**SOP Name:** Standard Procedure for Inspection of Retail and Wholesale Pharmacy (Post-Marketing Surveillance)

**Effective Date:**

**Revision No.:**

**Review Date:**

## Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Date</th>
<th>Modified by</th>
<th>Reason for change</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Authorship and Approvals

<table>
<thead>
<tr>
<th>Reviewed by</th>
<th>Job title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

DGDA reviewer signs to confirm technical content

<table>
<thead>
<tr>
<th>Reviewed by</th>
<th>Job title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

## Authorization

<table>
<thead>
<tr>
<th>Major General Md. Mustafizur Rahman</th>
<th>Job title: Director General, DGDA</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

## Distribution:

<table>
<thead>
<tr>
<th>Copy distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master copy</td>
</tr>
<tr>
<td>Controlled copy -1</td>
</tr>
<tr>
<td>Controlled copy -2</td>
</tr>
<tr>
<td>Controlled copy -3</td>
</tr>
<tr>
<td>Uncontrolled copy On request</td>
</tr>
</tbody>
</table>

Ref. SOP.: DGDA -
SOP No.: 

SOP NAME: Standard Procedure for Inspection of Retail and Wholesale Pharmacy (Post-Marketing Surveillance)

Effective Date:

Review Date:

TABLE OF CONTENTS

REVISION HISTORY ............................................................................................................................................ 1

1.0 BACKGROUND ........................................................................................................................................... 3

2.0 PURPOSE .................................................................................................................................................... 3

3.0 SCOPE ......................................................................................................................................................... 4

4.0 RESPONSIBILITIES ................................................................................................................................... 4

5.0 PROCEDURES ............................................................................................................................................ 4

5.1 Inspectors and Powers of Inspectors ........................................................................................................ 4

5.2 Duties of Inspectors .................................................................................................................................... 6

5.3 Inspection of Wholesale and Retail Pharmacy (Scope) .......................................................................... 6

5.4 Random Sampling and Drug Seizure ......................................................................................................... 9

5.5 Sample Collection Procedure for Quality Control .................................................................................. 9

5.6 Report Writing .......................................................................................................................................... 11

5.7 Follow Up .................................................................................................................................................. 12

5.8 Regulatory Management of PMS ............................................................................................................ 12

6.0 REFERENCES ............................................................................................................................................ 13

7.0 ADDENDA .................................................................................................................................................. 15
1.0 BACKGROUND

Post-marketing surveillance (PMS) refers to the monitoring of medicines after they have been released on the market or after clinical trials, in order to further establish proper methods of use of the medicines. Although premarket safety information is sufficient to form the basis of approval for a medicine's benefits and risks in the clinical trial population, it may not be entirely representative of the general public. Early PMS is defined as any safety assurance activities that are performed within a certain period following commencement of marketing by the marketing authorization holder of a drug in order to promote proper and rational use of the product in medical treatment. PMS will also help quickly identify the occurrence of serious adverse drug events, including quality and performance of the pharmaceutical product.

In Bangladesh, PMS is greatly needed because most medical products, especially generic drugs, have been manufactured overseas; therefore, PMS conducted in retail and wholesale pharmacies, drug shops, and outlets will address quality and safety issues of the products marketed in Bangladesh. In addition, because of the prevalence of counterfeit, spurious, and substandard drugs, it is incumbent on the DGDA to monitor the availability of these products and to disallow illegal and unsafe products to be put on or to remain in the market. A PMS system should endeavor to detect manufacturing problems, improve product quality, and provide easily accessible information on safety, long-term performance, complications, and consumer satisfaction.

2.0 PURPOSE

The purpose of this SOP is to provide guidance to DGDA officials on the steps required to conduct PMS of medicinal products available in retail and wholesale pharmacies, drug shops, and outlets. It is applicable to medicinal products, including traditional complementary and alternative medicines (TCAM), vaccines, and biological products.
The main purpose is proper inspection, sample collection and submission, and management of PMS activities to ensure that drug sellers adhere to the regulatory authority’s requirements.

