

Quality inspection guideline and check sheets for medical supplies

Quality Assurance and Standardization Division

Ministry of Health

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This publication contains the collective view of stakeholders from different clinical background.

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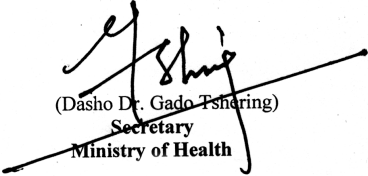
Foreword

Quality Assurance is a wide ranging concept covering all matters that individually or collectively influence the quality of a product or service. It is the totality of the arrangements made with the object of ensuring that products are of quality required for their intended use and services are of quality required for their intended output and standards. Quality assurance therefore also incorporates good manufacturing practices and other factors including quality inspection of the products before the intended use.

Quality Inspection is the act of monitoring or observing a product procedure, or service to insure compliance with the operational definition and to insure that all requirements or internal prerequisites are met. It is regarding sampling, specifications and testing in conformity with documentation and acceptance/rejection procedures which ensure that all necessary tests are performed and all features for the procured products are inspected. Performing all these procedures in a systematic manner would ensure quality medical supplies which are safe and effective resulting in delivery of quality health care services to the users. Hence, this guideline has been developed to ensure quality health care supplies and services.

I am pleased to introduce and share this guideline with all the health workers. I would like to express my appreciation to all

those involved in publication of this standard guideline. More so, I urge all those involved in the quality inspection to always adhere to this guideline and ensure all supplies are inspected prior to distribution to health centers. Lastly, I hope that this guideline would contribute in ensuring quality health care services to the people of Bhutan.



(Dasho Dr. Gado Tshering)
Secretary
Ministry of Health



1. Introduction:

The medical supply products of assured quality have the greatest potential for maximizing the impact and effort to accelerate access to better products. Ensuring quality assurance before distribution to the health centers for use in service delivery and treatment of patients is the responsibility of Quality Assurance and Standardization Division (QASD). Without a quality assurance system, organizations risk sourcing sub-standard, counterfeit or contaminated non-drugs and drugs, leading to complaints about products and product recalls, wastage of money and serious health risks to patients. Such problems affect the credibility of procurement system, cause financial losses and put patient's safety in danger.

This guideline is intended to cover only the quality inspection (QI) of medical supplies at the time of receipt at Medical Supply Depot (MSD) or Drug Vaccine and Equipment Division (DVED). It will provide detail procedure and standard operating procedures (SOPs) for quality inspection based on the category of the medical supplies. Only those medical supplies which have been certified by the QI Team as “Quality Passed” shall be distributed for use. However, this guideline will not be comprehensive and will not provide quality guarantee for each and every product, since the methodology is mostly based on organoleptic inspection and random sampling of the batches or group of products. The procurement agency and the users should continue post distribution surveillance to ensure quality.

2. Goal:

To ensure quality medical supplies those are safe, efficient and effective to provide enhanced quality, cost-effective and safe health care services in Bhutan. This guideline will also help to enhance the credibility in procurement of medical supplies.

3. Objectives:

- 3.1. To provide a systematic procedure for quality inspection of medical supplies to be implemented by Ministry of Health.
- 3.2. To set a uniform standard for inspection of medical supplies and will eliminate biasness.
- 3.3. To assess compliance with the import of products following regulatory provisions of the country.
- 3.4. To reduce the entry of substandard, counterfeit or contaminated medical supplies that leads to product recalls, wastage of resources and untoward health implications to patients.
- 3.5. To ensure transparency of quality inspection procedures/ parameters and impart accountability to those involved in the process.

4. General Quality Inspection Guidelines

- 4.1. All medical supplies procured or donated shall be subjected to QI and quality control using this guideline and the quality inspection check sheet (Annexure1-7).
- 4.2. The QI shall focus on organoleptic properties such as physical appearance, quality of labelling and packaging, optical bench observation for intravenous fluid, cold chain storage requirement etc. for all supplies.
- 4.3. For pharmaceuticals, samples shall be collected only for those suspicious products as per the sampling methodology (refer section 7) for analytical quality control test. The samples shall then be despatched to an appellate laboratory by PHL till such time the capacity and facilities is established within the country.
- 4.4. DVED upon receipt of consignment directly or upon intimation from MSD shall inform QASD within 5 working days along with the details of consignment such as copy of Purchase order, Invoice details and other relevant documents. The quality inspection shall be carried out within ten working days upon the receipt of the information from DVED/other procurement agencies.
- 4.5. The QI shall be coordinated by QASD in consultation with relevant stakeholders and specialities. A QI Team shall be constituted by pooling relevant technical experts from JDWNRH/other hospitals/Bio-medical Engineering Service (BES) and other relevant departments/divisions based on the technicality of supplies and shall be deputed

- to MSD, DVED or to the installation site by QASD, whenever deemed necessary.
- 4.6.** Wherever deemed necessary directives from the ministry shall be sought for medical supplies needing quality inspection at the site of origin. This would however be in line with the existing procurement manual.
- 4.7.** The QI Team should also focus on any error made during the selection in the previous year which can be amended in the subsequent year.
- 4.8.** Samples/selected medical supplies in consultation with DVED/MSD/relevant specialities shall be sent for quality inspection to DVED. Quality inspection will be done in DVED by the QI team. The sampling should be done as per the sampling procedure (refer section 4).
- 4.9.** *The thumb rule is that all medical supplies should have minimum of $\frac{3}{4}$ of the shelf life remaining upon receipt at MSD.* For those supplies which have shorter shelf life (as per the tender) shall be received as part shipment.
- 4.10.** Samples once selected during the tender selection by the tender award committee should be final and binding wherein no alternate products should be accepted. However, if the manufacture of the selected sample has been stopped by the manufacturer, the supplier should notify DVED and a copy to QASD prior to the supply of an alternate product for further approval.

- 4.11.** The QI team/QI inspector shall fill up the QI check sheet by recording their findings and signing on the same. Products not complying with the sample submitted earlier by the suppliers/standard/specifications or reported poor quality should be intimated to DVED, so that necessary action can be taken for rejection or replacement of the QI failed products as per the Terms of Reference of the tender.
- 4.12.** The QI Team/Inspector should ensure that the Quality Inspection Sheet is filled completely and should indicate NA (not applicable)/NR (not required) wherever deemed necessary against the specific parameter on the sheet.
- 4.13.** Upon completion of the QI, the QI Team/Inspector should seal the QI check sheet with appropriate label i.e. “Quality Passed” for QI accepted items/goods and “Quality Failed” for rejected items/goods accordingly.
- 4.14.** The QI Team/Inspector should furnish the QI Report to QASD. The QASD shall then forward the reports to DVED/MSD.

