# PHB





Dr. Arvind Kumar Gupta (M.Pharm, PDCR, PGDMM & Ph.D) GATE 2003 Qualified with 97.2 percentile Dr. S. N. Dev College of Pharmacy Shamli (U.P.)

OFFICE: BUILDING No. 3/314, OFFICE-1, GAUSHALA ROAD, SHAMLI DISTRICT SHAMLI (U.P.) – 247776 Mobile: +91-9719638415 Email: arvindrkgit@gmail.com, www.phbeducation.com

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**Supply Chain** refers to the entire network of entities, directly or indirectly interlinked and interdependent, involved in serving the same consumer or customer. It includes all stages of production and delivery of a product or service, from the initial supplier of raw materials to the end customer. The supply chain encompasses a wide range of activities including sourcing, procurement, production, logistics, and distribution. Effective supply chain management (SCM) aims to streamline these processes to enhance efficiency, reduce costs, and ensure timely delivery of products and services.

#### **Components of Supply Chain**

- **1. Sourcing and Procurement**: Identifying and acquiring the raw materials and components needed for production.
- **2. Manufacturing**: Converting raw materials into finished goods through production processes.
- **3. Warehousing**: Storing raw materials, work-in-progress items, and finished goods until they are needed.
- **4. Distribution**: Delivering finished products to customers through a network of distributors, retailers, or directly.
- **5.** Logistics: Planning, implementing, and controlling the efficient movement and storage of goods and services.
- **6. Customer Service**: Ensuring the final delivery meets customer expectations and managing returns and feedback.

#### **Inventory Control**

Inventory Control, also known as inventory management, is the process of overseeing and managing the ordering, storage, and use of a company's inventory. This includes the management of raw materials, components, and finished products, as well as warehousing and processing such items. The main goals of inventory control are to ensure that the right amount of inventory is available at the right time to meet customer demand while minimizing the costs associated with holding inventory. Effective inventory control involves tracking inventory levels, forecasting future demand, optimizing order quantities, and implementing systems to prevent overstocking or stockouts.

#### **Components of Inventory Control**

- **1. Inventory Tracking**: Using systems (manual or automated) to monitor inventory levels in real-time.
- **2. Demand Forecasting**: Predicting future inventory needs based on historical data, trends, and market analysis.

- **3. Order Management**: Determining optimal order quantities and timing to maintain adequate stock levels without overstocking.
- **4. Stock Replenishment**: Ensuring inventory is replenished as needed to meet demand.
- **5. Safety Stock**: Keeping a buffer of inventory to prevent stockouts in case of unexpected demand or supply chain disruptions.
- **6. Inventory Audits**: Regularly counting and verifying inventory to ensure accuracy and detect discrepancies.

# 3.1 Preparation of Drug lists – High Risk Drugs

High-risk drugs are medications that have a heightened risk of causing significant harm to patients if used incorrectly. Due to their potential for serious adverse effects, these drugs require special attention, stringent handling procedures, and precise administration. Proper management and monitoring are critical to ensuring patient safety when using these medications.

#### **Characteristics of High-Risk Drugs**

- 1. **Narrow Therapeutic Index (NTI)**: Small differences in dose or blood concentration can lead to therapeutic failure or severe adverse effects.
- 2. **Potential for Severe Adverse Effects**: These drugs can cause serious harm, including organ damage, severe allergic reactions, or death, if not used properly.
- 3. **Complex Dosing Regimens**: These medications may require precise dosing, specific timing, and careful titration to avoid toxicity or subtherapeutic effects.
- 4. **High Potential for Drug Interactions**: These drugs often interact with other medications, which can exacerbate their effects or lead to additional adverse reactions.