3.0 SCOPE

This procedure is applicable to inspections of retail, wholesale public and private pharmacies, drug shops, and outlets of medicines available in Bangladesh.

The following products categories are covered by this procedure:

- Medicinal products (allopathic and TCAM)
- Vaccines
- Biological products

4.0 RESPONSIBILITIES

It is the responsibility of the Director General of the DGDA and its Directors to ensure that this procedure is adhered to by all DGDA inspectors. This SOP is primarily based on the Drug Acts, Rules and Ordinance (Control) of 1940 to 2006, hereafter referred to as the Act.

5.0 PROCEDURES

5.1 Inspectors and Powers of Inspectors

Every DGDA inspector is a public servant within the meaning of the Bangladesh Penal Code and shall be officially subordinate to such authority as the Government may specify in this behalf. An inspector, within the local limits for which the inspector is appointed, and in any other area with the permission of the DGDA, may:

- Inspect any premises where any medical product is being manufactured, sold, stocked for sale, or distributed
- Take samples of any drug that is being sold, stocked for sale, or distributed
• Enter and search at all reasonable times with assistance, if necessary, any building, vessel, or place in which the inspector has reason to believe, from personal knowledge or information provided by any person, that inappropriate activities in regard to medicines are occurring. It should be written down that an offence specified by the Act has been or is being committed.

• Call any person from the neighborhood to be present as a witness in the course of a search or seizure or in connection with any other matter where the presence of witness is necessary.

• Require any person to appear before the inspector at any reasonable time at any proper place to give a statement, assistance, or information relating to or in connection with an investigation of an offence committed according to the Act.

• Lock and seal any shop or building where drugs are being stored or sold for sale without the necessary license under the Act.

• Forbid, for a reasonable period not to exceed three months, any person in charge of any premises from removing or disposing of any drug, article, or other item likely to be used as evidence of the commission of an offence under the Act.

If any person willfully obstructs an inspector in the exercise of the powers conferred upon the inspector by or under this Act or disobeys the lawful authority of the inspector, that person shall be punished with imprisonment (up to three years) or with a fine or both.

If an inspector seizes the stock of a drug, the inspector shall inform a magistrate as soon as possible and execute the magistrate’s orders as to custody of the individual committing the offense.

The DGDA has the power to cancel or suspend the license of any establishment that sells any products that do not conform with the provisions of the Act.
5.2 Duties of Inspectors

- To inspect not less than twice a year all establishments licensed for the sale of drugs within the area assigned
- To satisfy that the conditions of the drug retail licenses are being observed
- To obtain and send for test or analysis samples of any drugs that are being sold or stocked for sale
- To investigate any complaint made in writing
- To institute prosecutions in respect of breaches of the Act
- To maintain a record of all inspections made and actions taken in the performance of the inspector’s duties, including taking samples and seizing stocks, and to submit copies of such records to DGDA
- To conduct inquiries and inspections as necessary to detect the sale of drugs in contravention of the Act
- To detain packages from overseas if the inspector has reason to believe the package contains imported drugs, which are prohibited
- To ensure that no persons shall, in any public street, highway, footpath, park or on any public transport, peddle, hawk, or offer for sale or distribute free of charge any medicine (known as “footpath shops”)

5.3 Inspection of Wholesale and Retail Pharmacy (Scope)

5.3.1 Preparation for Inspection

- Make a tour index of the area for inspection
- Collect records and information from the area where the inspection will be conducted such as:
  - List of expired pharmacy license holders
Information on pharmacies with a show cause notice that have not taken any action
- List of pharmacies that were found noncompliant or where expired medicines were found and seized during the last inspection
- All regulatory measures previously taken against any such pharmacy

5.3.2 Inspection Process

The DGDA identification card should be worn during inspection, and the inspector should properly introduce him/herself

The inspector will:

- Ensure that the pharmacy signboard has all the information, such as owner's name and full address, and will make a record of it
- Check that there is no promotion or advertisement of unaffiliated products
- Inspect the premises and check that the premises are clean, tidy, spacious, hygienic, with appropriate conditions for storage and air conditioning
- Confirm that the retail (trade) license has not expired (valid for 2 years); if it has, the pharmacy is directed to state the reason; if necessary, the inspector will provide instructions and requirements to do so
- Verify that the appropriate drug licenses required for retail sale of all drugs are available and that they are displayed in a prominent place on the premises; the two categories of licenses are:
  - License to sell, stock, and exhibit for sale and distribute drugs specified in Schedule C (see the Act)
  - License to sell, stock, and exhibit for sale and distribute drugs other than those specified in Schedule C (see the Act)
• Make certain that only drugs that are registered in Bangladesh are available at the store and that:
  o Drugs are stored in accordance with the therapeutic group
  o A sufficient number of shelves are available
  o Heat-sensitive drugs are properly stored in the refrigerator and that non-medicinal products are not being stored in the refrigerator
  o Drugs that have expired are recorded, and removed from the shelves
  o The area allotted for the sale of drugs is restricted and separate from non-medicinal products
  o Medicines are not over-priced
  o The pharmacy is aware of any adverse drug events reported by consumers

• Verify that there is at least a grade C-level pharmacist available at the store for the sale and dispensing of products and verify that the pharmacist’s registration certificate contains his/her name, address, phone number, and national ID

• Check the documentation process and how records are preserved, either in paper or electronic format; purchase invoices, cash memos, records of products procured and supplied, and individual patient records should be checked; if they are not available, instructions should be given to comply

• Ensure that product labels or containers correctly indicate the composition of the medicine

• Check for any misbranded drugs and drugs without an administration registration (DAR) number; a drug is deemed misbranded or below standard quality when:
  o Some innocuous substance or ingredient is present
  o In the process of distribution, some extraneous substance has unavoidably become intermixed with it
5.4 Random Sampling and Drug Seizure

- When a drug is seized, the inspector shall tender a receipt using form 4 (addendum 1).
- When an inspector takes a sample of a drug for testing or analysis, the inspector should indicate the reason on form 5 (addendum 2) and give it to the pharmacist present.
- Samples shall be divided into four portions, effectively sealed, and suitably marked to permit the inspector to add his/her own seal and mark to all or any of the portions; if the drug is such that it is likely to deteriorate or be otherwise damaged by exposure, three or four samples should be taken:
  - One portion shall be sent to the government analyst at the National Control Laboratory (NCL) for test or analysis.
  - The second portion shall be provided to the court before which proceedings, if any, are instituted in respect of the drug.
  - The third portion shall be sent to the warrantor, if any, named under the provision of the Act.
- Every person in charge of any premises where any drug is kept for sale or distribution is legally bound to disclose to the inspector, when requested by the inspector, the place where the drug is being kept.
- The government analyst who tested the sample will provide to the inspector a signed report in triplicate.
- The inspector shall deliver one copy of the report to the person from whom the sample was taken and another copy to the warrantor, if any; the third copy shall be retained for use in any prosecution in respect to the sample.

5.5 Sample Collection Procedure for Quality Control

- Each sampling unit should be examined to ensure that it is intact and also checked for possible damage to the packets or products.
• Products with damaged containers or those found to be non-uniform should not be collected.
• Unlabeled sampling units should be rejected.
• Sample sizes depend on the formulation and the nature of analysis performed by NCL; see addendum 3 for the number of units to sample.
• Random sampling should be conducted to ensure that products meet required standards. The sampling should be done by randomly selecting the batches and collecting the required number of samples of the batches from the retail or wholesales pharmacies selected.
• Sampling should be done randomly throughout the divisions, districts, and sub-districts in Bangladesh.
• Each product should be assessed regularly (e.g., every 2–3 years), but particular attention should be accorded to products that are of prime importance to public health, such as those on the essential drug list, liquids, and injectables.
• The following important criteria must be considered during the sampling process:
  o Each sample will be properly labeled with appropriate details, which at minimum includes the type of product, batch number, and date of sample collection
  o The sampling process should be properly documented using the sample collection form and attaching it to the samples
  o Cartons and containers from which samples have been taken should be labeled accordingly; sample labels should include the batch number, date of expiry, price, and the container number from which the sample was taken, if known
  o The container used to store the sample should be labeled with sample type, name of material, identification code (if applicable), batch/lot number, quantity, date of sampling, storage conditions, and handling precautions
• For temperature-sensitive items, a mechanism for maintaining the required temperature should be employed during transportation, storage, and delivery of the samples to the
destination laboratory; if required, a temperature-controlled transportation van or a cold box/chamber (a “cooler”) must be used

- An appropriate courier service for sample transportation and delivery should be selected.
- Samples with the appropriate filled-out form(s) should be sent to the NCL for testing.

