# Compliance With Regulatory Requirements And Their Implementation Regarding The Storing And Distribution Of Pharmaceuticals In India, Us And Eu.

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## Abstract

Pharmaceutical distribution, storage, and warehousing are vital to an integrated supply chain management system. Good Distribution Practices (GDP) and Good Storage Practices (GSP) must be observed in all elements of pharmaceutical goods. Pharmacovigilance companies, agencies, and institutions play a significant role. Proper storage preserves medications' efficacy and physical integrity. The storage and distribution of materials and commodities should comply with labelling and avoid degradation. The purpose is to ensure the quality, safety, and identification of pharmaceutical goods throughout the supply management cycle. Best practices in storage and transportation, refrigeration and temperature control, and maintaining optimal conditions at warehouses and pharmaceutical storage facilities. The regulatory status of storage and distribution practices in India, the United States and the European Union have been analysed. Despite differences in regulations, the essential concepts remain the same. Storage and transportation must be updated consistently to guarantee the proper distribution of products.



**Keywords:** Good Distribution Practices, Good Storage Practices, Storage, Labeling, Warehousing, Transportation

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## INTRODUCTION

The successful operation of an integrated supply chain management system is inextricably linked to the distribution of pharmaceutical products. The principles of Good Distribution Practices (GDP) and Good Storage Practices (GSP) must be adhered to in every facet of the activities involved in the distribution and storage of pharmaceutical products. The keywords GSP and GDP are sometimes used interchangeably because they are both components of the pharmaceutical product management chain and, as a result, are closely connected. Consequently, the terms GSP and GDP are frequently used interchangeably.[1].

## Good Distribution Practice (GDP)

Good Distribution Practice (GDP) outlines how to distribute human medicines. The Good Distribution Practice (GDP) is a quality assurance system that specifies protocols for the acquisition, custody, and shipment of therapeutic pharmaceuticals for human use.[2].

## Principles and Applications

The concepts outlined in the GDP should be implemented into national and international legislation and regulations to safeguard the uninterrupted flow of goods from the manufacturer to the dispensing organization. To transfer drugs up and down the distribution chain, there must be a collaboration between regulatory authorities, law enforcement agencies, customs agencies, pharmaceuticalmanufacturers, pharmaceutical dealers, and pharmacies.[3], [4].

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## Good Storage Practices (GSP)

Good Storage Practices (GSP) is a term from the field of quality assurance that describes the actions taken to keep a pharmaceutical product in pristine condition while it is being stored. Good Storage Practices (GSP) aims to keep medications in optimal condition and prevent any unwanted changes to their potency or purity.[5].

## Principles and Applications

The storage contains starting supplies, packaging materials, semi-completed or in-process components, and finished items ready to transport. Sanitation, temperature, humidity, and the light and ventilation system are factors that must be considered while securing goods (air supply). Segregation When items are properly stored, they are safeguarded from deterioration, contamination, and damage. For the displays, recorders, and failure alerts to work effectively, there must be temperature- and humidity-controlled spaces. When executing stock control activities on materials, it is crucial to prioritize those with the shortest lifespans. Materials and products should be routinely inspected to verify that they are in good condition have appropriate seals and labels, and that there is no major damage or the stuff contained within containers.[5].

