Facilitation Handbook
for
Pre-Shipment Inspection (PSI)
and
Post-Delivery Inspection (PDI)
as part of
Quality Assurance in Procurement of Medical Goods

Ministry of Health and Population
Department of Health Services
Management Division
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Foreword

Pre-shipment inspection, post-delivery inspection and testing assure that goods ready for shipment by the supplier or, that goods delivered will meet all expectations of quality and safety as well as other contractual requirements as indicated in the procurement documents. These processes have been considered as effective means of contract enforcement ensuring procured goods can be rejected and/or payment can be withheld until the supplier present the evidence of compliance of contractual obligations.

Pharmaceutical products are being procured by all health institutions and health procuring entities in all Federal, Provincial and Local Level Governments. However, the health institutions are facing challenge of continuous supply of quality medicines. Inspection and testing are a vibrant part on the quality control, and it has great impact in procurement and supply chain.

This document is intended for the purpose of approved guidelines for pre-shipment inspection, post-delivery inspection, and sampling of pharmaceutical products at the various levels of health institutions dealing with procurement and storage of essential medicines and other products pertaining to the topic. It must be noted that quality must be built into the product before the process of procurement and supply. Inspection and testing are the parts of that continuous process to ensure quality pharmaceutical products are made available to the consumers.

This procedural guideline aims to organise the functioning and the management of pre-shipment and post-delivery inspection of the procured goods to ensure their quality and quantity in accordance with the requirements of health institutions as compliance with the policy and plans of the Government of Nepal in health sector.

Management Division
Department of Health Services
Ministry of Health and Population
Kathmandu
Nepal

Abbreviations

API	=	Active Pharmaceutical Ingredient
COA	=	Certificate of Analysis
CoPP	=	Certificate of Pharmaceutical Product
DDA	=	Department of Drug Administration
eLMIS	=	Electronic Logistics Management Information System
GMP	=	Good Manufacturing Practice
GRN	=	Goods Received Note
NDRA	=	National Drug Regulating Authority
Incoterm	=	International Commercial Term
ISO	=	International Organisation for Standardisation
NML	=	National Medicine Laboratory
NTG	=	National Treatment Guideline
PDI	=	Post Delivery Inspection
PIL	=	Package Leaflet Information
PSI	=	Pre-Shipment Inspection
QC	=	Quality Control
SOP	=	Standard Operation Procedure
SRA	=	Stringent Regulatory Authority
STP	=	Standard Treatment Protocol
WHO	=	World Health Organisation

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PREAMBLE

Pharmaceutical products are sensitive consumables that must undergo rigorous quality assurance process from prior to the beginning of the production process to the point where it reaches the final consumers. Due to such sensitive nature, stringent practices such as WHO-GMP and other equivalent authorised practices are in place wherever pharmaceutical products are manufactured and supplied. Within the framework of these requirements the pre-shipment inspection (PSI) and/or post-delivery inspections (PDI) processes are mandated in every procurement process.

PSI is performed prior to the shipment of the goods within the procurement process, to validate the quality and quantity of the products to ensure compliance with the agreed contractual terms and statutory requirement. PDI is performed after the receipt of the contractual products to ensure compliance with the agreed contractual terms and statutory requirement.

Both these processes are vital components of a successful procurement process and is a part of quality assurance system. They follow their own protocols and SOP(s) in accordance with international standards and with the relevant adjustments made by the regulatory authorities pertaining to the prevalent conditions and available resources.

In case of supply of the Pharmaceutical Products by the Manufacturers, the PSI will involve inspection of the products at the Manufacturer's facility before shipment. In case of supply of the pharmaceutical products from the non-Manufacturers, authorized by the Manufacturers (herein after Supplier), the PSI of the Pharmaceutical Products will involve inspection of the products at the Warehouses/Stores of the Suppliers. They will involve the storage conditions at the Warehouses of the Manufacturers/Suppliers, visual inspection of the product, packaging, labelling, marking, verification and correlation of Quality Assurance documents provided by the Manufacturers/Suppliers, with batch numbers of Manufacture, date of Manufacturer, Expiry date (to ensure the maximum shelf life as per the terms of the Contract), picking up of samples of each batch at random, getting it tested at the independent laboratory for its quality as per agreed standards, inspection of the loading process for transportation to the destination, etc.

PDI of the Pharmaceutical Products supplied either by the Manufacturer or the Supplier will involve inspection of the products at the Purchaser's Warehouse/Stores immediately after receipt. They will involve visual inspection of the product, packaging, labelling, marking, verification and correlation of Quality Assurance documents provided by the Manufacturers/Suppliers, with batch numbers of Manufacture, date of Manufacturer, Expiry date (to ensure the maximum shelf life as per the terms of the Contract), picking up of samples of each batch at random, getting it tested at the independent laboratory for its quality as per agreed standards, etc.,

The discussions and conclusions here undertaken into considerations are the prevalent system and conditions of the health sector of Nepal. These guidelines are applicable to all the levels of health institutions involved in the process of procurement and storage of pharmaceutical products at any given time and for any length of time.

PSI and PDI are important to:

- Ensure a transparent and fair procurement process.
- Ensure the proper quantities of the required pharmaceutical products reach the proper places at proper times.
- Adhere to the quality management systems in place for pharmaceutical products.
- Ensure that qualities of the pharmaceutical products are up to the required standards.
- Ensure the quantity supplied are as per the specifications mentioned on the bid document.
- Avoid any malpractice from any parties involved directly or indirectly in the procurement process.

Section I. PRE-SHIPMENT INSPECTION

1. Introduction

Pre-shipment inspection (PSI) is a part of quality assurance that is required for the continuation of GMP practices from manufacturing to procurement via supply chain. PSI does not mandate additional quality standards and parameters on pharmaceutical products; rather it is a process of validation of claimed quality standards by the manufacturers/suppliers before the process of shipment. It operates under the umbrella of WHO-GMP or other claimed equivalent quality standard certifications. PSI is required before dispatch of the products from the manufacturers/suppliers to the final stages. Hence, PSI is aimed at confirming the quality of pharmaceutical products as claimed in the quality specification documents provided by the manufacturer/supplier.

It is preferable that PSI be conducted by the purchaser or by an independent third-party agency (herein after third party) approved by the Purchaser without any prior prejudice at the premises of the Manufacturers/suppliers. Only after a thorough inspection that includes on-site inspections and lab analysis consignments will be cleared by the third party/regulatory authority for dispatch.