5. Guidelines for MSD

- 1.1.** Medical equipments requiring functionality testing at site shall be directly delivered to the designated site along with the relevant documents such as Purchase Order (PO), QI checklist and Invoice copy. It must be indicated in the terms and condition that the installation shall be

completed within two weeks upon receipt of the equipment at MSD.

6. Categories of Medical Supplies

1.1. Medical Equipments: - Medical equipments are a group of devices that are used for medical interventions in the process of patient's health care services. This guideline defines medical equipments into two following categories:

1.1.1. Electro-medical equipments: - Electro-medical equipments comprise of any medical equipment that are used for diagnostic or therapeutic purposes and requires electrical input for its functioning. It can be classified as either essential or non-essential equipment.

1.1.2. Non Electro-medical equipments: All medical equipments that are used for diagnostic and therapeutic purposes and do not require electrical inputs for its functioning.

1.1.3. Quality Inspection Parameters;

- i. Packaging
- ii. Labelling
- iii. Quantity

- iv. Specification
- v. Functionality
- vi. Operational/ User Manual
- vii. Quality Standard Credentials

1.1.4. Procedure for Quality Inspection;

- i. Start with visual examination.
- ii. Check and inspect the physical features of the equipment (shape, absence of any parts, external damage).
- iii. Compare the technical specification as per the approved catalogue or purchase order whichever is comprehensive.
- iv. Check the completeness of the supplies including all the necessary accessories. Check the supply of user manual or operational manual along with the equipment.
- v. Perform the functional test run at the installation site using varied conditions.
- vi. There shall be proper documentation of commissioning and handing taking over of the installed equipment from the concerned administration of the health facility.

1.2. Surgical Instruments: - Instruments or a device that are specially required to carry out special/invasive procedures.

1.2.1. Quality Inspection Parameters;

- i. Packaging (External)
- ii. Labelling
- iii. Specifications
- iv. Physical condition
- v. Functionality
- vi. Adaptability

1.2.2. Procedure for Quality Inspection;

- i. Arrange the packages in stacks
- ii. Check the invoice for quantity
- iii. Inspect the packaging for proper labelling, damages and record
- iv. Perform the sampling as per the sampling guidelines (Refer section 6)
- v. Samples collected should be visually inspected
- vi. Measure the dimensions as per specification in the

PO, or catalogue

- vii. Perform the basic functionality tests

1.3. General Medical Instruments: - Instruments that is used for general procedures by all the categories of health care professionals.

1.3.1. Quality Inspection Parameters;

- i. Specifications
- ii. Labelling
- iii. Packaging
- iv. Functionality
- v. Adaptability

1.3.2. Procedure for Quality Inspection;

- i. Arrange the packages in stacks
- ii. Check the invoice for quantity
- iii. Inspect the packaging for proper labelling, damages and record
- iv. Perform the sampling as per the sampling guidelines (Refer section 6)
- v. Samples collected should be visually inspected
- vi. Measure the dimensions as per specification in the PO, or catalogue

vii. Perform the basic functionality tests

1.4. Consumables:-Any medical or non-medical items required for general or therapeutic purpose and for day to day operation of health facility. Generally it comprises of disposable or re-usable items which can be used for a certain period. Pharmaceutical products, laboratory reagents and chemicals do not fall under this group. Consumables may be further sub divided as follows.

1.4.1. General Consumables:- Basic utility items required to facilitate and support the healthcare services including linens, sundries, dressing materials

1.4.1.1. Quality Inspection Parameters;

- i. Packaging
- ii. Labelling
- iii. Uniformity
- iv. Specification
- v. Functionality

1.4.2. Medical Consumables: – usually prescribed by the medical practitioner for a therapeutic purpose and will include all pre-packed sterilized consumables.

1.4.2.1. Quality Inspection Parameters;

- i. Packaging
- ii. Labelling

- iii. Uniformity
- iv. Specification
- v. Functionality
- vi. Compatibility
- vii. Suitability
- viii. Accelerated stimulation test

1.4.3. Procedure for Quality Inspection;

- i. Arrange the packages in stacks
- ii. Check the invoice for quantity
- iii. Inspect the packaging for proper labelling, damages and record
- iv. Perform the sampling as per the sampling guidelines (Refer section 6)
- v. Samples collected should be visually inspected
- vi. Measure the dimensions as per specification in the PO, or catalogue
- vii. Perform the basic functionality tests

1.5. Pharmaceutical Products: - All the finished pharmaceutical products including diagnostic agents such as radio-contrast agents and ingredients used for extemporaneous compounding. Such substances are intended to furnish pharmacological activity or other direct effect in

the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

1.5.1. Quality Inspection Parameters;

- i. Labelling specifications
- ii. Batch analysis certificate
- iii. Secondary packaging and primary packaging
- iv. Physical characteristics

1.5.2. Procedure for Quality Inspection;

- i. Arrange the consignment for sampling
- ii. Verify the necessary documents and cross check with the physical quantity.
- iii. Verify the batch analysis certificate.
- iv. Collect the sample as per the recommended sampling procedure.
- v. Examine both the secondary and primary packaging for legibility, completeness and intactness of the label and the integrity of the seal. Look for any physical damage or any other indications of tampering.
- vi. Examine the following physical characteristics of different dosage forms as follows:

- ✓ General appearance such as colour, texture and odour for all kinds of dosage forms.
- ✓ Shape, discoloration, abrasion, cracks, embossing and breakage lines.
- ✓ Test for uniformity of weight for both tablets and capsules wherever feasible.
- ✓ Flowability, crystallization, lump formation and presence of foreign materials in powders.
- ✓ Clarity and colour, presence of microbial growth in case of liquid dosage forms such as parenterals; dispersibility and flowability for suspensions, phase inversion, caking and viscosity of emulsions.
- ✓ Ease of flow, spread-ability and content uniformity for semisolid dosage forms.