## Basic Prerequisites for the GDP and the GSP

- The roles, duties, and interdependencies of each employee must be specified. Detailing one's obligations and commitments is crucial. Economic, political, social, or other issues or conflicts of interest shouldn't affect generic medicines or generic pharmaceutical businesses' services.
- Skilled and competent workers must meet GDP and GSP benchmarks. All employees, regardless of rank, should be trained on product security, counterfeit identification, and prevention.
- A quality system must have the right organizational structure, method, processes, and resources to ensure a product or service and its documentation meet quality requirements.
- Unauthorized individuals must be kept out of storage areas. All employees must follow corporate regulations and procedures for a safe, productive workplace. Always maintain your workplace clean and pest-free.
- Preparing vehicles and equipment for transporting, storing, or handling pharmaceutical commodities minimizes product contamination, stability, and package integrity.
- Pharmaceutical wholesalers must keep detailed records of everything they receive. Your records should include the following:
- Number of medications delivered or received, supplier's name and location, date
- Storage conditions should be indicated on both the primary container and the mechanism used to close the container of the medicinal product. Depending on the situation, this information can be printed on the nearest suitable container, such as an ampule, or the container-closure system (a blister package) (e.g., carton). The outermost container must have storage conditions and environmental warnings.
- These acts can compromise the pharmaceutical supply chain's safety and security and must be continuously monitored.
- Customer complaints should have a structured process. All complaints and other information regarding substandard or illegal pharmaceuticals must be thoroughly investigated.
- When an FDA-approved pharmaceutical product is suspected of being faulty or counterfeit, a documented process and qualified person in control of product recalls are necessary. If a recall is needed owing to a difficult-to-identify counterfeit product, the original manufacturer and health authorities should be contacted.
- GDP and GSP performance and compliance should be inspected to discover and remedy problems. Each identification's repercussions should be noted. The final report should include all inspection results and suggestions. The project must be monitored effectively.[6], [7].

## Good Storage and Distribution Practices (GSDP)

Space is allocated for raw materials, notably pharmaceutical packaging to maximise output. This place is commonly referred to as a "warehouse" or "warehouse facility."

### *Objectives*

To ensure the secure, timely, and high-quality delivery of medications and medical supplies

from manufacturers to patients. In this procedure, three stages are involved:


**Figure 1.** Stages Involved

## Prerequisites

Products are safeguarded systematically. The minimum wall spacing is 50cm with adequate airflow. Products on shelves should be categorized. For each product, a stroke sheet should be arranged. Unopened cartons maintain product safety. Flammables should be stored separately. The place has been disinfected and medication & equipment handled carefully. Workers and inventory must be safe. Temperature, humidity, and air quality are key features of the GDSP**.** Discard improper items and educate patients about medication administration.[8].

## Equipment Storage Spaces

Initial inspections, cleanliness checks, and weight checks happen at the reception. Sample placement facilities should avoid cross-contamination. Chemical storage rooms and rooms for other specialized goods like AC and freezer items. Rejected items might be saved or discarded. Appropriate equipment can avoid cross-contamination in the dispensing area**.**


**Figure 2.** Good Warehousing Practices in Regulated Countries [9]

## India

## Drugs and Cosmetics Act of 1940, and Rules of 1945, Schedule M

## Regulatory measures in India- GDP

Medicines and cosmetics are sold, bought, distributed, and imported in India by the 1940 and 1945 statutes. Schedule M of the Act specifies excellent manufacturing procedures for pharmaceutical product deposits. Machinery and equipment must be stored in spaces created and suited for start-and-processing conditions, intermediate materials, final goods, and bulk, and quarantined, discharged, denied, despatched, or revoked items. Clean, dry, and at the right temperature are required. Submitted, monitored, and registered storage conditions (temperature, humidity) are required. Pest and vermin control processes need storage area housekeeping, rodent management, and reporting. Receiving and shipping bays must store supplies and items on adequate shelves, containers, and platforms. In Schedule M, the producer is responsible for protecting and stabilizing medications throughout shipping.[10].

## Storage of Medications in a Warehouse

- The storage area must be well-protected, physically robust, and broad enough for safe storage and handling. Storage spaces need enough illumination for precise and secure functioning.
- Quarantined biological products, released, discharged, shipped, or revoked commodities, and counterfeit items must be segregated.
- Clean, dry, and temperature-controlled storage facilities and buildings must be developed or changed to ensure optimum storage conditions.
- Since they include biological materials, the receiving and dispatch bays must be safeguarded. Incoming organic containers must be cleaned before being stored, if feasible.
- Separate broken or damaged commodities from unusable supplies.[11].

## Label Storage Condition

- Process medications and materials based on stability analysis labelling. All medications must be processed per label.
- Specific storage conditions must be listed on the product's label.
- Stability tests verify the consistency of a drug or product, allowing for shelf-life predictions, correct storage, and labelling.