The contract between the Purchaser and the Manufacturer/Supplier should include a specific condition that PSI does not relieve the Manufacturer/Supplier from its obligation and responsibility for the quality and conformity of the Products supplied by it as per the agreed terms and statutory requirement and in case of any deficiency is found after the receipt of the consignment at the Purchaser's end, either by visual inspection and/or lab analysis of samples of the batches, the Manufacturer/Supplier should replace the entire quantity of supply of the relevant batch at its full risk and cost. Further the contract conditions also include additional clause stating that even if the products are initially found to be of standard quality in the lab test and distributed to the end users, but at a later date during the shelf life period of the product found to be of not of standard quality by sample analysis undertaken by the Purchaser and/or statutory regulatory authority, as per relevant Pharmacopeia standards, the entire unconsumed quantity, recalled from the end user by the Purchaser should be replaced by the Manufacturer/Supplier at its own risk and cost with new batch of the quality tested product.

2. Reasons for PSI

The various commonly encountered reasons for PSI are:

- The products supplied may differ from the ones mentioned during the bidding process due to various reasons seen/unforeseen. For instance, drugs of different type may be supplied, or different dosage forms may be supplied than the ones claimed.
- The quality of the products may vary during the time of supply.
- The quantity of the products may vary during the time of supply.
- The process of supply can affect the final quality of the products. For instance, packaging of the products and method of handling/shipment.

3. Objectives of PSI

The objectives of PSI in accordance with the quality assurance system of pharmaceutical products are:

- Conformity of the products intended for dispatch to the quality standards as per contractual terms and statutory requirement by physical/visual inspection.
- Authenticate the manufacture of specific pharmaceutical products, normally in response to a claimed specification during bidding.
- Evaluate the procedures and controls implemented in the manufacturing of the product.
- Picking up of samples at random for verification in lab analysis, for its conformity to the relevant Pharmacopeia standards and statutory requirement.
- Verification of dates of Manufacturer and Expiry of the batches intended for dispatch to ensure maximum shelf life as per the terms of the contract.

- Allowing dispatch of the batches of the products cleared in the lab analysis for its conformity to the standards.
- Ensuring proper loading of the consignment for transport.

In case of inspection of the Manufacturing premises is part of the bid evaluation process the objectives will be the following:

- Verification of the licenses for manufacture of the Products, issued by the regulatory authority for its conformity and validity on the date of bidding and the intended contract period.
- Evaluation of the procedures and controls implemented in the manufacture and testing of the products according to Good Manufacturing Practice (GMP) prescribed in the bidding document.
- Examination of Non-Conviction certificate issued by the regulatory authority.
- Verification of market standing certificate for the prescribed period indicted in the bidding document, by verification of batch manufacturing document.

4. Principles of PSI

The core principles of PSI to ensure proper and fair inspection of the drug products are:
Set SOP(s) for the entire process of PSI

a. Inspection of products on site
b. Documentation of inspection
c. Evidence of inspection, such as photographs
d. Qualified and authorised personnel
e. Detailed and accurate reports

5. Priorities of PSI

PSI must include all the necessary and stated tests as mandated by the contract and quality specification documents. The tests must include but may not be limited to the following:

a. Check the storage conditions as per SOP.
b. Check quality of the consignment and extraction of samples in accordance with the standard protocol.
c. Check items listed in the contract requirements against the contract technical specifications and other relevant documents.
d. Check the final quality of the supplied products against the contractual agreements and requirements.
e. Conduct dimensional checks.
f. Verify manufacturer's test for the quality of raw materials and final products
g. Check the number of primary, secondary, and tertiary units in each supply unit against the contractual agreements and mark inspected.
h. Relay the sample collected to the authorities for further quality checks and for storage for future validation processes.
i. Make a detailed report, clearly stating damages and non-conformity to the contractual agreements.

6. Pre-PSI requirements

The following general requirements are necessary for PSI:

a. GMP certifications and other relevant/required quality certifications.
b. Registration at the National Drug Regulating Authority (NDRA) – Department of Drug Administration (DDA) in case of Nepal.
c. Certificate of Pharmaceutical Product (CoPP) and/or Marketing License.
d. Complete documentation required from the supplier/manufacturer.
e. Set protocols for PSI on part of the inspecting authority.
f. Informed and agreed upon date and site between the inspecting authority and supplier/manufacturer.

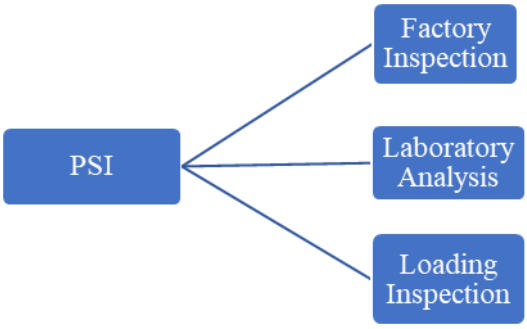
g. Necessary arrangements such as equipment and personnel for effective and thorough inspection.

7. Post-PSI requirements

a. Detailed and complete report of the inspection process.
b. Sample for lab analysis and future reference.
c. Detailed report of lab analysis.
d. Follow-up inspection if requested/required.

8. Components of PSI

PSI consists of following prime components:



8.1 Factory inspection

The first step is the inspection of the facilities of the Manufacturer. The aim of factory inspection is to assess the manufacturing capacity and capability of the manufacturer to ensure proper quality of the finished products. This inspection may be performed by personnel of the regulatory/procuring authorities or a third-party delegated by the regulatory/procuring authorities.

The Factory Inspection may be done before selection of a Manufacturer as a direct bidder or the Manufacturer who authorized a Supplier as a bidder. The scope of inspection can be varied depending on the Manufacturer or products. A typical factory inspection can include, but not be limited to the following:

a. The general information about the plant and its capacity to meet the demands while maintaining quality and quantity within set deadlines.
b. Details on the personnel involved at the plant, both directly and indirectly in the actual manufacturing process.
c. Verification of licences such as industry registration, production and marketing licences, and quality assurance certifications such as WHO-GMP and other equivalents.
d. Equipment and machinery and SOP(s) for the production of the products.
e. Quality control (QC) laboratory infrastructure and SOP(s) available on site.
f. The overall quality assurance system in place on site.
g. Packaging and storage infrastructure along with the shipping facilities available.
h. Confidential appraisal of the company's financial standing.
i. Non-employment of child labour in any area of operation.
j. Any other special stipulations as envisaged by the Purchaser and included in the bidding document.

For the PSI of the products intended to be supplied by the selected bidder (Manufacturer/Supplier) against a valid purchase order of the Purchaser, the factory inspection will be limited to:

a. Verification of storage conditions.
b. Verification and correlation of test certificates for the final product by the Manufacturer.
c. Verification of dates of manufacture and expiry of the batches intended for dispatch.

d. Picking up of samples of each batch at random for lab test.
e. Allowing dispatch after receipt of results of lab test for the products conformity to the relevant standards and statutory requirement.
f. Verification of packing conditions as per agreed terms.
g. Documentation of the entire process as per SOP.