1.6. Laboratory reagents and chemicals: - This category comprise of reagents and chemicals that are intended for use in a healthcare diagnostic laboratory. Almost all the laboratory reagents have short expiry date and are liable for change in stability and homogeneity when subjected to adverse or prolonged storage condition. The laboratory chemicals usually have high shelf life and are stable for a long time at room temperature. The reagents and chemicals require quality inspection parameters that are different from each other.

1.6.1. Quality Inspection Parameters;

- i. Physical appearances such as turbidity, agglutinations and texture
- ii. Pack size
- iii. Batch analysis certificates
- iv. Stability of the reagent
- v. Transportation mode
- vi. Leaks and other related damages
- vii. Packaging and labelling
- viii. Manufacture date and expiry date
- ix. Reproducibility and precision of the reagent (conducted in the Laboratory)

1.7. Vaccines and Biological: - This category includes healthcare products that are biological in nature and require advanced safety handling protocols. The stability of these products is highly sensitive to physical changes particularly to temperature variations. The risk to people's health cannot be guaranteed should these products leak out to the environment. Similarly, the intended efficacy of these products is considerably compromised if not handled with required protocols of storage, transport

and distribution.

The products under this category include vaccines, reference serum samples, immunological products, toxins, venoms, and bacteriological reference strains for quality control of culture and susceptibility testing in the laboratory.

1.7.1. Quality Inspection Parameters;

- i. Vaccine Vial monitor reading
- ii. Cold chain system maintenance
- iii. Storage conditions
- iv. Pack size
- v. Lot release certificate/ Batch analysis certificates
- vi. Transportation mode
- vii. Leaks and other related damages
- viii. Packaging and labelling
- ix. Manufacture date and expiry date

7. Sampling Methodology

- i. All medical supplies should be arranged systematically to represent the entire consignment. It should be either stacked or evenly displayed so that sampling

will be uniform, representative and appropriately randomized.

- ii. The consignment should be arranged in stacks of 5x5x5 (length x breadth x height) boxes or cartoons or containers for each batch. The samples should be drawn or picked in a randomized manner from the unopened secondary (outer) packages.
- iii. Sampling should be conducted as per the procedure and must have the representative numbers as indicated against each category.
- iv. Random or blind pick sampling may be done as and when necessary or when the bulk of the supply is large and there are no batch or lot numbers. The sampling is done wherein a set of number of products is drawn or picked depending on the number of batches or lots received/ containers received per consignment.
- v. All medical supplies, irrespective of equipments or consumables which has specification in terms of measurement (weight, size, area, thickness, length), measurement test should be performed as indicated in the sampling procedures. Not more than 5% of the samples measured should deviate from the measurement specified.

7.1. Sampling method for equipments

- i. High end electro-medical equipments should be inspected individually at the site of installation or at MSD/DVED using appropriate QI form and installation and handing taking report.
- ii. The inspection team should ensure that every possible features of an equipment received is thoroughly inspected.
- iii. Reports of equipment installation and handing taking of the equipment should be furnished to DVED and QASD.
- iv. Sampling as per prescribed procedure such as lot sampling or batch sampling is applicable to other non-electro medical equipments. This includes sampling from all the different lots received.

7.2. Sampling method for pharmaceutical products

- i. Assess if the pharmaceutical products received were stored according to the manufacturers or international standard recommended storage conditions (temperature and humidity).
- ii. Samples must be kept and stored according to the rec-

ommended storage conditions till the QI is over.

- iii. Sample size (number of units/sample):
- ✓ At least 5 primary packages should be opened from each batch stacked for sampling. Minimum 10 unit dose preparation (such as tablets, capsules and sachets) and 10 units for injectables from the 5 primary packages should be collected from the stacks as recommended above. The sampling should be repeated for each batch if the supplies are made in more than one batch.
 - ✓ Effort should be made to collect, whenever possible, a minimum of **5 samples** for each product per batch per sample collection round.
 - ✓ There is no need to collect sample of the same batch of the product again unless some unusual labeling, packaging, expiry date, manufacturing date or physical characteristics of the product are observed.
 - ✓ This quantity/number of sample units should be sufficient for complete screening using physical and visual inspections. In case of suspicion and if further laboratory testing is recommended, re-sampling will be done as per the sampling protocol of the Drug Testing Laboratory.

7.3. Sampling method for all medical and general consumables

- i. Sampling will be conducted in a randomized manner wherein the sample selected will be representative of the particular batch or lot or consignment.
- ii. In case of medical consumables, effort should be made to collect the samples for all the different containers of same batch as well as from all the different batches.
- iii. However, general consumables should be sampled only from different packaging and should be representative of the whole consignment irrespective of number of containers received per batch.
- iv. The total quantity sampled should not be less than 20% of the total quantity received or 10 pieces whichever is greater.

7.4. Sampling method for instruments

- i. Inspect every 5th piece from the lot and inspect at least 10 pieces if the total number of instrument is less than 50 or more than 20. The instruments should be properly arranged to facilitate good sampling practices (randomization and representativeness).
- ii. If the total number of instruments is equal to or less

than 20, inspect all. However, inspect all the batches/lot/ consignment in similar manner if the consignment consists of two or more different batches or part shipment or lot.

- iii. Pick every 9th piece from each lot if the total quantity is more than 100 pieces. Effort should be made to inspect at least 25 pieces.

7.5. Sampling method for powders in bulk packaging

- i. Arrange the consignment in stacks of secondary packaging as for pharmaceuticals.
- ii. Sampling should be conducted in a randomized manner.
- iii. Collect from at least 2 secondary packages a minimum 5 primary packaging.