## Stored Tablets/Capsules

### *Storage labels:*

- Store product cold and dry and keep it free from light and moisture.
- Keep the product away from light and moisture while storing it cool and dry.
- Store in a dry, cold environment.
- Keep in a cool, dry, dark location.
- Capsules should be stored in a cool, dry location.

### *Storage of Emulsions*

- In an airtight container, store emulsion away from light, heat, and freezing. Emulsions must be kept cold.

### *Storage of Suspensions*

- Suspension should be kept cool and dry, not in the refrigerator.
- Freezing should be halted at a very low temperature to prevent the agglomeration of suspended particles.

### *Storage with labels*

- Put in a cool, dry place out of the path of both heat and light.
- Keep the flask cold, dry, and at 30 degrees Celsius.
- Keep at 25 degrees Celsius and out of the humidity.

### *Storage of Ointments*

- Volatile ingredients should be kept in a firmly sealed jar.
- The ointment should be kept cold and out of direct sunlight.

### *Storage of Pastes*

- Store in a cold, well-sealed container to reduce humidity evaporation.

### *Storage of syrups*

- The syrup should be kept in a corked, cold, dark container. The syrup shouldn't exceed 25°C.
- Keep cool and dry, out of direct sunlight.

### *Storage of Oral Drops*

- Store in a cold, dry, light-restricted place.
- Store out of direct sunlight at temperatures below 30°C.

### *Storage of Injections*

- Keep in a cool, dark place where the temperature never gets above 25 degrees.[11].

## UNITED STATES OF AMERICA (USA)

### United States – Food and Drug Administration

It describes how to preserve a preparation's integrity, including its look, before it reaches the client. Most things indicate storage conditions.

### Warehouses

Tracking temperature differences in a warehouse over time helps generate a meaningful temperature profile that covers changes and conditions in different locations. These findings contain information on stocking and storing products.

### Configuration of Temperature Profiles

Thermometers or other temperature-recording devices can be used to produce temperature profiles. Maximum and lowest temperatures should be recorded in 3 consecutive 24-hour periods. In temperature profiling, consider room size, space heater placement, sun-facing walls, low ceilings or towers, and warehouse location.



### Labelling, storage, and stability

Pharmaceutical firms evaluate the most effective dose, side effects, delivery mode (oral, injectable, transdermal, etc.), overdosing effects, safety, and efficacy while designing drugs. Understanding storage impacts on preparation take time. These tests indicate if the drug is stable at room temperature, needs refrigeration, or must be frozen, and any storage deterioration.

❖ If no storage condition is chosen, a prescription drug may be stored at "controlled" room temperature to assure identity, potency, efficiency, and purity.

❖ Properly storing prescription pharmaceuticals requires manual, electromechanical, or electronic humidity and temperature monitoring tools and/or documentation.

❖ All stored medications must be documented.

### Buildings and Facilities Storage

The drug's storage temperature must be

within label restrictions. Drug product structures should be large enough for their intended purpose. This should avoid pollution-causing congestion. Buildings and facilities should be constructed to monitor environmental conditions and use easily-cleaned materials. Report sanitation and pest control frequency, materials, and processes. Software must be educated to manage storage conditions. Installations should have a fire, water, and explosive tests.[12].

## USA Guidelines –GDP

The USP includes labelling indications in its standards. Labelling needs stable data. In the EU, accelerated stability figures (e.g. 40%/75% RH) require a labelling declaration. Storage conditions should be considered when analysing transient temperature spikes exceeding the authorised ambient temperature range. "Effective Storage and Practice of Shipment" outlines pharmaceutical storage, distribution, and shipment. Transport requirements include: Travelers should avoid excessive heat or cold. Pre-calibrate temperature-calculating equipment. Items needing controlled room temperature storage must be transported in vehicles having an MKT no higher than 25°C. Vehicle design and extremes should reflect climate. Certification should contain 24-hour temperature charts for hot summer, normal, and cold winter days. Temperature cycling should be studied for commodities requiring particular storage conditions. Temperature cycling tests examine low- and high-temperature stability. Cold-chain commodities require temperature mapping.[12], [13].