8.2 Laboratory analysis

The sample extracted from the on-site inspection must be tested to ascertain the quality of the product that includes raw materials, packaging materials, and the final product itself in a well-equipped laboratory by qualified personnel.

The lab analysis should be delegated to an independent third-party laboratory preferably accredited by a National Accreditation Board for Laboratories or similarly qualified institution. The Purchaser or the third-party agency who draw the sample of each batch should ensure that the identity of the product and its Manufacturer are removed/ masked prior to sending the laboratory for analytical testing, for its conformity to the relevant pharmacopoeia standards. The selection of analytical laboratory by the Purchaser may be by nomination or by a transparent bidding procedure setting out various qualification criteria as per pharmacopoeia standards.

Typical scope of work for lab analysis by the laboratory should include:

a. Receipt of samples, testing as per the relevant pharmacopoeia standards and the contractual terms of the Purchase, and confirm that the items are in accordance to the contractual obligations.
b. Communicate the test results in the standard format listing out the actual values of the parameter against the permitted parameters set out in the pharmacopoeia standards.
c. Clearly indicating whether the samples of the products tested is in conformity or non-conformity to the relevant pharmacopoeia standards and stated in-house methods.
d. Issue a clearance report that clearly states the values of various required parameters of testing.

8.3 Loading inspection

The inspection of loading process involves the following:

a. Verify storage conditions
b. Report any damage or non-conformity to the products.
c. Ensure total compliance of packaging with the contractual agreements.
d. Ensure that the number of primary, secondary, and tertiary units comply with the contractual agreements.
e. Ensure proper loading and unloading operations of the final products.
f. Ensure proper standard of transport vehicles and containers to ensure that the consignment reaches the Purchaser’s Warehouse safely.
g. Ensure that adequate precautions are in place in the transport vehicles and containers to avoid any damage and loss of the products.
h. Check all the relevant documents.
i. Validate the consignment by marking it with the authorised seal/stamp, both on the consignment and the container.

A detailed report must be submitted by the inspector, or the personnel involved in the supervision process along with relevant evidences such as photographs. The report must also consist of the lab analysis report of every product and batch.

Section II. POST-DELIVERY INSPECTION

1. Introduction

Post-Delivery Inspection (PDI) for pharmaceuticals will involve verification of integrity of packaging, labelling, marking, verifying quality assurance documents, visual examination of the products and quantity verification against the packing list. In some cases, drawing of samples at random for each batch and sending them out for laboratory testing by an independent third party to verify quality, formulation, strength, dimensions, and other characteristics may also be done if necessary as per the relevant pharmacopeia standards. This will also involve inspection of condition, quality, and quantity of goods to assure that the received goods are of the same goods and quantity mentioned in the contract.

PDI is a part of the procurement process to ensure quality pharmaceutical products are available to the consumers. It is preferable that PDI be conducted by the authorised and qualified team at the Purchaser. Otherwise, an independent third party may be appointed for inspection and quality testing.

2. Reasons for PDI

The various reasons for PDI are:

- It is necessary to ensure the supplied products meet the criteria in terms of quantity, quality, efficacy and safety as per terms of the contract and relevant pharmacopeia standards
- The arrangement for open tenders makes the procuring agencies susceptible to offers that seem to be favourable financially but that are not always up to the required standards in terms of quality.
- There could be cases where the supplied products may not meet the required criteria in terms of quality, efficacy, and safety.
- The purchaser must ensure that the supplied products which are found to be not of standard quality never reaches the consumers and returned to the suppliers.
- The supplier agency sometimes may not be liable to a refund after receipt, so PDI has to be done before the financial transactions have been finalized.
- New and unknown suppliers may lack in maintaining the agreed upon delivery time, quality, and quantity of the products.

3. Objectives of PDI

The objectives of PDI in accordance with the quality assurance system of pharmaceutical products are:

- Conformity of the products supplied to the quality standards as per contractual terms and statutory requirement by physical/ visual inspection.
- Picking up of samples at random for verification in lab analysis, for its conformity to the relevant Pharmacopeia standards or any specified standard by relevant authority and statutory requirement.
- Verification of dates of Manufacturer and Expiry of the batches supplied to ensure maximum shelf life as per the terms of the contract.
- Allowing distribution only the batches of the products cleared in the lab analysis for its conformity to the standards to the consumers.
- Monitoring of supply chains and distribution channels from manufacturer to recipient and ensure the end products for utilization are adherent to the required authorised standards.

PDI process involves visual inspection of the tangible features of the entirely of the pharmaceutical products that includes dosage form to packaging and labelling, and additional parameters such as quality inspection of the pharmaceutical products via analytical methods, and adherence to the authorized and registered standards as stated in the legal documents of the procurement and quality system process.

4. Components of PDI

PDI follows the following components:

Visual	Quality control	Documentation
General appearance of pharmaceutical products such as appearance, colour, odour, number, form, dates of manufacture and expiry, etc. Includes inspections done on site.	Analytical tests such as assay and other stated tests in the quality control documents. Includes tests performed at QC laboratories.	Adherence to the end product supplied to registered product specifications such as number of units supplied to type of dosage forms, in house test reports of the Manufacturer, correlating document for batch number, manufacturing date and documents of PSI, if carried out. Includes inspections done on site.

4.1 Visual Inspection

Visual inspection involves physical inspection, packaging inspection and labelling inspection:

Physical inspection

S.N.	Dosage form	Parameters	Definition
1	Tablets	Shape and size	Uneven tablet shape and size
		Capping/lamination	Separation of layers
		Chipping	Loss of parts of tablet surface
		Mottling	Uneven colouring of coating
		Cracking	Cracks on tablet surface or entire tablet
		Hardness	Tablets are too brittle
		Sticking	Tablets stick to the strip/blister
		Double impression/press	Double prints on tablet surface
2	Capsules	Shape and size	Uneven capsule shape and size
		Unhinged capsules	Cap and body are separated or loose
		Disfigurement	Dents on cap and body
		Telescoping	Cap and body mis-align causing the body to split and cover the cap
		Brittleness	Brittle capsule cap and body
3	Liquid Preparations	Particulate matter	Presence of external particles
		Viscosity	Too viscous or too watery
		Caking	Hard non-dispersible solid precipitate at the bottom
		Phase separation	Permanent separation of oil and water phases
		Colour	Non-compliance with the registered colour
		Odour	Foul odour
		Flavour	Non-compliance with the registered flavour
4	Parenteral Preparations	Particulate matter	Presence of external particles
		Viscosity	Too viscous or too watery
		Caking	Hard non-dispersible solid precipitate at the bottom
		Phase separation	Permanent separation of oil and water phases
		Colour	Non-compliance with the registered colour
5	Powders	Agglomeration	Powders form hard agglomerates.
		Particulate	Presence of external particles.

		contamination	
		Moisture	Presence of moisture.
		Flow-ability	Poor flow ability of powder.
		Texture	Coarse or lumpy powder, or crystalline/amorphous in contradiction to the stated texture.