Reference:

A model quality assurance system for procurement agencies.
World Health Organization (2007) Geneva, Switzerland

A guide for the development of medical device regulations:
Pan American Health Organization 2002

Guidelines for Health Care Equipment Donation, 5th Draft,
World Health Organization, WHO/ARA/97.3

<http://procurement.ifrc.org/catalogue/quality.aspx>

<http://procurement.ifrc.org/catalogue/overview.aspx?volume=2&groupcode=203&familycode=203003>

<http://hinfo.humaninfo.ro/gsdldata/collect/healthtech-docs/index/assoc/s15250e/s15250e.pdf>

QUALITY INSPECTION (QI) CHECK SHEET FOR EQUIPMENTS

1. Name of the health facility: 2. Date of QI:
3. Name of the equipment: 4. Model No: 5. Serial No:
6. Manufacturer: 7. Quantity ordered: 8. Purchase & invoice order no:
9. Ordered specification: 10. Receipt specification: 11. Supplier:
12. QI conducted with reference to: Catalogue/Sample/Purchase order/Invoice/Generic Specification
13. Packaging: Satisfactory/Unsatisfactory (*Tick one*)
- If Unsatisfactory, state observation:
-
14. Labeling: Satisfactory/Unsatisfactory (*Tick one*)
- If Unsatisfactory, state observation:
-
15. Physical condition of the equipment: Damaged/ Not Damaged (*Tick one*)
- If Damaged, describe the nature of damage and reject the supply:
-
- | | | |
|---|------------------------------|---------------------|
| 16. Operational manual | Yes/No/NR | (<i>Tick one</i>) |
| 17. User manual | Yes/No/NR | (<i>Tick one</i>) |
| 18. Service manual | Yes/No/NR | (<i>Tick one</i>) |
| 19. Electrical voltage and phase power (KVA/KW) | Acceptable/Not acceptable/NA | (<i>Tick one</i>) |
| 20. Electrical Frequency: | Acceptable/Not acceptable/NA | (<i>Tick one</i>) |
| 21. Operational environmental condition: | Acceptable/Not acceptable/NA | (<i>Tick one</i>) |
| 22. Accessories/Consumables | Complete/Incomplete/NA | (<i>Tick one</i>) |
| 23. Efficiency wherever indicated | Acceptable/Not acceptable | (<i>Tick one</i>) |
| 24. Functionality testing conducted | Functional/non-functional | (<i>Tick one</i>) |
| 25. After sales service | Provided/Not provided | (<i>Tick one</i>) |
| 26. Conformity to technical Specifications | Yes/No | (<i>Tick one</i>) |
| 27. Safety of the equipment | Acceptable/Not acceptable/NA | (<i>Tick one</i>) |
28. Warranty (No. of years) 29. Date and place of installation:
30. Quantity received: 31. Quantity rejected: 32. Quantity accepted:
- If rejected, reasons for rejection of items:
-
-

Name and signature of the QI inspectors:

1.

2.

3.

Note: Not Applicable (NA), Not Required (NR)

QUALITY INSPECTION (QI) CHECK SHEET FOR PHARMACEUTICALS

(One form for one particular drug)

Name of the health facility: b. Date of QI: c. Name of the drug:
 d. Strength: e. Dosage form: f. Year of supply: g. Purchase & invoice order no.: h. Invoice Qty:
 i. Manufactured by: j. Manufacture date: k. Expiry date: l. Supplied by:
 m. Sample size: n. Batch No.: o. Batch analysis certificate (Yes/No):

Secondary packaging		Primary packaging		Organoleptic properties
Material specification		Material specification (plastic, aluminum etc)		General appearance (shape, size, engraving, etc)
*Integrity of seal pack		*Integrity of seal pack		*Any discoloration or abnormal odor (Yes/No)
* Labeling quality		*Security features if any (hologram, bar coding, etc)		*Presence of foreign material or microbial growth (powders and liquids)
*Any physical damage detected (Yes/No)		*Labeling quality (legibility & completeness)		*Uniformity of weight
		Is packaging insert available (Yes/No)		Variation in weight and size (tablets and capsules)
		8Any physical damage detected (Yes/No)		*Clarity of solution (parental only)
				Any other parameters (if applicable)

ACCEPTED/REJECTED (Tick one)

If rejected, justify:

Comments if any:
 Drug test: (a) Qualitative: (b) Quantitative: (For time being no capacity to conduct test for all the drugs, only suspicious drugs are sent for testing outside the country)

Name and signature of QI Inspectors:

1. _____
2. _____
3. _____

QUALITY INSPECTION (QI) CHECK SHEET FOR VACCINES & BIOLOGICALS AND OTHER THERMO-LABILE SUBSTANCES

- a. Name of the health facility: b. Date of QI: c. Name of the product:
 d. Purchase order & invoice No.: e. Quantity ordered: f. Manufactured by: g. Batch No.:
 h. Sample size: i. Manufacture date: j. Expiry date: k. Lot No.: *Lot release certificate (Yes/No):
 l. Recommended storage temperature: m. Cold chain maintained (Yes/No): (Note: VVM incase of vaccines).....

Packaging & labeling	Organoleptic properties
Material specification	General appearance
*Integrity of seal pack	*Is the appearance complying with the finished product specification
*Labeling quality (legibility & completeness)	*Clarity
Is packaging insert available (Yes/No)	*Presence of foreign material or microbial growth Any other parameters (If applicable)
ACCEPTABLE/REJECTED (Tick one) If rejected, justify:	

Comments if any:

Name and signature of QI Inspectors:

1.
2.
3.

Note: State NA wherever not applicable, * mark indicates mandatory for QI to be passed

QUALITY INSPECTION (QI) CHECK SHEET FOR GENERAL CONSUMABLES

a. Name of the health facility: b. Date of QI:
 c. Purchase & invoice order no.: Name of the supplier:

Sl. No.	Item description	Functionality (functional or not/NA)	Conformity to specification (Yes/No)	Packaging (satisfactory or not)	Qty. ordered	Qty. accepted	Qty. rejected	Mfg. date	Expiry date	Manufacturer	Sample size	QI reference (catalogue/sample/purchase order/invoice)

Those items that need weighing and measurement as well as other necessary checks has to be carried out on the random sampling (e.g. bandages, gauzes, cottons, plasters etc)

Comments if any:

Reason for rejection:

Name and signature of QI Inspectors:

1.
2.
3.

Note: State NA wherever not applicable

QUALITY INSPECTION (QI) CHECK SHEET FOR MEDICAL CONSUMABLES

a. Name of the health facility: b. Date of QI: c. Name of the item: d. Year of supply:
 e. Manufactured by: f. Supplied by: g. Purchases & invoice order No:
 h. Sample size: i. Batch No: j. Manufacture date: k. Expiry date: l. Invoice Quantity:
 m. Quality standard mark: (ISO/CE/GMO/ISI) - Tick

Secondary (outer) packaging		Primary (immediate product) packaging		Organoleptic properties
Material specification	Material specification	General appearance		
Integrity of seal pack	Integrity of seal pack	Any discoloration or abnormal odor (Yes/No)		
Labeling quality	Security features if any (hologram, bar coding etc)	Compliance to the approved sample/catalogue		
Any physical damage detected (Yes/No)	Labeling quality (legibility & completeness)	Uniformity of dimensions		
	Any physical damage detected (Yes/No)	Any other parameters (if applicable)		
ACCEPTED/REJECTED (Tick one)		Quantity rejected:		Quantity accepted:
If rejected, justify:				

Comments if any:

Name and signature of QI Inspectors:

1.
2.
3.