**Table 1.** Requirements for safe warehousing and labelling in the USA

| Statements Regarding Labels | Conditions for Storing |
|---|---|
| Freezer | -25°C to -10°C |
| Refrigerator | • Usually, 2 to 8°C.<br>• If the MKT is below 8°C, 0-15°C excursions are permitted. Manufacturers may tolerate short-term rises of up to 25°C for 24 hours.<br>• Transient spikes over 24 hours need stability data. |
| Cool Place | 8 to 15 °C |
| Controlled room temperature | • Typically, between 20 and 25 degrees Celsius.<br>• If the MKT is less than 25°C, 15-30°C excursions are permitted. If the manufacturer allows it, short-term spikes up to 40°C for 24 hours are allowed.<br>• Stability data must support short-term surges over 40°C. |

## EUROPEAN UNION (EU)- EUROPEAN MEDICINES AGENCY (EMA)

## Distribution best practices (GDP)

Maintaining medicine quality throughout the distribution process is possible thanks to a set of quality management procedures known as good distribution practices (GDPs).

## Good Storage Techniques (new)

The implementation of reliable storage procedures is an essential component of quality control, as it serves to guarantee the correct maintenance of the medicinal products' original levels of potency and efficacy during the storage process.

## Premises, Warehousing and Storage

During transport, pharmaceuticals must be handled following "good storage practises" (GSP). The WHO Guide to Good Storage Practices (WHO Committee of Experts on Pharmaceutical Preparations. 37th report) provides more details on the standards for preserving pharmaceutical products in general (WHO Technical Report Series, No. 908, Annex 9).

## Storage areas

❖ Bulk and finished products are quarantined goods, and released, rejected, returned, or recalled goods require optimal storage conditions. Keep them clean, dry, and warm. Special storage conditions should be noted on labels (e.g., temperature, relative humidity). Cleaning and testing necessitate space between medications.

❖ Maintain secure and vermin-free storage places. A defined health programme should include cleaning frequency and techniques for premises and storage facilities. Implement a documented pesticide management strategy. It must not contaminate pesticides or medications. Appropriate waste-cleaning measures should be in place to avoid contamination.

❖ Receiving and shipping facilities should be weatherproofed. Until they're handled, incoming pharmaceutical containers should be cleanable.

❖ Pollution and cross-contamination should be avoided when sampling in storage. Developing sample area cleaning techniques.

❖ Refused, expired, recalled, or returned products must be physically or electronically separated. The commodities and places must

be specified.

❖ Radiation, drugs, and other poisonous, sensitive, or dangerous medical products, as well as commodities that constitute a criminal, fire, or explosion risk, should be stored separately (e.g., fuel flukes, solids, and gas pressurization).

❖ The Good Manufacturing Practices (GMP) outlined below should be adhered to when handling pharmaceuticals.

❖ When handling and storing prescriptions, avoid contamination, mixing, and cross-contamination.

❖ Forbidden medications must be discovered and isolated before their fate is decided.

❖ Retailer adherence to national narcotics laws and regulations, as well as international narcotics treaties, is paramount.

❖ Those items that are broken or damaged should be separated from the rest of the stock and insulated.

❖ Storage facilities should be well-lit to ensure safe operations.

## Europe- European Commission- GDP

The EU Standards on good distribution practice were established by the European Commission in 1994. (GDP). In March 2013, amended standards for storing or allocating medicines in the EU were issued, taking into account Directive 2011/62/EU. It replaces GDP guidelines in March 2013. Pharmaceutical wholesale distribution is crucial to integrated supply chain management. The distribution network for medicines is complex and has numerous actors. These rules outline the tools wholesalers should use to do business and prevent counterfeit medications out of the lawful supply chain. If these guidelines are followed, the safety and dignity of medications will be ensured. Directive 2001/83/EC defines wholesale distribution as "acquiring, keeping, providing, or exporting non-medicinal commodities to the public." Importers, wholesalers, pharmaceutics, and anyone authorised to distribute medicines to the public will be engaged. Wholesalers need a licence. Distributors must meet GDP requirements per Directive 2001/83/EC Article 80(g). A manufacturing licence covers marketing licenced pharmaceuticals. Producers who engage in distribution will boost GDP. Wholesale distribution is a company's presence or service in free zones and free storage locations[14].

