



REPÚBLICA DE MOÇAMBIQUE

MINISTÉRIO DA SAÚDE

Pre-shipment inspection and testing scheme Guidelines for Exporters in India

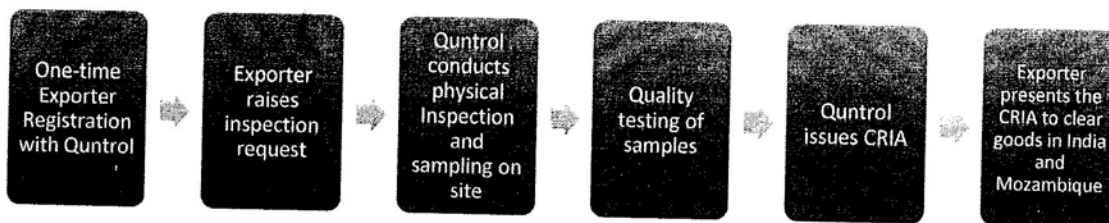
1. Introduction

The Government of Mozambique, Ministério da Saúde has introduced the Pre-shipment inspection and testing program, based on Ministerial Decree 2017 of 06 March to address issues related to counterfeit and substandard quality medicines entering the country. This program requires all imported pharmaceutical products from India to be inspected and tested for conformity to quality standards before they are exported out of India. This is a mandatory process to be followed for all consignments imported into Mozambique from India.

The Government of Mozambique, Ministério da Saúde has assessed and solely appointed Quntrol Laboratories, an independent inspection and testing company, to carry out mandatory pre-shipment inspection and quality testing of all shipments. An exporter shall require a Clean Report of Inspection and Analysis (CRIA) issued by Quntrol to clear their goods in both India and Mozambique. Without this mandatory document, goods will not be accepted in the importation process.

Quntrol shall conduct document verification, physical inspection of the consignment and random sample collection for laboratory testing for each shipment. If conformity is established, Quntrol shall issue the mandatory CRIA document. If conformity is not established, Quntrol shall issue a Non-Conformity Report.

Following process is implemented to comply with the pre-shipment inspection scheme:



One-time exporter registration will begin in February 2018. Existing exporters are required to complete the registration process in February 2018.

Exporters are required to obtain the mandatory CRIA document for all consignments shipped from March 2018 onwards.

2. Detailed Process

2.1. Process for exporter registration:

A pharmaceutical exporter or manufacturer in India who intends to ship pharmaceutical products from India to Mozambique shall carry out one-time registration with Quntrol. Registration shall be mandatory before inspection requests can be raised by the exporter.

- a. Visit www.quntrol.com
- b. Click on "Login" tab and "New Exporter Sign up"
- c. Enter your official email address, create a secure password and click "Sign up"
- d. A verification link will be sent to your official email address. After clicking the verification link, you will be able to login to your account with your official email address and password created in the previous step.
- e. Login to your account to begin the Exporter Registration process.
- f. Exporter Registration Form (ERF) can be accessed by clicking "Exporter Registration" tab. You are required to read the introduction and fill all sections including:
 - i. Company Information – Company details, address, contact details, specify contact person details designated to liaise with Quntrol for pre-shipment inspection activities.
 - ii. Site Information – Specify your preference for inspection to be carried out at your manufacturing/warehouse site or at the port warehouse. Enter details about your manufacturing site or warehouse where inspection shall be carried out. Upload valid Manufacturing License copy and GMP Certificate copy for the manufacturing site. These documents must be attested by an authorized signatory within the company.
 - iii. Importer Information – Enter details of the company importing your shipments
 - iv. Registered Product Information – Download the format given to fill details about your products registered with Ministério da Saúde, Mozambique. Details to be given include product details, specifications (specify the pharmacopoeia or in-house specs), product registration number, date of registration and expiry, and which market is the product intended to be sold in (private, tender, donor). Upload the completed file in this section of the Exporter Registration Form.
 - v. Past Shipment Information (if applicable) – If you have shipped pharmaceutical goods to Mozambique in the last 3 years, please give details about the past shipments in the format that can be downloaded within this section. Details to be given include year and month-wise product shipments up to last 3 years. Product details, specifications (specify the pharmacopoeia or in-house specs), number of batches shipped for that particular product, manufacturing site address, name of the importer and indicate whether the product is registered or not registered by Ministério da Saúde.
- g. Submit the form after reading and accepting the terms and conditions document. Specify details about the authorized person who has completed the form.
- h. Quntrol shall verify the validity and completeness of the submitted details and approve the registration. Thereafter, the exporter shall pay a one-time non-refundable registration fee of INR 20,000 plus applicable taxes.
- i. This shall complete the registration process for the exporter. The exporter can now raise and manage inspection requests by logging into their account from March 2018 onwards.
- j. Existing exporters are required to complete the Registration process within the month of February 2018.

2.2. Process for Raising an Inspection Request:

From March 2018 onwards, a pharmaceutical exporter or manufacturer in India who intends to ship a consignment of pharmaceutical products from India to Mozambique shall raise a request for inspection by logging into their account on the Quntrol website www.quntrol.com.