Note: State NA wherever not applicable

DZONGKHA SECTION

༡ རྟོན།

ལམ་སྟོན་འདི་གི་ཐབས་ལམ་གཙོ་བོ་རང་ སྤྲོད་ཇུས་ཀྱི་རིགས་ཚུ་མཁོ་སྐྱབ་འབད་དེ་དུས་ཚོད་
 གཅིག་ལུ་སྤྲོད་ཇུས་བཀའ་སྲུང་སྲེ་ཚན་(ཨེམ་ཨེམ་ཱི) ཡང་ཅིན་ ཱི་མི་ཨི་ཱི་ ནང་ལུ་ཕྱིས་
 ལེན་འབད་བའི་སྐབས་སྤྲོད་ཚད་བརྟག་ཞིབ་འབད་མི་ཚུ་གི་ལག་ལེན་འཐབ་ནི་འི་དོན་ལུ་ཨིན།
 འདི་ནང་ སྤྲོད་རིགས་དང་ཅ་ཆས་ཚུ་བཀའ་སྲུང་གི་བྱ་རིམ་དང་ཚད་གཞི་དང་ལྷན་པའི་བརྟག་
 ཞིབ་ལམ་སྟོན་ཚུ་ལ་གསལ་སྲེ་བཀོད་དེ་ཡོད། སྤྲོད་རིགས་དང་ཅ་ཆས་བཀའ་སྲུང་མ་འབད་
 བའི་ཉེ་མར་ བརྟག་ཞིབ་སྲེ་ཚན་གྱིས་དབྱེ་ཞིབ་ལས་མཐར་འཁྲུལ་ཞེན་མ་ལས་མ་གཏོགས་
 བཀའ་སྲུང་འབད་མི་ཚོགས། ཨིན་རུང་ལམ་སྟོན་འདི་གི་ཐོག་ལུ་སྤྲོད་རིགས་དང་ཅ་ཆས་རེ་རེ་
 བཞིན་གྱི་སྤྲོད་ཚད་ཚུ་དེས་ཏིག་སྲེ་ལས་ལེན་མི་ཚུ་གསལ། གཅི་འབད་བཟེ་བ་ཅིན་ འདི་ཡང་
 ཐབས་ལམ་ཚུ་གཙོ་བོ་རང་བཞིན་གྱི་དངོས་ཇུས་བརྟག་ཞིབ་དང་། དཔེ་ཚད་ཀྱི་འཕྲོད་རིམ་ག་
 ཐོབ་ཐོག་ལས་འབད་ནི་དེ་གིས་ཨིན། སྤྲོད་རིགས་དང་ཅ་ཆས་ཚུ་བཀའ་སྲུང་འབད་བའི་ལུ་
 ལས་མཁོ་སྐྱབ་དང་ལག་ལེན་འཐབ་མི་ཚུ་གིས་ སྤྲོད་ཚད་བརྟག་ཞིབ་འབད་དགོ།

༢ དམིགས་གཏང།

འབྲུག་རྒྱལ་ཁབ་ནང་སྤྲོད་བཅོས་ཞབས་ཏོག་གི་སྤྲོད་ཚད་ཅན་དང་། ཉེན་སྲུང་དང་ལྷན་མ། ལེ་
 བན་ཅན། ལུས་ལྷན་ཅན། གོང་ཚད་རན་ཏོག་ཏོག་གསོ་བའི་སྤྲོད་བཅོས་ཞབས་ཏོག་སྤྲོད་
 ཐབས་ལུ་ ལམ་སྟོན་འདི་གིས་གཙོ་བོ་ཉེན་ལ་མེད་པའི་སྤྲོད་རིགས་དང་ཅ་ཆས་ཚུ་མཁོ་སྐྱབ་
 འབད་དེ་བཀའ་སྲུང་འབད་ཐབས་ཀྱི་དོན་ལུ་དམིགས་ཏེ་ཨིན།

༣ དམིགས་དོན།

༣.༡ སྤྲོད་རིགས་དང་ཅ་ཆས་བཀའ་སྲུང་བརྟག་ཞིབ་ལས་ལུགས་དང་འཁྲུལ་བཀའ་
 སྲུང་བརྟག་དབྱེད་འབད་ཚུ་ གསོ་བའི་ལྷན་ལག་གིས་ལག་ལེན་འཐབ་ནི་འི་དོན་
 ལུ།

- 3.2 ཚད་གཞི་དང་ལྷན་པའི་སྤྲོད་རིགས་དང་ཅ་ཆས་བཀའ་སྲུལ་བརྟག་ཞིབ་གཅིག་མཚུངས་བཟོ་ནི་དང་། རོར་འབྲུལ་མེད་པ་བཟོ་ནི།
- 3.3 སྤྲོད་རིགས་དང་ཅ་ཆས་ནང་འབྲེན་འབད་ནི་ཚུ་རྒྱལ་ཁབ་ཀྱི་ཁྲིམས་ལུགས་དང་འཁྲིལ་བརྟག་ཞིབ་འབད་ནི།
- 3.4 སྤྲོད་རིགས་དང་ཅ་ཆས་ཀྱི་རིགས་ཚུ་ཚད་གཞི་དང་མ་ལྷན་མ། ཡང་ན་ རྩམ་མ་དང་བཅོམ་རྩམ་ཅན་གྱི་སྤྲོད་རིགས་དང་ཅ་ཆས་བཀའ་སྲུལ་ལས་བརྟེན་ཅ་ཆས་ལོག་བཏང་དགོཔ་འཐོན་ནི་དང་། སྤྲོད་རིགས་དང་ཅ་ཆས་ཀྱི་རྒྱ་འཕྲོག་བརྟག་འབྲོལ་ནི་དང་། ལྷག་པར་དུ་ ནད་པ་ཚུ་སྤྲོད་བཅོམ་འབད་བའི་སྐབས་ གཞོད་སྤྱོད་མར་ཕབ་བརྟུབ་ནི་གི་དོན་ལུ་དང་།
- 3.5 བརྟག་ཞིབ་ཅིམ་པ་འདི་དྲུངས་གསལ་གྱི་ཐོག་ལས་འགན་འཁྲིལ་ཅན་གཅིག་ལུ་བཟོ་ནི་གི་ཐབས་ལམ་ཅིག་ཨིན།