# **Examples of High-Risk Drugs**

- 1. Anticoagulants: Such as warfarin, heparin, and direct oral anticoagulants (DOACs).
  - **Risks**: Bleeding complications, including hemorrhage.
- **2. Insulins**: Used to manage blood glucose levels in diabetes.
  - **Risks**: Hypoglycemia, which can lead to seizures, coma, or death.
- 3. Opioids: Such as morphine, oxycodone, and fentanyl.
  - **Risks**: Respiratory depression, addiction, overdose, and death.
- **4. Chemotherapeutic Agents**: Used in cancer treatment, such as methotrexate, vincristine, and doxorubicin.
  - **Risks**: Severe toxicity, including bone marrow suppression, organ damage, and secondary malignancies.
- 5. Immunosuppressants: Such as cyclosporine, tacrolimus, and mycophenolate.
  - **Risks**: Increased risk of infections, organ toxicity, and malignancies.

- 6. Antiarrhythmics: Such as amiodarone and digoxin.
  - **Risks**: Cardiotoxicity, arrhythmias, and other serious cardiac events.
- 7. Sedatives and Anesthetics: Including propofol and midazolam.
  - **Risks**: Respiratory depression, sedation, and hypotension.
- 8. Neuromuscular Blocking Agents: Such as succinylcholine and vecuronium.
  - **Risks**: Respiratory paralysis if not administered and monitored correctly.
- 9. Oral Hypoglycemics: Such as sulfonylureas (e.g., glipizide) and meglitinides.
  - **Risks**: Hypoglycemia, which can be severe and prolonged.
- 10. Parenteral Nutrition: Intravenous nutrition solutions.
  - **Risks**: Infection, metabolic imbalances, and nutrient deficiencies or toxicities.

# Strategies for Managing High-Risk Drugs

- **1. Standardized Protocols and Guidelines**: Develop and implement standardized protocols for prescribing, dispensing, and administering high-risk drugs.
- **2. Education and Training**: Provide ongoing education and training for healthcare professionals on the safe use of high-risk medications.
- **3. Double-Check Systems**: Implement double-check procedures, especially during preparation and administration, to reduce errors.
- **4. Clear Labeling and Storage**: Use clear and distinctive labeling, and store high-risk medications separately to avoid confusion and mix-ups.
- **5. Patient Education**: Educate patients about their medications, including potential risks, proper use, and what to do in case of adverse effects.
- **6. Monitoring and Follow-Up**: Regularly monitor patients for signs of toxicity or adverse effects and adjust therapy as needed.
- **7. Use of Technology**: Utilize electronic prescribing, barcoding, and automated dispensing systems to enhance accuracy and reduce errors.
- **8. Reporting and Learning from Errors**: Encourage the reporting of medication errors and near misses, and use this information to improve safety practices.

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# Preparation of Drug lists – Emergency drugs

Emergency drugs are medications that are essential for the immediate treatment of lifethreatening conditions and medical emergencies. These drugs are typically fast-acting and are used to stabilize patients, manage acute symptoms, and prevent further deterioration while definitive treatment is administered.

# **Common Emergency Drugs and Their Uses**

- 1. Epinephrine (Adrenaline)
  - Uses: Anaphylaxis, severe asthma attacks, cardiac arrest.

• Action: Acts as a vasoconstrictor, bronchodilator, and increases heart rate and cardiac output.

#### 2. Atropine

- Uses: Bradycardia, organophosphate poisoning, pre-anesthetic medication.
- Action: Increases heart rate by blocking the vagus nerve, reduces secretions.

# 3. Nitroglycerin

- **Uses**: Chest pain (angina), heart failure, hypertensive emergencies.
- Action: Vasodilator that reduces cardiac workload and improves blood flow to the heart muscle.

#### 4. Amiodarone

- **Uses**: Ventricular arrhythmias, atrial fibrillation.
- Action: Antiarrhythmic that stabilizes the heart's electrical activity.

#### 5. Adenosine

- **Uses**: Supraventricular tachycardia (SVT).
- Action: Slows conduction through the AV node, restoring normal heart rhythm.