Packaging

S.N.	Dosage form	Parameters
1	Solid dosage forms	Number of tablets/capsules per unit Exposed tablets/capsules Integrity of the packaging duplex and cartons Supply of the stated additional components such as patient information leaflets
2	Liquid preparations	Amount of preparation in the container Leakage Integrity of the shape of containers Supply of the stated additional components such as applicators and patient information leaflets
4	Parenteral preparations	Amount of preparation in the container Leakage Cracks and chips on the containers Supply of the stated additional components such as applicators and patient information leaflets
5	Powders	Amount of preparation in the container Leakage Supply of the stated additional components such as applicators and patient information leaflets

Packaging of the supplied products must be as stated in the registered and approved standards of the products at the national regulatory body.

Labelling

The visual inspection of the labelling must confirm the following:

a. The generic name of the drug is tangible and readable.
b. The name is clearly mentioned along with the generic name.
c. The name of the manufacturer is clearly stated with all the required details.
d. Batch number and batch size of the supplied quantities.
e. The manufacture and expiration dates are clearly mentioned on all levels of packaging.
f. Number of individual units or the amount of drug contained.
g. Presence of unique identifiers, if required. (e.g. Ministry of Health and Population emblem, article code, etc.)
h. Storage conditions, drug schedule, and relevant statutory cautions if required.

4.2 Quality inspection

Quality inspection is performed on samples taken from the supplied product batch. Quality inspection entails QC analysis according to the recognized pharmacopoeias or registered in-house QC analysis methods.

The QC process can be assigned to independent laboratories that have been authorized by the regulatory bodies. The quality inspection reports from these laboratories must be comprehensive and authoritative in terms of determining the quality and safety of the supplied pharmaceutical products.

4.3 Document inspection

Inspection of documentation is to ensure that the Manufacturer/Supplier provides all the required documents at the time of receipt. Documents such as supplier invoice, quality assurance documents, and supply logistics documents must be verified during the time of receipt. These documents are to be used to verify the supplied products in terms of quantity and quality.

The documents provided by the suppliers must make clear two aspects of the products and the manufacturer; they are quality control and product information.

The quality control documentation ensures that the manufacturer and the supplier if separate have a proper quality control system in places such as certifications recognized by the regulatory authorities such as GMP-Certification.

Product information documentation ensures that the products are registered with the regulatory authorities. These registrations are a seal of approval for the safety, efficacy, and quality standards of the pharmaceutical products. Any doubts over the authenticity of the documents must be verified with the regulatory authorities of the country of origin. Although the above-mentioned inspections must be performed before the procurement process, they are advised for repeat to ensure the process and the products have remained compliant through the entire process.

5. Management, Infrastructure, and Personnel

Post-delivery inspection requires that the management and infrastructure are available for the purpose, and the personnel involved in the inspection process be at least in accordance with the minimum required standards. The management must allow for a thorough, unbiased, and accurate inspection of the products at the time of receipt without any delay or hindrance to the inspection process. A quality system must be in place that allows for analytical controls and self-inspection. This quality system entails standard operating procedure (SOP) for sample collection and documentation, to analytical processes and the following steps to deal with any inspection results. The system must allow for a swift response and reporting protocols in cases of negative inspection results.

- It is preferred that the procurement and inspection bodies work independently from one another.
- The infrastructure must be adequate at least to allow for a thorough, unbiased, and accurate inspection. This includes proper equipment and instruments, access to necessary amenities such as sample storage, lab analysis, transportation, and safe documentation of inspection records. The sampling facilities must ensure the safety of the personnel involved in the sampling process. Furthermore, the facility must allow for avoidance of contamination and cross contamination of the batches while exposed to the environment during the sampling process.
- The personnel involved in PDI must adhere to the integrity of the process and the institution.

The principles of personnel for PDI are as follows:

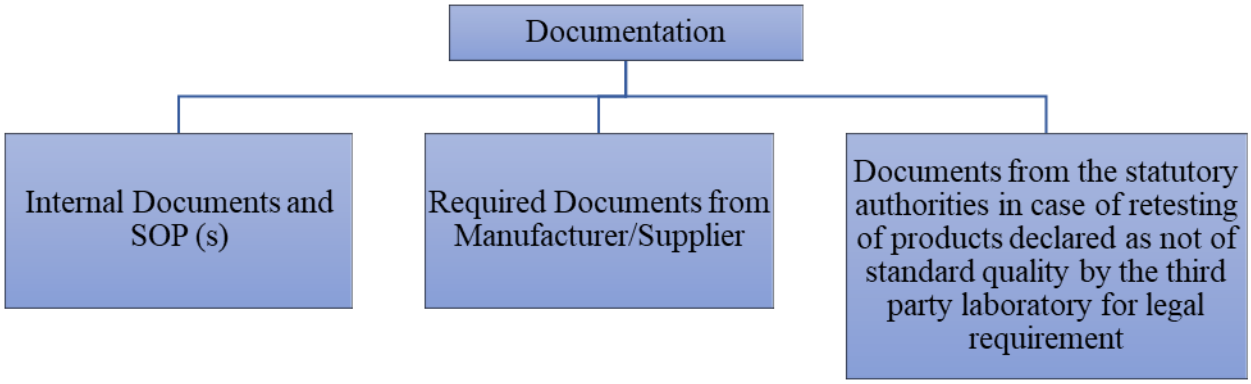
a. Must involve only qualified and authorized personnel.
b. Pharmacists must be involved in PDI along with other pharmaceutical staff.
c. All involved personnel must be trained and briefed about any inspection process.

It is advisable that the inspection team on site includes a registered pharmacist. In the absence of a registered pharmacist, the personnel must be adequately trained to follow the general protocol of the inspection process. The personnel must be allowed authority of the inspection process and all required materials must be provided for a streamlined and fair process.

6. Documentation

Documentation is a vital part of quality system related to PDI. All the processes involved in PDI must be documented such as in SOP(s) and all the tasks and results.

All documents must be clear and precise, and with all the necessary information available. There are three types of documentation required.