༤ སྤྲོད་བཏང་སྤྲོད་ཚད་བརྟག་ཞིབ་ལམ་སྟོན།

- 4.1 སྤྲོད་རྩམ་བཀའ་སྲུལ་མཁོ་སྐྱབ་འབད་ཡོད་མི་དང་། རྟོགས་རམ་ལས་བརྟེན་མཁོ་སྐྱབ་འབད་དགོཔ་ཚུ་ག་ར་སྤྲོད་ཚད་བརྟག་ཞིབ་དང་འཁྲིལ་དགོཔ་དང་། ལམ་སྟོན་དང་དབྱེ་ཞིབ་འབྲི་ཐོག་དིགཞེས་ཀྱི་ཐོག་ལས་སྤྲོད་ཚད་ཚད་འཛིན་འབད་ནི།
- 4.2 སྤྲོད་ཚད་བརྟག་ཞིབ་འདི་གཙོ་བོ་རང་བཞིན་གྱི་ལུས་པ་དང་། ལ་ཡིག་གི་སྤྲོད་ཚད། བསྐྱམ་ཚད། བསིལ་རྒྱུ་རྒྱ་ཉོག་ཉོག་ལ་སོགས་པ་ཚུ་བཀའ་སྲུལ་ལུ་འབད་བའི་སྐབས་ལུ་བརྟག་ཞིབ་འབད་དགོ།
- 4.3 སྤྲོད་རིགས་སྤྲོད་ཚད་བརྟག་ཞིབ་ཀྱི་དོན་ལུ་ དོགས་སྤང་ཡོད་པའི་སྤྲོད་སྤྲོད་ག་པ་ཅིག་འབྲུ་ཞིན་མ་ལས་ དཔེ་ཚད་ཀྱི་ལམ་ལུགས་དང་འཁྲིལ་བཀའ་ཐབས་ཀྱི་དོན་ལུ་ སྤྲོད་ཚད་དབྱེ་ཞིབ་འབད་དགོ།

༢.༢ ལྷན་རིགས་དང་ཅ་ཆས་སྣོད་པའི་གནས་ཚུལ་འདི་ལྷན་རྒྱས་དང་ཅ་ཆས་སྣེ་ཚན་གྱི་
སྤྱི་ཚད་དེས་བརྟན་དང་གནས་ཚད་སྣེ་ཚན་ལུ་ཉིན་མ་ ༥ གི་ནང་འཁོད་ལུ་སྤན་ལྷ་
འབད་དགོ། ལྷན་ཚད་དེས་བརྟན་དང་གནས་ཚད་སྣེ་ཚན་གྱི་སྤན་ལྷ་ཐོབ་ཞེན་མ་ལས་
ཉིན་མ་ ༡༠ གི་ནང་འཁོད་ལུ་སྤྱི་ཚད་བརྟན་ཞེན་འབད་དགོ།

༢.༥ ལྷན་ཚད་བརྟན་ཞེན་སྣེ་ཚན་གྱི་འགོ་འདྲེན་ཐོག་ལས་འབྲེལ་གཏུགས་ཡོད་པའི་སྣེ་
ཚན་ནང་ལས་མཁས་མཚོག་ཚུ་དང་གཅིག་ཁར་སྤན་རིགས་དང་ཅ་ཆས་སྣེ་ཚན་དང་།
ཡང་ཅིན་ ལྷན་རིགས་དང་ཅ་ཆས་བཀྲམ་སྤེལ་མཚོན་ཁང་ནང་ ལྷན་ཚད་བརྟན་ཞེན་
འབད་བར་འགྱུ་དགོ།

༢.༥ ལྷན་ཚད་བརྟན་ཞེན་སྣེ་ཚན་གྱི་བརྟན་ཞེན་ཐོག་ལེབ་འདི་ཚང་མ་སྣེ་འབྲི་དགོས་མ་
ཚད་ དེ་ནང་སྤྱི་ཚད་བརྟན་ཞེན་འབད་མི་གི་མིང་དང་། གོ་གནས། མཚན་རྟགས་ཚུ་
ཡང་གསལ་ཉེན་ཉེ་སྤྱི་བཀོད་དགོ།

༢.༦ བརྟན་ཞེན་ཐོག་ལེབ་འདི་ ལྷན་ཚད་དེས་བརྟན་དང་གནས་ཚད་སྣེ་ཚན་ལུ་སྣོད་
ཞེན་མ་ལས་ ལྷན་རྒྱས་དང་ཅ་ཆས་སྣེ་ཚན་དང་། ལྷན་རྒྱས་བཀྲམ་སྤེལ་སྣེ་ཚན་ལུ་
ཡིག་འདྲ་གཏང་དགོ།

༥ ཅ་ཆས་གྱི་དབྱེ་བ།

༥.༡ དཔུང་གྱི་ཅ་ཆས་འདི་གཙོ་བོ་གཤམ་གསལ་གཙོ་དྲུང་ལུ་ལག་ལེན་འཐབ་ནི་ཨིན།

༥.༡.༡ ལྷན་ཚད་བརྟན་ཞེན་གྱི་ཚད་གཞི།

- ཕྱི་འབྲུག་ཚད།
- ལ་ཡིག།
- གཅིག་མཐུན།
- ཕྱི་འབྲུག་སྤྲུང་ས།
- ལག་ལེན་འཐབ་བཏུབ་དང་མ་བཏུབ།