5.6 Report Writing

- Each inspector should log into the DGDA web portal (http://dgda.gov.bd/) with their user ID to fill out the data entry form with the following information:
  o Name and address of the pharmacy inspected
  o Issues with any drug license
  o Renewal of drug license
  o Drug samples collected and sent
- Each inspector should write a report after inspection that includes the name of the retail shop, address, retail license number, and pharmacist’s name
- The report should be clear, concise, accurate, objective, and include introduction, observations, deficiencies, summary of findings, and conclusion; it should also state whether samples were taken, seized, or banned
- Each inspector signs the report written on the letterhead of the DGDA
- A copy of the report should be sent to the retail pharmacy with a timeframe for corrective actions, if any
- The report should be filed in DGDA in such a manner that ensures integrity and confidentiality and preserves personal data
5.7 Follow Up

- The DGDA inspector should conduct a follow-up visit, if needed, after the specified period (to be determined by the inspector) allowed for correction, in cases where corrective action is cited.
- The DGDA should follow up on complaints or reports on issues relating to risks arising in connection with products.
- The DGDA should verify that corrective actions have been taken that will prevent or reduce risks caused by products.
- The inspector should follow-up on any drug sample that was sent to NCL for analysis to ensure that the results are sent to DGDA.

5.8 Regulatory Management of PMS

- DGDA should routinely and regularly conduct PMS activities; however, due to the shortage of human resources, a risk-based PMS should be in place when:
  - Products are recalled or banned by the Drug Control Committee
  - There are complaints about a product
  - Results of quality or safety failure studies become known
  - Information is received from other regulators in other countries
  - Other evidence of increased risk associated with a product is uncovered
  - Complaints about overpricing are received
  - Essential products are unavailable or there is a shortage
- DGDA should ensure that products that do not conform to product requirements are identified and controlled to prevent their unintended use or delivery
- A documented procedure should be established to define the controls and related responsibilities and authorities for dealing with nonconforming products
• Where applicable, the DGDA should deal with nonconforming products by one or more of the following:
  o Take action to eliminate the detected nonconformity
  o Authorize its use, release, or acceptance
  o Take action to preclude its original intended use or application
• When a nonconforming product is corrected, it should be subject to reverification (reanalysis) to demonstrate conformity to the requirements
• Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, should be maintained by DGDA
• DGDA should establish a procedure for a feedback system to the public to provide early warning of quality problems through newsletter publication, media, text services, and presentation on the DGDA website
  • Information on any substandard and falsified medical products, combined with adverse drug event reports, should be made freely available within a reasonable timeframe to the public and widely publicized in both print and electronic media
• DGDA should ensure the rational use of drugs by conducting surveys, e.g., through questionnaires on a yearly basis, on the systems of prescribing, dispensing, and patient compliance

6.0 REFERENCES
• The Drug Acts and Rules, 1940 to 2006; reprinted in April 2008 by DGDA
<table>
<thead>
<tr>
<th><strong>SOP No.</strong></th>
<th>............</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SOP NAME:</strong></td>
<td>Standard Procedure for Inspection of Retail and Wholesale Pharmacy (Post-Marketing Surveillance)</td>
</tr>
<tr>
<td><strong>Effective Date:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Review Date:</strong></td>
<td></td>
</tr>
</tbody>
</table>

# 7.0 ADDENDA

Addendum 1

## THE BENGAL DRUGS RULES, 1946

**FORM 4.**

*(See rule 14.)*

*Receipt for stock of drugs seized under section 22 (c) of the Drugs Act, 1940.*

The stock of drugs detailed below has this day been seized by me under the provisions of clause (c) of section 22 of the Drugs Act, 1940 from the premises of M/s............................................................

situated at ..........................................................................................................................................................