#### 6. Dopamine

- **Uses**: Hypotension, shock, heart failure.
- Action: Increases cardiac output and improves renal blood flow by stimulating dopaminergic and adrenergic receptors.

#### 7. Lidocaine

- **Uses**: Ventricular arrhythmias, local anesthesia.
- Action: Antiarrhythmic that stabilizes cardiac cell membranes, reducing excitability.

#### 8. Naloxone (Narcan)

- **Uses**: Opioid overdose.
- Action: Opioid antagonist that reverses the effects of opioids.

# 9. Glucose (Dextrose)

- **Uses**: Hypoglycemia.
- Action: Rapidly increases blood glucose levels.

#### 10. Diazepam (Valium)

- Uses: Seizures, anxiety, muscle spasms.
- Action: Benzodiazepine that enhances the effect of the neurotransmitter GABA.

#### 11. Magnesium Sulfate

- **Uses**: Torsades de pointes, eclampsia, severe asthma.
- Action: Acts as a smooth muscle relaxant and stabilizes cardiac rhythm.

#### 12. Furosemide (Lasix)

- **Uses**: Pulmonary edema, heart failure, hypertension.
- Action: Diuretic that reduces fluid overload and decreases blood pressure.

# 13. Calcium Gluconate

- **Uses**: Hyperkalemia, hypocalcemia, calcium channel blocker overdose.
- Action: Provides calcium necessary for cardiac and neuromuscular function.

# 14. Sodium Bicarbonate

- **Uses**: Metabolic acidosis, hyperkalemia, certain drug overdoses (e.g., tricyclic antidepressants).
- Action: Neutralizes acid in the blood, helping to restore normal pH levels.

# 15. Hydrocortisone

- **Uses**: Severe allergic reactions, asthma, adrenal insufficiency.
- Action: Corticosteroid that reduces inflammation and suppresses the immune response.

# Administration and Safety Considerations

# 1. Dosage and Administration:

- Ensure accurate dosing based on patient age, weight, and condition.
- Administer drugs promptly in emergency situations, following established protocols.

# 2. Storage and Accessibility:

- Store emergency drugs in a designated, easily accessible location, such as crash carts or emergency drug kits.
- Regularly check expiration dates and replace expired medications.

# 3. Education and Training:

- Train healthcare providers in the proper use, indications, and administration of emergency drugs.
- Conduct regular drills and simulations to ensure readiness.

# 4. Monitoring and Follow-Up:

- Monitor patients closely for therapeutic effects and potential adverse reactions.
- Document all administered medications and patient responses accurately.

# 5. Interprofessional Collaboration:

- Work closely with the entire healthcare team to ensure coordinated and effective emergency care.
- Communicate clearly during emergencies to ensure timely and appropriate treatment.

Schedule H1 drugs are a specific category of prescription medications regulated under the Drugs and Cosmetics Rules in India. These drugs are subject to strict regulations due to their potential for misuse and the need for careful medical supervision. The schedule was introduced to ensure proper monitoring and to prevent over-the-counter sales without appropriate prescriptions. Here's a detailed overview of Schedule H1 drugs:

# Features of Schedule H1 Drugs

# 1. Prescription Requirement:

- These drugs can only be sold on the prescription of a registered medical practitioner.
- The prescription must be retained in the pharmacy for a specific period (usually two years) for inspection purposes.

# 2. Labeling Requirements:

- The packaging must display a specific symbol: "Rx" in red on the top left corner of the label.
- A prominent warning stating "Schedule H1 drug Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

# 3. Record Keeping:

- Pharmacists must maintain a separate register recording the details of the patient, prescribing doctor, and the dispensed quantity of the drug.
- These records must be readily available for inspection by regulatory authorities.

# 4. Drugs Included in Schedule H1:

- Schedule H1 includes antibiotics, habit-forming drugs, and certain other medications requiring stringent controls. Some commonly known drugs in this category include:
  - Third and fourth-generation antibiotics like cephalosporins and carbapenems.
  - Anti-TB drugs like Rifampicin and Isoniazid.
  - Specific habit-forming drugs like Tramadol and certain anti-anxiety medications.