4.7.2 ལྷ་ས་ཚད་བརྟག་ཞིབ་ཀྱི་རིམ་པ།

- ཅ་ཆས་སྐྱོམ་འདིག་རིམ་སྤེལ་བཞག་དགོ།
- ཚོང་ཟོག་འབོར་ཚད་ཐོ་ཡིག་དབྱེ་ཞིབ་འབད་དགོ།
- ལྷ་ས་སྐྱོམ་ཀྱི་ཁ་ཡིག་འདི་ཚད་དང་ལྷན་ཏོག་ཏེ་ཡོད་མེད་བལྟ་དགོ།
- ཅ་ཆས་སྐྱུས་ཚད་འདི་ལམ་སྟོན་གྱི་དཔེ་དང་འཁྲིལ་ཏེ་གདམ་ཁ་བརྒྱབ་དགོ།
- ཅ་ཆས་དཔེ་ཚད་ཀྱི་དོན་ལུ་གདམ་ཁ་བརྒྱབ་ཡོད་མི་འདི་ལེགས་ཤོམ་སྤེལ་དབྱེ་ཞིབ་འབད་དགོ།
- མཁོ་སྐྱབ་བཀའ་རྒྱ་དང་ ཡང་ཅིན་དངོས་ཐོ་དང་འཁྲིལ་ ཚད་གཞི་བལྟ་དགོ།
- བེད་སྤྱོད་འཐབ་བཏུབ་མ་བཏུབ་ཚུ་དབྱེ་ཞིབ་འབད་དགོ།

6 མཁོ་ཆས་ཀྱི་རིགས།

མཁོ་ཆས་ཀྱི་རིགས་ཟེར་མི་འདི ཉིན་ལྟར་བཞིན་དུ་ལག་ལེན་འཐབ་དགོ་པའི་སྐྱུན་བཅོས་ཅ་ཆས་ཀྱི་རིགས་ཚུ་ལུ་གོ་ཤ་ཨིན། དེ་ཡང་ཅ་ཆས་ཚར་གཅིག་ལག་ལེན་འཐབ་མི་རིགས་གཅིག་དང་། ཚར་གཅིས་དང་གསུམ་ལོག་སྟེ་ལག་ལེན་འཐབ་བཏུབ་མི་རིགས་གཅིས་སྤེལ་ཡོད་པ་ཨིན། དེ་འབད་མ་ད་ ལྷ་ས་རིགས་ལུ་གོ་ཤ་ཨིན། མཁོ་ཆས་ཀྱི་རིགས་ནང་དབྱེ་བ་ལག་གཅིས་གཤམ་གསལ་ལྟར།

6.1 ལྷིང་བཏང་མཁོ་ཆས་ཀྱི་རིགས།

ལྷིང་བཏང་མཁོ་ཆས་ཀྱི་རིགས་ཟེར་མི་འདི ལྷ་ས་བཅོས་ཞབས་ཏོག་དང་གསོ་བའི་འཕྲོད་བསྟེན་གྱི་དོན་ལུ་གཤམ་ཆེ་བའི་ཅ་ཆས་ དཔེར་ན་ རས་དང་མུ་རྒྱུ་འབྲུ་ནི་གི་ཅ་ཆས་ཚུ་ལུ་གོ་ཤ་ཨིན།

6.1.1 ལྷ་ས་ཚད་བརྟག་ཞིབ་ཀྱི་ཚད་གཞི།

- བསྐྱམ་ཐངས།
- ཁ་ཡིག།



- ཤོ་སྒྲོམ་སུ།
- ཚད་གཞི།
- སྤྱི་ལོ་གནས་སྟངས།
- ལག་ལེན་འཐབ་བརྟུབ་དང་མ་བརྟུབ།

6.2 སྤྲོན་བཅོས་ཀྱི་མཁོ་ཆས།

སྤྲོན་བཅོས་ཀྱི་ཅ་ཆས་ཟེར་མི་འདི་ སྤྲོན་བཅོས་དང་གཤམ་སྤྲོད་འབད་བའི་སྐབས་ ལག་ལེན་འཐབ་བརྟུབ་ནི་འཛུགས་ འབྲུབ་མེད་པའི་ཅ་ཆས་ཀྱི་རིགས་ཚུ་ལུ་གོ་མ་ཞིན།

6.2.1 སྤྲོན་ཚད་བརྟུག་ཞིབ་ཀྱི་ཚད་གཞི།

- སྤྱི་ལོ་བསྐྱམ་ཐངས།
- ལ་ཡིག།
- ཤོ་སྒྲོམ་སུ།/གཅིག་མཐུན།
- སྤྱི་ལོ་གནས་སྟངས།
- ལག་ལེན་འཐབ་བརྟུབ་དང་མ་བརྟུབ།
- མཐུན་བརྟུབ།
- འོས་འབབ་ཅན།

6.2.2 སྤྲོན་ཚད་བརྟུག་ཞིབ་རིམ་པ།

- ཅ་ཆས་སྒྲོམ་འདི་རིམ་པ་སྐྱེ་བཞག་དགོ།
- ཚོང་ཐོག་འབོར་ཚད་ཐོ་ཡིག་དབྱེ་ཞིབ་འབད་དགོ།
- སྤྲོན་སྒྲོམ་ཀྱི་ལ་ཡིག་འདི་ཚད་དང་ལྡན་ཏེ་གཏོ་ཏེ་ཡོད་མེད་བཟུ་དགོ།
- ཅ་ཆས་སྤྲོན་ཚད་འདི་ལམ་སྤོན་ཀྱི་དཔེ་དང་འཁྲིལ་ཏེ་གཤམ་ལ་བརྟུབ་ དགོ།
- ཅ་ཆས་དཔེ་ཚད་ཀྱི་དོན་ལུ་གཤམ་ལ་བརྟུབ་ཡོད་མི་འདི་ལེགས་ཤོམ་སྐྱེ་ དབྱེ་ཞིབ་འབད་དགོ།

- མཁོ་སྐྱབ་བཀའ་རྒྱུ་ ཡང་ཅིན་དངོས་ཐོ་དང་འཁྲིལ་ ཚད་གཞི་བཏུ་དགོ།
- བེད་སྐྱོད་འཐབ་བཏུབ་མ་བཏུབ་ཚུ་དབྱེ་ཞིབ་འབད་དགོ།