SOP(s) must be available for the actual inspection process, reporting process, and analysis process. These SOP(s) must be strictly implemented in order to ensure fair, swift, and ordered PDI process.

The documents required from the Manufacturer/Supplier are as follows:

a. Copy of the contract or orders from the Purchaser.
b. Manufacturer/Supplier's invoice.
c. WHO-GMP or other recognized quality assurance certification of the manufacturer.
d. Product registration certificate.
e. Product specification certificates that include product information, packaging information, and labelling information.
f. Batch specification certificates that include number of units per batch and number of batches in a particular shipment.
g. Quality control certificates of the products and packaging materials.

In case of retesting of the products and declared as not of standard quality by the independent third-party laboratory the documents from the statutory authorities are required for legal procedure.

The personnel involved must document all the steps involved in PDI. The inspection process must be documented on site in cases of field inspection.

7. Quarantine/Confiscation

The Purchaser should keep all the consignments under quarantine till the lab analytical reports are in conformity to the relevant pharmacopeia and ensuring no mix up with the quality pass stock.

In cases where the products supplied do not meet the stated and agreed upon requirements or if the inspecting personnel has reasonable grounds to raise questions over the procurement process, the products can be put under quarantine or confiscated for further actions. When such a scenario transpires, the personnel will have to report the case thoroughly and swiftly and prepare a detailed report and checklist.

Such shipments must be referred for QC analysis and other necessary steps as soon as possible to avoid further damage, potential tampering, or hinder the supply process of essential pharmaceutical products. During the process, the products must be stored properly and securely.

The above process is also applied to the extent of relevant for the recalled batches from the consumers based on the analytical report by the statutory authority for non-conformity.

Section III. SAMPLING GUIDELINES

1. Introduction

The entire process sampling must follow an approved SOP. The size of the sample must, in general, be sufficient for all analyses and retention samples. The sample must be representative of the entire supplied batch. They must be of the same batch and from the same location. Pooling of samples must be avoided since it can lead to distorted analyses due to masking of quality problems such as low potency and contamination.

If the products received are of same batch but received at different locations of the Purchaser then the sample of the same batch must be drawn from each locations independently and the Purchaser may select at random any one of the sample of the same batch and send it to laboratory analysis of the batch after following necessary procedures for removing the identity of the product and its Manufacturer as per the SOP.

The Sample Collection Team performs sampling after receipt of Medicine and health commodities in designated place or upon request of supplier or in case of non-compliance either in quality of a product or other defects.

Sample Collection Team is formed by government bodies of Federal, Provincial or Local Governments consisting of Technical Officer, Procurement Officer, Management Officer, and person assigned by government bodies having knowledge on related field. The personnel involved in the sampling process preferably must be pharmacy degree holders in accordance with the prevalent organisational structure. Other personnel involved in the sampling but are not pharmacists must be thoroughly trained and directed through the entirety of the process.

2. Sampling Procedures

Sampling process can consider prior experience with the supplier or the product. In case of huge batches and new suppliers and products, two independent sampling and analysis processes is recommended. If more than one batch are present in the supply unit, one sample from each batch will suffice provided that the batches were manufactured at approximately the same time.

The samples extracted from the supplied batch must be stored properly and documented thoroughly and accurately. In case for QC analysis, sample must be provided promptly in proper sealed conditions from the site to the laboratory. In addition to the sample provided for QC analysis, a retention sample must be maintained and documented for in case of future analysis requirements. Where possible, sampling must be performed in designated specialized booths. The sampling area must ensure that no cross-contamination occurs to the sample and the product batch.

A common procedure for collection of samples is:

a. The number of samples to be taken is determined by $\sqrt{N}+1$ rule. The number of lots and batches to be sampled from invoice is determined by this rule. For example, if there are 45 items, then number of samples taken is $\sqrt{45}+1 = 7$.
b. Again, sampling of number of boxes of each batch is also determined by $\sqrt{N}+1$.
c. The sampling and the batch number selection follows systemic random sampling technique.
d. The sampling is done under the witness of supplier representative.
e. The samples should be analysed for compliance with the product specification.

Primary packaging must be adequately protected during sampling to avoid contamination. Adequate identification must be provided during sampling to avoid mix-up of the packaging materials. In cases of sensitive products such as ampoule and vials, their end use must be put into consideration during the sampling process and necessary precautions must be applied during the sampling process. All other packaging must also be properly stored and documented to avoid cross-contamination and false labelling.

3. Sample Quantity

The samples must be taken from the ready materials for shipment in case of PSI and from the supplied batch in case of PDI. The quantity of sample must be as stated by the national regulatory body. For example, sampling for medicine is determined by the authorised testing laboratory such as National Medicine Laboratory (NML) or other quality testing laboratory.

4. Sample Parts

For testing requirement, 3/3 separate sample parts is taken from each batch. Each part must have seal and signature of supplier's representative and sample collection team. Out of these three sample parts, one is handed over to supplier's representative with covering letter, one part is kept as control sample in store for future verification if any dispute arises, and one part is sent to laboratory for testing.

5. Reporting

The Sample Collection Committee must send a report as soon as possible to the concerned authority. The report must be in the following format:

SN	Description	Description	Remarks
1	Name of item		
2	Contract reference number		
3	Consignment number		
4	Consignment arrived date		
5	Sampled date		
6	Name of supplier		
7	Name of manufacturer		
8	Name of sampled item		
9	Quantity supplied		
10	Unit packing		
11	Primary packing		
12	Secondary packing		
13	Number of batches		
14	Batch numbers		
15	Sampled batches		
16	Sampled quantity		
17	Specimen of the seal		
18	Physical description of goods at arrived destination		
19	Manufactured date		
20	Expiry date		
21	Shelf-life remained in months		
22	Storage condition		
23	Sampling team members and their		
24	Analytical report ref no.		
25	Other relevant information		

6. Sample Collection Form

Serial Number: _____

Name of location/place where sample was taken:

. . . . . .

. . . . . .

. . . . . .

Address (with telephone and fax number, if applicable):

. . . . . .

. . . . . .

Date of sampling: . . . . . .

Names of personnel who took samples:

1. . . . . .

2. . . . . .

Product name of the sample: . . . . . .

Name of (active) starting material (INN, generic or scientific name)

With dosage strength: . . . . . .

Dosage form (tablet, capsule, etc.): . . . . . .

Batch/lot number: . . . . . .

Date of manufacture: . . . . . Expiry date: . . . . . .

Registration or license number (if applicable): . . . . . .

Name of the manufacturer: . . . . . .

Number of sample unit taken (tablet, capsule, etc.: at least 20 but not more than 30 units): . . . . . .