## Good Storage Techniques (new)

## Warehousing Sites

## Site Layout

### *Natural disasters*

Recognizing natural dangers like flooding, landslides, and earthquakes, as well as extreme weather occurrences like hurricanes and tornadoes, is crucial when deciding where to locate storage facilities. To protect pharmacy personnel and drugs.

### *Access to the website*

Storage facilities should include ample parking for large cars, especially emergency vehicles. The rationale behind this is to guarantee that the facility will run efficiently.

### *Site safety is important*

Guard the perimeter of the property and the storage facilities from any intruders. Arson, robbery, or other criminal activities must be averted. The safety precautions should be suited to the location and value of the commodities.



### *Condition of the site*

Remove dust, filth, garbage, and debris. Keep rodents off the job site. Regularly collected waste should be discarded in closed containers. Prevent dust, grime, and vermin in storage structures.

## Conditions of storage

❖ Stability test results used to create labels must be compatible with how medicines are typically stored.

❖ Separate storage is required for medicines and, if feasible, health commodities, as they are sensitive to light, heat, and moisture and must be protected from the elements. Products that require precise storage conditions require extra attention.

❖ Washing pharmaceutical product cans before putting them away in storage is recommended.

❖ Good stock security and safekeeping are the responsibilities of the warehouse.

❖ Preventing spills, breakdowns, corruption, and mix-ups requires proper medication handling and storage.

❖ Physical or technological separation of expiring and saleable medicines must be

provided.

❖ Regular stock inventories are required by law. Examine and record stock mishandling.

## Labeling and Contents of Storage Receptacles

❖ Storage and transportation in containers of all pharmaceutical items that do not impair the quality and protect against biological influences, such as microbial infection. Container labels must be clear, durable, indelible, and transparent. Labelling information should follow any national container labelling laws.

❖ Distributor etiquette should be written in at least one language. Shipping containers don't need a detailed material summary to avoid theft, but they may contain processing and storage area specifics and protections to guarantee the product is always processed appropriately.

❖ If a pharmaceutical product is to be transported beyond the manufacturing system's regulations, the producer's name, address, special transport circumstances, and any regulatory provisions such protective symbols must be included on the label.

❖ Marking containers require worldwide and/or national abbreviations, names, or codes.

❖ Caution is suggested when using dry ice in cans. The medication product shouldn't come into touch with dry ice for safety and effectiveness reasons.

❖ Broken containers should have written management instructions. Toxic and dangerous items get special scrutiny.[15], [16].

**Table 2.** Conditions of Storage, Labeling, and Testing in Europe

| Testing conditions where the product is stable | Required labelling statement | Ph. Eur |
|---|---|---|
| 20°C/60% RH (long term)<br>40°C/75% RH (accelerated)<br>Or 30°C/65% RH (long term)<br>40°C/75% RH (accelerated) | The medicinal product does not require any special storage conditions | |
| -250°C /60% RH (long term) 30°C/60 or 65% RH (intermediate) or 30°C/65% RH (long term) | Do not store above 30°C or store below 30°C | |
| 25°C/60% RH (long term) | Do not store above 25°C or store below 25°C | Room Temperature:15-25°C |
| 5°C ± 3°C (long term) | Store in a refrigerator or store and transport in a refrigerator | In a refrigerator: 2-8°C |
| < -15°C | Store in a freezer or store and transport frozen | In a deep freeze: < -15°C |