པ དཔེ་ཚད་འབད་ཐངས་ཀྱི་ཐབས་ལམ།

- སྐྱན་རྫས་ཀྱི་རིགས་གསར་པ་ལྟོད་མི་ཚུ་ག་ར་ལས་དཔེ་ཚད་འབྲུ་ཞིན་མ་ལས་གོ་རིམ་སླེ་བཀའ་བཞག་དགོ། སྐྱན་རིགས་གསར་པ་ལྟོད་མི་ཚུ་བཞག་རིམ་དང་འཁྲིལ་སྐྱོམ་ནང་གཞིབ་དགོ། འདི་ཡང་ $u_X u_X u$ (རིང་ཚད་ X ཀྱི་ཚད་ X མཐོ་ཚད) དེ་ལས་དཔེ་ཚད་ཀྱི་སྐྱོམ་ནང་ལས་འབྲུ་བའི་སྐབས་ག་ཚུད་པ་སླེ་འབྲུ་དགོ།
- དཔེ་ཚད་བརྟག་ཞིབ་འབད་བའི་སྐབས་གོ་རིམ་དང་འཁྲིལ་དབྱེ་ཁག་ལྷེད་དེ་ཨང་རྟགས་བྱིན་དགོ།
- ཅ་ཆས་ཀྱི་འཐོན་རིམ་ཨང་མེད་མི་དང་། ཡང་ཅིན་ ཅ་ཆས་འབོར་ཆེན་སླེ་ཡོད་པའི་སྐབས་དཔེ་ཚད་འདི་ག་ཚུད་པ་སླེ་འབྲུ་དགོ།
- ཅ་ཆས་བརྟག་ཞིབ་འབད་བའི་སྐབས་ ཅ་ཆས་ཀྱི་ལྷིད་ཚད་དང་ ཡང་ཅིན་ སྐྱོམ་ཚུང་ རྒྱ་ཚད་ ལྷག་ཚད་ རིང་ཚད་ཚུ་དཔེ་ཚད་བརྟག་ཞིབ་ཀྱི་ལམ་ལུགས་དང་འཁྲིལ་ཉེ་འབད་དགོ་པ་མ་ཚད་ ཅ་ཆས་ཀྱི་ཚད་གཞི་ ལས་སྐྱོན་བརྒྱ་ཆ $u\%$ ལས་བརྒྱལ་ལྷག་ཆད་འཐོན་ནི་མི་འོང་།

པ. ༡ སྐྱན་རིགས་ཀྱི་དོན་ལུ་དཔེ་ཚད་བརྟག་ཞིབ་ཐབས་ལམ།

- སྐྱན་རིགས་ཚུ་བསིལ་དྲོད་དང་ལྡན་མ་སླེ་བཞག་ཡོད་མེད་བརྟག་ཞིབ་འབད་དགོ།
- སྐྱུམ་ཚད་བརྟག་ཞིབ་འབད་མ་ཚར་ཚུན་བསིལ་དྲོད་དང་ལྡན་མ་སླེ་བཞག་དགོ།
- དཔེ་ཚད་གཤམ་གསལ་ལྟར་བརྟག་ཞིབ་འབད་དགོ།
 - དཔེ་ཚད་བརྟག་ཞིབ་ཀྱི་དོན་ལུ་ དཔེ་ཚད་གོ་རིམ་སླེ་གཞིབ་བཞག་མི་གས་ལས་འཐོན་རིམ་རེ་རེ་ལས་ཕྱི་ཤོག་གཙོ་བོ་ཉུང་ཤོས་ལ རེ་འབྲུ་དགོ།
 - སྐྱན་རྫས་དང་ཅ་ཆས་ཚུ་གི་ཁ་བྱང་དང་། བསྐྱམ་ཐངས། ལུས་རྫོགས་ལྷ་ཚོས།

བཅོ་སྐྱོན་ལྔ་ཚོས། ཕྱི་འཛམ་པ་རྒྱ་དབྱེ་ཞིབ་འབད་དགོ།

པ. 2 སྤྱི་བཏང་སྐྱོན་གྱི་མཁོ་ཆས་དང་སྐྱོན་ཚུ་དཔེ་ཚད་ལམ་ལུགས།

- སྐྱོན་ཚུ་གྱི་འཐོན་རིམ་ཨང་གཅིག་ཨིན་ཅུང་སྐྱོན་སྤྱོད་སོ་སོ་ནང་ལས་དཔེ་ཚད་རེ་རེ་བཏོན་ཞིན་མ་ལས་བརྟག་ཞིབ་འབད་དགོ།
- མཁོ་ཆས་སྐྱོན་གྱི་སྐབས་ལུ་དཔེ་ཚད་འདི་འབོར་ཆེན་ནང་ལས་དཔེ་བཏོན་ཞིན་མ་ལས་བརྟག་ཞིབ་འབད་དགོ།
- དཔེ་ཚད་བརྟག་ཞིབ་གྱི་འབོར་ཚད་འདི་བརྒྱ་ཆ་ལས་ 20% ཡང་ཅིན་ དཔེ་སྤྱོད་ 70 དེ་ཅིག་མང་ཅུང་འཕུ་ཞིན་མ་ལས་བརྟག་ཞིབ་འབད་དགོ།

པ. 3 ཕྱི་རིགས་འབོར་ཆེན་བརྟག་ཞིབ་ལམ་ལུགས།

- ཕྱི་རིགས་རྒྱ་གར་ལས་དཔེ་ཚད་འཕུ་ཞིན་མ་ལས་གོ་རིམ་སྤྱི་བཟུམ་བཞག་དགོ། སྐྱོན་ཚུ་རིགས་གསལ་པོ་ལྟེ་མི་རྒྱ་བཞག་རིམ་དང་འཁྲིལ་སྐྱོན་ནང་གཞིབ་དགོ། འདི་ཡང་ ༥_X ༥_X ༥ (རིང་ཚད་X རྒྱ་ཚད་X ཐོ་ཚད) དེ་ལས་དཔེ་ཚད་གྱི་སྐྱོན་ནང་ལས་འཕུ་བའི་སྐབས་གཞུང་པ་སྤྱི་འཕུ་དགོ།
- དཔེ་ཚད་འདི་གཞུང་པ་སྤྱི་འཕུ་ཞིན་མ་ལས་བརྟག་ཞིབ་འབད་དགོ།
- བསྐྱམ་སྐྱོན་དཔེ་ཚད་བར་རིམ་གཉིས་དེ་ཅིག་དང་། བསྐྱམ་སྐྱོན་གཙོ་བོ་ཅུང་ཤོས་ ༥ དེ་ཅིག་བརྟག་ཞིབ་འབད་དགོ།