Brief physical/visual description of sample:

. . . . . .

. . . . . .

. . . . . .

. . . . . .

. . . . . .

Signature of person(s) Taking samples

1. . . . . .

2. . . . . .

Signature of representative of the establishment where sample(s) was taken (optional)

Note: *This sample collection form should always be kept with the sample collected. Proper sampling procedures should be followed.*

Section IV. STANDARD PROCEDURES FOR QUALITY ASSURANCE

1. Introduction

The procured goods must be reflected by specifications and qualification criteria and the supplier must fulfil that. The purchaser may appoint a reputed third party for the PSI and/or PDI or, assign its officials as inspector or to perform the PSI or PDI job.

On receipt of pharmaceuticals, they shall be sampled and tested. Where a consignment is large or it would take a considerable amount of time to carry out 100% inspection, a standard sampling procedure should be followed. It is also not practicable to test all pharmaceutical products each time they are procured. So, such products must be preferably obtained from manufacturer who have certified quality assurance procedures in place. The emphasis shall be on ensuring that the manufacturer has followed appropriate quality control procedures and international standards such as approved procedures of WHO are followed throughout the manufacturing process.

2. Performance Standards for PSI and PDI

Following performance standards shall be followed in PSI and PDI:

- The pharmaceutical products shall be registered with DDA, Nepal
- The technical specifications shall be recommended for use by the National Treatment Guideline (NTG) and Standard Treatment Protocol (STP)
- The supplier shall have tested each batch of finished product at the manufacturer's laboratory before shipment to check its compliance with the specifications as indicated in the bidding document. The test certificate should be accompanied with each shipped good.
- As far as practicable PSI shall be carried and the certificates of inspection with Certificate of Analysis (COA) for each batch of product shall accompany each shipment.
- Past performance evaluation criteria with regards to quality systems and compliance shall be one of the evaluation criteria as indicated in the bidding document.
- Where PSI is not carried, PDI shall be carried out by the appointed inspector and the COA shall be issued by the approved laboratory.
- On receipt, the warehouse/store staff shall verify that the received goods are in accordance with the specifications and qualification criteria as indicated in the bidding document and contract.
- Generally, PSI and PDI are not be carried if the manufacturer is WHO prequalified and SRA approved, provided all the necessary documentation on compliance with WHO-GMP.

3. Procedures for Receiving and Storage of Medicines

When the shipment arrives, inside or outside normal working hours, at the warehouse receiving area, contents should be quarantined until they have been checked. The receiving officials systematically check the cases and their contents against the supplier's invoice. Discrepancies, variations and damage should be noted. Prompt and accurate inspection of all consignment is essential to ensure that suppliers fulfil their contracts. Every consignment must have borne the insurance of damage or loss. Thus, any damage or loss must be claimed as per the Incoterm used in the contract.

The number of packages delivered should be noted in a register and signed by both the person receiving and the person delivering the goods. The receiving officials should immediately check the number of boxes and the status in which they have been received (any sign of damage or tampering etc.). The receiving team of the store/warehouse will receive the goods verifying the presence of accompanying documents (waybill, packing list, challan, certificate of quality control of each batch delivered, certificate of PSI etc.)

The receiving team shall adopt following procedures for PDI:

- The team should check for discrepancies between the order, the delivery bill and the supplier labels. The team should unpack the received deliveries and look out the following discrepancies which should be noted using a form and be communicated to the person delivering the goods:
    - Missing boxes of cartons;
    - Open boxes or cartons;
    - Missing items;
    - Quantity different from one shown on the packing list;
    - Wrong items (items not ordered)
    - Damaged, broken or poor-quality items.
- The team will verify that technical specifications fully confirm to that spelt out in the contract. In addition, the compliance with product labelling will be assessed as well as remaining minimum 3/4 shelf-life of the product if the shelf-life is 24 months or remaining 5/6 shelf-life if the shelf-life is more than 24 months or as per the agreed terms of the contract. The integrity of packages, seals of consignment and uniformity of the containers will be checked.
- If more than one batch of products are delivered, it will be subdivided in accordance with the batch numbers of the suppliers, and then inspection of each container carefully conducted to ensure it was not contaminated, tampered, or damaged. Any container suspected to be substandard or incomplete will be separated.
- If the containers cannot be checked immediately, which is often the case for large shipment, the sealed and undamaged boxes should be quarantined until inspection. The contents on the boxes that are damaged or that have a broken seal should be inspected immediately against the packing list. It should be insured that the items delivered correspond to the items ordered, and that the quantities conform to those on the Delivery Note (Challan).
- Notification in writing for any problem identified shall be made in the presence of the transporter of the supplier. Products having remaining shelf-life less than as mentioned above shall not be accepted.
- Discrepancies, variations, and damage are noted on the invoice. The annotated invoices is signed and dated by the authorised staff member. Observations are summarised on the delivery report. Any damage of the container and any other problem related to quality will be subject to an investigation and informed to the concerned authority.
- If delivery is compliant, goods are validated provisionally subject to the report of independent quality control laboratory. The form of quarantine reception is completed and the provisional acceptance report is prepared. Any problem identified are mentioned in the report.
- In order to collect samples for testing, a random sampling is performed according to the procedure mentioned in Section III.
- After sampling, the goods are placed in quarantine. The goods remain in quarantine until the results of independent quality control found to comply with the product specifications, which will also allow release for use. Copies of certificate of analysis, copies of store receipts are kept secured.
- In case of rejection, a letter of rejection is sent to the concerned authority and to the supplier with copies of test results. Strict precautions must be taken to prevent rejected goods being used. Rejected goods must be clearly demarcated and stored in a locked room accessible only to authorised personnel. They should be returned to the supplier.
- On complete verification of the received goods, the receiving store shall record the quantity of each goods received, batch number and expiry date on a Goods Received Note (GRN), which is subsequently signed.
- After completing the receiving procedure, the goods must be physically stored in the warehouse and entered into stock ledger (stock record, inventory list of warehouse register), or in the eLMIS system. It is important that the correct unit with batch number and expire date appears in all records.
- Once goods are certified as received, safe custody risk passes to the warehouse and the warehouse in charge.

- After completing all above, the warehouse/store will send the signed GRN and other relevant reports with the supplier's invoice to the accounts section for necessary payments. The reports will have mentioned any deduction due to discrepancies in the delivery, if applicable.