- a. Click on "Raise Inspection Request" tab to access the Inspection Request Form (IRF).
- b. Select the site at which you would like Quntrol to conduct physical inspection and sampling
- c. Select the Importer of the consignment
- d. Submit required information and documents for the consignment. All uploaded copies, as mentioned below, should be attested by the authorized signatory of the company. Failure to provide all necessary information and/or documentation will result in delays to the physical inspection.
 - i. Invoice of the goods in the consignment to be shipped to Mozambique.
 - ii. Detailed final packing list for the goods in the consignment to be shipped to Mozambique.
 - iii. Copy of the Import license Boletim de Inspeção de Especialidades Farmacêuticas (BIEF) issued by the Department of Pharmaceuticals, Ministério da Saúde, Mozambique.
 - iv. Provide details about the Products that will be shipped in the consignment. For each product, following information and documents must be uploaded:
 1. Batch numbers and respective case/shipper box numbers.
 2. COA for each product and all its batches in the consignment.
 3. MOA in case in-house method has been used for analysis and release of the products.
 4. Copy of valid product manufacturing license (product permission) as issued by a related Indian Authority.
 5. Product registration certificate issued by Ministério da Saúde, Mozambique in case product is already registered.
 - v. The exporter shall confirm that they have read and understood the guidelines for pre-shipment inspection provided.
- e. After the exporter has submitted the inspection request, Quntrol will verify and check the details and documents provided in the IRF. Quntrol shall raise its invoice to the exporter for the pre-shipment inspection and testing services.
- f. After receiving the payment, Quntrol shall verify if the quantity of goods mentioned in the invoice and packing list are in line with the BIEF and then shall assign a mutually convenient date for physical inspection, usually within five days of receiving full payment. The goods must be inspected prior to the loading into the container if the goods are being shipped as a Full Container Load. The date and time of inspection therefore must take into account the arrival of the container and the loading plans.
- g. The exporter shall ensure that the consignment will be "Inspection ready" on the assigned date of inspection. Inspection ready consignment means that the goods are 100% manufactured, packed and QA released. In case the exporter would like to revise the date of inspection or cancel the inspection request on the assigned mutually agreed date or the day before, Quntrol has been authorized and reserves the right to retain a part of the sum paid.

2.3. Process to be followed for the physical Inspection:

Before the inspector arrives at the site premises, the exporter shall ensure that:

- a. The consignment is inspection ready which means that the consignment is 100% manufactured, packed and QA released. Quntrol shall only carry out inspection of the goods

that are inspection ready. The Inspector is authorized to wait for a maximum of one hour upon arrival at the inspection premises until the consignment is presented to him/her for inspection. In case the consignment is not 100% inspection ready and presented to the inspector within the one-hour waiting period, the inspection request will be cancelled. In this case, Quntrol has been authorized and reserves the right to retain a part of the sum paid. The next inspection request for the same consignment shall be considered as a new request altogether. In case the exporter requests the Quntrol inspector to stay back at the site until the goods are ready for inspection, Quntrol shall use its discretion to accommodate such requests. If so, the costs related to accommodation, transport and food shall be borne by the exporter.

- b. Original documents of the copies that were submitted at the time of inspection request (as mentioned in 2.2.d. above) and provided at the time of registration (as mentioned in 2.1.f.ii. above) shall also be made available for verification by the inspector on site.
- c. In case the exporter has selected the port warehouse for inspection, it is the exporter's responsibility to obtain the necessary permissions from the port authorities to allow inspection and sampling to be done by Quntrol. The exporter shall assign its clearing agent to act and sign on behalf of the exporter and be responsible for all activities required of the exporter during the inspection as per these guidelines. Necessary authorization letter will have to be submitted to Quntrol.

On the date of the inspection, Quntrol shall provide the details of the assigned Quntrol inspector to the exporter. The inspector shall visit the selected manufacturing/warehouse/port warehouse site on the assigned date and time and report to the exporter's assigned person.

The exporter is expected to present the goods in adequate condition and make arrangements at their own cost for handling and presentation of the goods so as to enable the inspector to perform the inspection.

The inspector will carry out physical inspection and sampling as follows:

- a. Document verification - Documents submitted by exporter at the time of raising inspection request (as mentioned in 2.2.d. above) and provided at the time of registration (as mentioned in 2.1.f.ii. above) shall be verified by the inspector against the originals provided by the exporter's assigned person on site. You are required to present the original documents to the inspector at the time of inspection.
- b. Physical inspection of the consignment – The inspector shall verify the products, their batch numbers and quantity in the consignment as per the final packing list and BIEF.
- c. Visual inspection of the label – The inspector will check the product label compliance and shelf life.
- d. Sampling for lab analytical testing – Samples of each product in the consignment shall be withdrawn for the purpose of analytical testing to be carried out at the laboratory. In case there is more than one batch for a product in the consignment, following methodology shall be applied to calculate the number of batches at random from which samples of the product shall be withdrawn.

No. of batches to be sampled for a product = $\sqrt[3]{(\text{Total no. of batches for the product} + 1)}$

For example, if there are 6 batches of Product A in the consignment, then the Inspector shall collect samples from 2.7 (3) batches.