**Table 3.** Comparison between GSP and GDP in India, the United States, and the European Union

| Sl.No. | Parameters | INDIA | USA | EUROPE |
|---|---|---|---|---|
| 1. | Regulation | Rule 64 and 65 of the D&C Act 1945 describe medication sales and distribution. | Other Regulations-WHO Annex 5 to USP 1083 (Supply Chain Integrity) | 5th November 2013 GDP (2013/C343/01) |
| 2. | General Principle | • GDP covers forward and reverse movement of drugs.<br>• Assertion of consensus between all distribution intermediaries | • Reduces illicit drug sales and promotion | • The wholesaler must keep up a good QMS system.<br>• A responsible person is chosen to follow the GDP and WDA. |
| 3. | Regulation of the distribution of pharmaceutical products | • Activities are regulated by the government.<br>• Pharmaceuticals must be imported and exported with permission.<br>• If there is subcontracting, the standards must be the same as the original distributor. | ND | ND |
| 4. | Organization & Management | • Responsible person selected for chainwide quality system<br>• Responsible technical person corrects deviations.<br>• Safety practices are monitored | • Product quality is examined for adulteration, misbranding, and distribution pattern during importation. Must be sold lawfully. | • Mandatory customer and supplier qualification.<br>• Wholesale distribution is done by field distributors with a market authority. |
| 5. | Personnel | • Standard Operating Procedures train and qualify personnel for GDP tasks.<br>• Participants must wear clothing and take safety precautions.<br>• Maintaining personal hygiene. | ND | ND |
| 6. | Quality System | • Implementation of the appropriate CAPA<br>• Inspection, auditing, and compliance certificate by external bodies<br>• Deviations are noted and investigated<br>• Maintain traceability documents. | • Supply chain failure is reduced by risk assessment and management.<br>• Effective supplier collaboration and distribution and risk-reduction cooperation are crucial. | • Implement CAPA, validation, and change control<br>• Required deviation documentation |
| 7. | Premises | • Good Storage Practices are strictly followed when storing items.<br>• Storage facilities are secure with enough illumination.<br>• People are restricted from entering the storage facility.<br>• Maintain a documented pest control and cleaning programme.<br>• Cross-contamination is avoided by sampling in a clean location<br>• Distribution process uses First Expiry First Out.<br>• Extra safety is established for radioactive items, drugs, etc. | ND | • Equipment must be stored properly on-site<br>• Validating important processes<br>• The distribution method always follows a "first expire, first out" system |
| 8. | Temperature | ND | Temperature mapping protection measures should be in place to avoid fraud or manipulation of items in storage, eliminate unsold or underused inventory, and maintain records | Temperature mapping protection measures should be in place to avoid fraud or manipulation of items in storage, eliminate unsold or underused inventory, and maintain records |



| | | | | |
|---|---|---|---|---|
| **9.** | Recall | • System setup and monitoring<br>• Returning fake medicine treatments | Recall procedures must include all relevant documentation | • System is installed and checked routinely<br>• Instructions for returning potentially tainted medications |
| **10.** | Returned product or falsified product | ND | ND | • Suspected counterfeit pharmaceuticals are isolated by distributors and reported to MAH<br>• Separately described, treatment medications should have a documented procedure |
| **12.** | Equipment | ND | ND | • Computerized system brings detailed equipment use<br>• Only authorised employees enter information |
| **13.** | Pricing of Product | ND | ND | • Checks are needed to choose the right goods<br>• The chosen item should have a long shelf life |
| *ND- not defined | | | | |

## CONCLUSION

Based on publicly accessible documentation, this study indicates the current regulatory landscape for the storage and distribution of medications in India and a few other nations. The current regulatory status of storage and distribution procedures in India, the United States, and the European Union have been compared. While there is a larger degree of variation in the selected nations' legislation, the concepts upon which they are based remain consistent. Considering India's varied climates, the country needs laws that are both rigorous and practical to improve the storage and delivery of medicines. To tighten up the laws and guarantee the quality and safety of medicines in India, several proposals and suggestions have been made for enshrining them in Indian law. The procedure for carrying it out will be explained in full. The study accomplished all of its targets and objectives.

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Since this work does not involve any animal studies it does not require Ethical approval

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