4. Shipment Discrepancy Reportage

Any errors in shipment must be recorded on the Shipment Discrepancy Report. Errors in shipping may include the following:

- Damaged product, including:
    - Broken tablets, medicines that past their expiry date or near to expiry
    - Items that have no labels
    - Refrigerated items that arrive at room temperature or are warm
    - Inappropriate storage procedure during transportation
- Requirements from the bidding document and contract document have not been met
- Items listed on the invoice/delivery note that are missing from the shipment
- Items received that were not ordered or were not listed on the invoice/delivery note

The shipment discrepancy report should be written by the officer and should be witnessed by another staff member. The shipment discrepancy report will include:

- Date of shipment
- Name of receiving officer
- Name of witnessing pharmacy staff member
- Invoice number
- Number of boxes received
- Number of other containers received (e.g., drum, carton etc.)
- For each item that is damaged, missing or incorrect following information must be noted:
    - Serial No.: Where the product is reordered (if the reporting item missing from the shipment, it will be left blank)
    - Item description: Generic name, strength/concentration, dosage form
    - Code No.: Number, which is specific to each item, strength/concentration, and dosage form
    - Unit: Unit of item (i.e., number of tablets per package)
    - Quantity broken, missing or error: Items broken/missing/found in error
    - Comments: Describing nature of error (i.e., broken bottle, expiration date, missing, that were not ordered or not listed on invoice etc.)
    - Signature and names of receiving officers and witnessing staff member (preferably pharmacist)

The original copy of the shipment discrepancy report is sent to the concerned authority for action and one copy is kept on receiver's record.

Annex 1: GENERAL INSTRUCTIONS FOR INSPECTOR

The process of inspection may follow set protocols and be objective to established scientific facts and standards. Nevertheless, inspection is also subjective and depends on the involved personnel's intuition and interpretation of the situation on hand.

Inspecting personnel must keep the following things in mind:

- Plan ahead of the inspection.
- Always maintain a neutral view.
- Do not suggest answers.
- Do not rush the process of inspection.
- Always correct mistakes.
- Check for incomplete checklist.
- Always maintain records.
- Do not report anything fabricated or suggested upon.
- Plan a follow-up inspection if necessary.
- Note any additional requirements and/or discrepancies.

A person of agency responsible for PSI and/or PDI, and testing should have distinct answer to the following questions:

- What level of quality best meets the purchaser's requirements?
- How often will the item be used and how long is it expected to last?
- Do the supplies meet safety standards?
- Is the labelling and packaging of acceptable quantity?
- Is the goods supplied with necessary instructions for handling and storing?

The inspector must ensure that the manufacturer is able to manufacture the product in accordance with the certifications that has been asked in the contract document. Each batch of the pharmaceutical product shipped should be manufactured in compliance with GMP to ensure batch-to-batch consistency. The actual size of manufacture of the product should be known and specified. Each manufacturing site specified in the product information should be inspected to assess compliance with WHO-GMP. Manufacturers of the active pharmaceutical ingredient (API) used should be inspected as part of the assessment procedure to ensure that the API was manufactured in accordance with GMP. The inspector shall verify the performance of manufacturer of product and data submitted in the relevant product information files.

The inspector will verify the authenticity and validity of the certifications provided.

The inspector shall carry out sampling and testing before the shipment and/or verification of the same after the arrival of goods. Internationally accepted sampling procedures shall be followed by the inspector for the testing for all medicines.

Different products and different situations call for different levels of PSI, whereas sometimes not at all. The inspector shall monitor the conformity to standards and quality during manufacturing process. The inspector shall request manufacturer to provide appropriate certification of laboratory testing. Those certifications are to be verify and included in the report. Inspector is also required to verify the integrity of the packaging, quantity and physical testing of the items at the destination in the presence of the authorised representative of the manufacturer/supplier. If any major discrepancy is found or noticed against the agreed specification, quantity and other terms and conditions, it must be reported to the purchaser.

In addition, the inspector shall perform the following:

- Obtain and verify the supplier's COA or compliance to verify physical characteristics and chemical details, type, batch numbers and shelf-life as appropriate.

- Check that the items have a shelf-life not less than specified in the contract.
- Check that all packages are serially marked, and labelling/marking is exactly as specified in the contract.
- Check that the dimensions of the packing are as specified in the contract and marking and handling descriptions are clearly displayed to ensure proper handling in transit and at the delivery destination.
- Check that all individual items, internal packing, and external packages are exactly as specified in the contract.
- Check that the primary packing is not damaged, opened or tampered with and that the shipping mark requirements are correct.
- Check the packing against appropriate transportation and commodity regulations, and ensure that it is adequate for the safe shipment of goods by the contracted mode of transport.
- Check the stability of cartons/pallets and that all waterproofing of the packing is sufficient if the consignment is to be transported by open truck or left exposed during transit.
- Prepare a detailed report against each of the above and arrange for those present at the inspection to sign the report in agreement of the findings.
- Take photographs where possible and relevant, and attach them with the report.
- Submit the report to the purchaser. Any discrepancies found in the course of inspection must be reported immediately.

Annex 2: CHECKLIST FOR PSI AND PDI

General Checklist

S.N.	Parameter/activity	Observation	Remarks
1.	**General** Describe the general observation of the consignment and product		
a	Date of goods ready for PSI (in case of PSI) or Date of delivery met (in case of PDI)		
b	Quantity ready/delivered as per contract/purchase order		
c	Sample drawn based on batch size and sample plan as per relevant ISO 2859-1 and/or ISO 3534-2, or as agreed between the parties		
d	Item specifications against contract technical specifications		
e	End product quality and finish against the contractual requirements		
f	Dimensional checks		
g	Verification of manufacturer's test reports		
h	Packing, pallet size, shipping marks against contractual requirements and stamp of "inspected" by the inspecting authority		
i	Collection of samples as required by the recipient party/authorities		
j	Report of any damage or non-conformity with the contract		
k	Any other agreed upon ad-hoc activities stated in the contract		
2.	**Labelling** Make sure labelling includes all the right information including how the item should be stored. The product label should clearly state the following:		
a	INN of the active ingredient		
b	Dosage form		
c	Quantity of active ingredient(s) in the dosage form and the number of units per package		
d	Number of units per package		
e	Batch number		
f	Date of manufacture		
g	Expiry date (in clear language, not in code)		
h	Pharmacopeia standard		
i	Instructions for storage		
k	Manufacturer's name and address		
l	Labelling should always be in English and Nepali		
m	The full label should again appear on the collective package		

n	Directions for use, warnings, and precautions		
o	For articles requiring reconstitution prior to use, a suitable use time		
3. Packaging Check that packaging is robust, not damaged or discoloured, and that lids have not off the contents spilled.			
4. Expiry date and Quality Check the expiry date and visual test of quality			
a	Shelf-life is as per the bid document, like: Remaining shelf-life should not be less than 3/4 of shelf-life for 24 months and that 5/6 for shelf-life more than 24 months		
b	Appearance for colour changes and for unusual smells, in particular that: tablets are not chipped, broken, sticky or cracked; tubes of creams and ointments are not cracked; injections have no particles; clear vaccines are nor cloudy; and bottles and vials are not cracked or chipped of seal broken		
5. Certification Check that the supplier has provided the following certificates and documents			
a	Manufacturing License		
b	GMP Certificate for company and product		
c	Certificate of Pharmaceutical Product (CoPP) or Marketing License		
d	Product supply specifications (product information, quantity, packaging)		
e	Certificate of Analysis		
f	Product Registration (Product License)		
g	Certificate of Origin		
h	Authorised pre-shipment inspection report (if PSI done)		
i	Other particulars as required by the purchaser		

