under Section 111(d) of the Customs Act, 1962. The importers, may however please be given the option to have the goods wither reshipped to the country of origin or have them destroyed in the presence of Assistant Drugs Controller (India) or a Custom Officer, provided under Rule 41 (1) of the Drugs and Cosmetics Rules.

In this connection two copies of the relevant test report received from the Director, Central Drugs Laboratory, Kolkata /Central Research Institute, Kasauli / NIB Noida / NARI –NIV Pune / IVRI –Izzat Nagar, CDTL, Mumbai, Chennai, Chandigarh are enclosed, one of which may please be retained for your record and the other forwarded to the importer along with the show cause memo to be issued to them.

The goods are lying in the docks /air-shed/ were cleared on a Letter of Undertaking for test pending the receipt of the test report.

Party's reply when received may please be forwarded to this office.

Asstt. Drugs Controller (India)

To,

Dy. Commissioner of Customs.

.....

Annexure – 6

File No.

Office of the Assistant Drugs Controller (India)

Mumbai / Kolkata / Chennai / Delhi/

Ahmadabad / Hyderabad/Cochin

Date

To

The Drugs Controller (India),

Dte. General of Health Services,

New Delhi .

Subject: - Testing of ……..Manufactured by M/s……

MEMORANDUM

Reference B/E No. ……..Date…….

A sample of the subject drug sent for test under Rule 40 of the Drugs and cosmetics Rulefrom a consignment imported by
M/s……

(Name and full address of the importers), has since been reported by the Director, C.D.L. Kolkata / C.R.I. Kasauli / NIB Noida / NARI –NIV Pune / IVRI –Izzat Nagar, CDTL, Mumbai, Chennai, Chandigarh as "NOT OF STANDARD QUALITY" as defined in the Drugs and Cosmetics Act and the Rules there under for the reasons given below :

"The Sample does not conform to ……..

in respect of ……...

State the Reasons:

(1)

(2)

(Vide Test Report No. Date. Refers)

The quantity imported is……and the C.I.F. Value……

The Customs authorities have been advised to take necessary action under Rule 41(1) of the Drugs and Cosmetics Rules in respect of the above goods which are lying in the Docks / were cleared on Letter of undertaking for test.

The action taken may please be approved.

Asstt. Drugs Controller (India)

Copy forwarded for information to: All Port Offices of CDSCO.

Annexure – 7

No.

Subject: Dated:

……

1. The goods specified above have on test been found to be not of standard quality. A copy of the test report is attached herewith for your information. The import of these goods are prohibited under Section 10(a) of the Drugs and Cosmetics act read with Section 11 of the same act and liable to absolute confiscation under Section 111 (d) of the Customs act, 1962.
2. You are hereby required to show cause why action should not be taken to confiscate the goods under Section of the Customs Act.
3. You are required to indicate whether you would like to re-export the goods to the country of origin as per option given in rule 41 (1) of the Drugs and Cosmetics Rules, 1945.
4. You are further required to show cause why a personal penalty should not be imposed on you under the aforesaid section.
5. Your written explanation should be presented within ……day hereof to the undersigned along with all the documentary evidence. You should also indicate in the written explanation whether you wish to be heard in person before the case is adjudicated.
6. If you fail to submit the written explanation in time or do not appear before the adjudicating authority when the case is posted for hearing, the case will be adjudicated on the basis of the evidence on record without any further reference to you.

Appraising Department **DY. COMMISSIONER OF CUSTOMS,**
Dated……. **APPRAISING DEPTT.**

To,

…….

…….

Annexure – 8

File No.

Office of the Assistant Drugs Controller (India)

Mumbai / Kolkata / Chennai / Delhi/

Ahmadabad / Hyderabad/Cochin

Date.

1. Name and address of the Importer
2. Name and address of the Manufacturer
3. Description of Goods.
4. Quantity Imported
5. C.I.F. Value
6. Bill of Entry No Date :
7. I.G.M. No. Lines No. Date:
8. Steamer Name / S.S. / Flight Name No. Date:

The import of these goods are prohibited under Section 10 (bb) --- of the Drugs & Cosmetics Act, read with Section 11 of the same Act and the goods are liable to absolute confiscation u/s. 111-D and punishable u/s. 135 of Customs Act, 1962. In terms of Section 10 (bb) etc. etc. and Section 11 of Chapter III of Drugs & Cosmetics Act, 1940, prosecution can be launched by Customs after sanctioning the same under Section 137 of the Customs Act, 1962.

ASSTT. DRUGS CONTROLLER (INDIA) /

DY. COMMISISONER OF CUSTOMS