Date: ..............................................

**DETAILS OF DRUGS SEIZED**

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Name of the Product</th>
<th>Name of the Manufacturer</th>
<th>Country of Origin</th>
<th>Batch No./Mfg.Dt./Exp.Dt.</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date: ..............................................

**Inspector**
Addendum 2

THE BENGAL DRUGS RULES, 1946
FORM 5.
(See rule 15.)

Intimation to person from whom sample is taken.

To .................................................................................................................................................................................

I have this day taken from the premises of M/s ...........................................................................................................

samples of drugs specified below for the purpose of test or analysis.

Date: .........................

Inspector

DETAILS OF SAMPLES TAKEN

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date: .........................

Inspector

Ref. SOP.: DGDA -
Minimum Sample to be submitted to DGDA for Laboratory

Tests & analysis

<table>
<thead>
<tr>
<th>Sl No</th>
<th>Dosage Form</th>
<th>Requirement for NCL/CDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Capsule Blister/ Strip/Loose</td>
<td>100</td>
</tr>
<tr>
<td>02</td>
<td>Tablet Blister/ Strip/ Loose</td>
<td>100</td>
</tr>
<tr>
<td>03</td>
<td>Liquid Upto 30ml Pack size</td>
<td>4</td>
</tr>
<tr>
<td>04</td>
<td>Liquid Upto 114ml Pack size</td>
<td>4</td>
</tr>
<tr>
<td>05</td>
<td>Liquid above 200ml Pack size</td>
<td>4</td>
</tr>
<tr>
<td>06</td>
<td>Injection 1-2ml</td>
<td>100</td>
</tr>
<tr>
<td>07</td>
<td>Injection 5ml</td>
<td>40</td>
</tr>
<tr>
<td>08</td>
<td>Injection 10-20ml</td>
<td>40</td>
</tr>
<tr>
<td>09</td>
<td>Injection (Dry powder) 250mg, 500mg,1gm, 2gm</td>
<td>40</td>
</tr>
<tr>
<td>10</td>
<td>IV Fluid 500/1000ml</td>
<td>12</td>
</tr>
<tr>
<td>11</td>
<td>IV Fluid 100ml</td>
<td>12</td>
</tr>
<tr>
<td>12</td>
<td>Infusion set</td>
<td>24</td>
</tr>
<tr>
<td>13</td>
<td>Disposable Syringe</td>
<td>50</td>
</tr>
<tr>
<td>14</td>
<td>Ointment Cream Up to 10 Grams (Skin)</td>
<td>12</td>
</tr>
<tr>
<td>15</td>
<td>Ointment Cream Up to 10 Grams</td>
<td>24</td>
</tr>
<tr>
<td>16</td>
<td>Ointment Cream Up to 25 Grams (Skin)</td>
<td>12</td>
</tr>
<tr>
<td>17</td>
<td>Tincture 500ml</td>
<td>5</td>
</tr>
<tr>
<td>18</td>
<td>Oral Sachet</td>
<td>30</td>
</tr>
<tr>
<td>19</td>
<td>E/E/N Drops 5ml-10ml</td>
<td>20</td>
</tr>
<tr>
<td>20</td>
<td>Raw Materials (Active Ingredient) 5gm x 1</td>
<td>8</td>
</tr>
<tr>
<td>21</td>
<td>Inhaler</td>
<td>15</td>
</tr>
<tr>
<td>22</td>
<td>Aerosol 250ml</td>
<td>8</td>
</tr>
<tr>
<td>23</td>
<td>Serum / Vaccine (single dose Ampoule / Vail)</td>
<td>120</td>
</tr>
<tr>
<td>24</td>
<td>Vaccine (Multi dose, 10 dose)</td>
<td>60</td>
</tr>
<tr>
<td>25</td>
<td>Vaccine (Multi dose, 20 dose)</td>
<td>30</td>
</tr>
</tbody>
</table>

Approved by Deputy Chief (NCL)

Ref. SOP.: DGDA -