Total quantity to be sampled will be equivalent to 1 set for analysis + 1 set for repeat analysis + 1 set to be reserved by exporter as control sample. You may refer to the table below to check the quantity of sample that will be withdrawn by the inspector.

Dosage Form	Quantity required for one set	Quantity that will be sampled for three sets
Oral solids – tablets, capsules	60 tablets/capsules	180 tablets/capsules
Liquid injections less than 3ml	50	150
Liquid injections 5-100ml	40	120
Liquid injections >100 ml (LVP)	18	54
Powder injections	40	120
Eye drops, Ear drops	40	120
Liquid orals, syrup, dry syrup	10	30
Ointments, creams, gels, lotions	15	45
Sprays, inhalers	10	90
Sachets	20	90

- e. The exporter shall replace this quantity, manufactured in the same batch, in the presence of the Inspector such that the quantity of goods in the consignment is exactly as per the final packing list and BIEF. In case the required replacement quantity is not available, then the exporter shall inform the same to the inspector. The exporter shall modify the packing list accordingly.
- f. Sealing of the shipper boxes - The inspector shall seal the shipper boxes from which samples were withdrawn for testing and for physical inspection of the label. Photographs of the shippers shall be taken.
- g. Sealing the samples withdrawn – The inspector shall seal the samples withdrawn. The seal shall be signed by the inspector and the exporter's assigned person. The exporter shall provide outer boxes/cartons/cooling case needed for sending the samples by courier.
- h. Physical Inspection Report (PIR) - The Inspector shall complete the PIR which shall be signed by the Inspector and the exporter's assigned person. Copy of this report shall be made accessible to the exporter for their records on the system. The PIR report refers only to the physical inspection of the goods and at this stage it is pending verification by Quntrol head office. In case of non-conformity at this stage, Quntrol will inform the exporter about the result. If the exporter is able to correct the non-conformity and the evidence of such revision is confirmed by Quntrol through re-inspection if required, Quntrol shall carry on with the remaining part of the process.

2.4. Process that will be followed for lab testing of samples:

Quntrol shall send the sealed samples to the assigned accredited analytical laboratory in its network. The laboratory shall carry out complete analytical testing of the sample as per the pharmacopoeia method and specifications. In case the exporter or manufacturer has used in-house methods, the laboratory shall carry out the analysis as per their in-house methods and specifications.

The exporter is required to provide the applicable reference standards and/or working standards to carry out the pre-shipment testing, if required by Quntrol.

After completion of the analysis of the withdrawn samples in the lab, the COA will be generated. In case the COA establishes that a sample is out-of-specification, Quntrol will contact the exporter to inform them about the result. If the exporter is not satisfied with the results in the COA, the exporter shall have an option to request for repeat analysis of the withdrawn samples in the concerned lab. In this case, the 2nd set reserved for repeat testing will be used to conduct the analysis. If required, the repeat testing can be done in the presence of the exporter's representative in order to avoid any discrepancies. The exporter shall submit a request to Quntrol for the same. Quntrol shall have the

right to charge the exporter for additional costs related to such repeat testing.

2.5. Clean Report of Inspection and Analysis (CRIA) issued by Quntrol:

Upon completion of the above activities, Quntrol shall issue the CRIA to the exporter if conformity is established in inspection and analysis. Approximate timelines for issuance of CRIA will depend on the product and its method of analysis. If it is a pharmacopoeia specs oral solid, oral liquid and topical dosage, it will typically take ~10-12 working days from the date of sampling on site. For oral liquids, injectable products and others requiring sterility testing, it will typically take ~15-20 working days from the date of sampling on site. In case the product is analyzed based on the exporter's in-house methods, the time required to issue CRIA will depend on the methods used. The timelines mentioned above will get extended in case repeat analysis is required. Copy of the CRIA will be available with Ministério da Saúde, Mozambique.

It shall be mandatory for the exporter to present the mandatory CRIA to Assistant Drug Controllers at all sea ports and airports in India, as and when implemented, who in turn shall release the goods for export after verifying the CRIA in the shipping documents. Similarly, the CRIA document will be required to clear the goods at the port in Mozambique as well.

The CRIA once issued shall be valid for a period of 90 (ninety) days from the date of issuance and therefore the shipment of the said consignment must be performed during this validity period. In case, the goods are not shipped within this period, the exporter will have to re-apply for the pre-shipment inspection and testing process.

Non-Conformity Report shall be issued by Quntrol in case of non-conformity in the physical inspection report and/or lab analytical report. Results of repeat testing of the samples, if opted by the exporter, will be taken into consideration before issuance of the report by Quntrol. In case of repeat testing, Quntrol shall issue the CRIA if the sample passes the specifications and provided conformity is established in the physical inspection.

The above-mentioned process may change from time to time and the same will be communicated to you as and when the changes are implemented.

3. Queries or Clarification

Quntrol has a highly experienced and knowledgeable team based in Mumbai who can be contacted for any questions or clarifications required.

For further details, please email support@quntrol.com or call +91-9820166225.