Product Specific Checklist

S.N.	Parameter	Observation	Remarks
6. All Shipments Compare the goods with the supplier's invoice and original purchase order or contract.			
A	Number of containers delivered is correct		
b	Number of packages in each container is correct		
c	Quantity in each package is correct		
d	Medicine is correct		
e	Dosage form is correct		
f	Strength is correct		
g	Labelling is correct		
h	Unique identifiers are present, if required. (article code, other code etc.)		

i	No visible evidence of damage (describe)		
j	Sample is taken for testing (if pre-acceptance sampling is a standard procedure)		
7. Tablets For each shipment, tablets of the same medicine and dose should be consistent.			
A	Tablets are equal in size		
b	Tablets are similar in shape		
c	Tablets have a consistent colour. None have signs of discolouration or different shades/colour		
d	Tablets are free of capping		
e	Tablets have identical tablet scores/marks		
f	Tablets are free of spots on the surface		
g	Tablets are intact without any signs of chipping or breakage		
h	Tablets are free of uneven edges and adherent particles		
i	Tablets are free of moisture		
j	Tablets do not stick to the packaging		
k	Tablets are fully enclosed in packs without any exposure		
8. Capsules For each shipment, capsules of the same medicine and dose should be consistent.			
A	Capsules are equal in size		
b	Capsules are similar in shape		
c	Capsules have a consistent colour. None have signs of discolouration or different shades/colour		
d	Capsules have identical markings		
e	Capsules are free of spots on the surface		
f	Capsules are intact without any signs of leaks or breakage		
g	Capsules are free of uneven edges and adherent particles		
h	Capsules are not brittle		
i	Capsules do not stick to the packaging		
k	Capsules are fully enclosed in packs without any exposure		
l	There are no open or empty capsules		
9. Liquid Preparations Liquid medicine packed in the container should be consistent.			
A	Absence of foreign particulate contaminants		
b	Proper viscosity		
c	Proper colour, odour, and taste		
d	Absence of phase separation		
e	Absence of hard non-dispersible cakes		
f	No leaks from containers		
g	Containers do not have cracks on them		
h	Absence of leeching		
i	Presence of necessary complimentary		

	components such as applicators and PIL		
j	Proper amount of product in the container		
10. Parenteral preparations Parenteral are all products for injections. Please check that			
a	Absence of foreign particulate contaminants		
b	Proper viscosity		
c	Absence of phase separation		
d	Absence of hard non-dispersible cakes		
e	No leaks from containers		
f	Containers do not have cracks on them		
g	Absence of leeching		
h	Presence of necessary complimentary components such as applicators and PIL		
i	Proper amount of product in the container		
11. Powders Each powder medicine packed should be identical. Please check that			
a	Absence of foreign particulate contaminants		
b	Proper flow-ability		
c	Absence of hard agglomerates		
d	Absence of moisture		
e	Proper amount of product in the container		
f	Proper sealing of product in container		
g	Presence of necessary complimentary components such as applicators and PIL		
h	Proper colour as stated in the documents		
i	Proper texture		
12. Cold Chain Goods Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling (e.g., vaccines), starting at the manufacturer and ending with the administration of the product to the client. Please check that			
a	The optimum temperature for refrigerated vaccines is between +2^{o}C and +8^{o}C		
b	The optimum temperature for frozen vaccines is -15^{o}C or lower		
c	Necessary arrangements have been made for specified vaccines to protect from light		
d	There are no cracks in the walls of Cold Box, Vaccine Carrier, and Ice Packs		
e	In case of PDI, Lot Release Certificate along with the shipment documents		
f	Vaccines must be unpacked, inspected and stored in cold chain equipment immediately after shipment. Following must be checked: • Lot Number • Cold Chain packing • VVM status • Status of Temperature Monitor • Diluents are supplied sufficient to the vaccines		

REFERENCES

MoHP, 2016, National List of Essential Medicines, Fifth Revision 2016, MoHP, GoN

MoHP, 2021, National List of Essential Medicines, Sixth Revision, 2021, MoHP, GoN

MoHP, 2018, Procurement Handbook 2074, LMD, DoHS, GoN

MoHP, 2015, Operational Manual, Standard Operating Procedures for LMD's Procurement and Contract Management Section based on World Bank's 2006 Guidelines and Nepal Government's Public Procurement Act, DoHS, MoHP

MoHP, 2015, National Immunization Program, Effective Vaccine Management Standard Operating Procedure, MoHP, DoHS

MoHP, 2020, Healthcare Warehouse Management Manual, MoHP, DoHS

WHO, 2002, Guidelines on Packaging Pharmaceutical Products, WHO Technical Report Series, No, 902, WHO

WHO, 2002, Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies, WHO

WHO, 2007, A Compendium of Guidelines and Related Materials Vol. 2, 2nd Edition, Good Manufacturing Practices and Inspection, WHO

WHO, 2017, Technical Requirements for Pharmaceutical Products in ITBs/ RFQs, WHO

WHO, 2010, WHO Good Distribution Practices For Pharmaceutical Products, WHO

WHO, 2005, WHO Guidelines for Sampling of Pharmaceutical Products and Related Materials, WHO

WHO, 2002, WHO Guidelines on Pre-approval Inspections, Annex 7, WHO

WHO, 2009, Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Annex 2, WHO

WHO, 2018, Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Annex 10, WHO Technical Report Series, No. 1010, WHO

WHO, 2006, A Model Quality Assurance System for Procurement Agencies, No. 937, Annex 6, Geneva, WHO

IFIA, 2002, Code of Practice for PSI IFIA Edition 6, May 2002, IFIA

USP 41-NF 36, 2017, Plastic Packaging Systems and Their Materials Of Construction, USP

USAID, 2014, Quantification of Health Commodities, A Guide to Forecasting and Supply Planning for Procurement, USAID

ASTM International, 2002, Standard Specification for Rubber Surgical Gloves, ASTM International

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