# **Examples of Schedule H1 Drugs**

- 1. Antibiotics:
  - **Cefixime**: A cephalosporin antibiotic used to treat bacterial infections.
  - **Meropenem**: A broad-spectrum antibiotic used for severe infections.
- 2. Anti-TB Drugs:
  - **Rifampicin**: Used in the treatment of tuberculosis.
  - **Isoniazid**: Another critical medication for tuberculosis management.

# 3. Analgesics and Anti-Anxiety Medications:

- **Tramadol**: A pain reliever used for moderate to severe pain.
- Alprazolam: Used for the management of anxiety disorders.

# **Regulatory Intent**

The inclusion of drugs in Schedule H1 is primarily to:

- Prevent self-medication and ensure that the drugs are used under medical supervision.
- Reduce the risk of antibiotic resistance by controlling the use of antibiotics.
- Prevent the misuse and abuse of habit-forming drugs.

# Pharmacists' Responsibilities

Pharmacists play a critical role in the enforcement of Schedule H1 regulations:

- They must ensure that drugs are dispensed only against valid prescriptions.
- Accurate record-keeping and compliance with labeling requirements are mandatory.
- Pharmacists should counsel patients on the correct use of these medications.

# Impact on Healthcare

The introduction of Schedule H1 aims to improve patient safety and drug efficacy. It helps:

- Ensure appropriate use of potent medications.
- Protect public health by reducing the risk of drug resistance and medication abuse.
- Promote rational prescribing practices among healthcare professionals.

Understanding and adhering to the regulations surrounding Schedule H1 drugs is essential

for healthcare providers, pharmacists, and patients to ensure safe and effective medication use.

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# **Preparation of Drug lists – NDPS drugs**

NDPS (Narcotic Drugs and Psychotropic Substances) drugs refer to substances regulated under the Narcotic Drugs and Psychotropic Substances Act, 1985, in India. This legislation aims to control and regulate the production, distribution, and consumption of narcotic drugs and psychotropic substances to prevent misuse and abuse. Here's an overview of NDPS drugs and their regulation:

# Key Features of NDPS Act

# 1. Regulation and Control:

- The Act regulates the manufacture, possession, sale, purchase, transportation, warehousing, use, consumption, import, export, and transshipment of narcotic drugs and psychotropic substances.
- Only authorized entities and individuals can engage in these activities, subject to stringent conditions and licenses.

# 2. Prohibition and Punishment:

- Unauthorized activities related to NDPS drugs are prohibited.
- The Act prescribes severe penalties, including fines and imprisonment, for violations. Penalties vary depending on the nature and quantity of the substance involved.

# 3. Preventive Measures:

- The Act includes provisions for the seizure and forfeiture of property related to drug offenses.
- Special provisions exist for the treatment and rehabilitation of drug addicts.

# **Examples of NDPS Drugs**

- 1. Narcotic Drugs:
  - **Opium and its derivatives**: Such as morphine, codeine, and heroin.
  - **Cannabis**: Including marijuana, hashish, and cannabis resin.
  - Coca and its derivatives: Such as cocaine and crack.

# 2. Psychotropic Substances:

- **Amphetamines**: Used as stimulants, including methamphetamine.
- **Benzodiazepines**: Such as diazepam, lorazepam, and alprazolam.
- **MDMA**: Commonly known as ecstasy.
- **LSD**: A hallucinogenic substance.

# **Regulatory Bodies and Enforcement**

- 1. Narcotics Control Bureau (NCB):
  - The NCB is the central authority responsible for enforcing the provisions of the NDPS Act.
  - It coordinates with state agencies and international bodies to control drug trafficking and abuse.

# 2. State Police and Excise Departments:

- These agencies assist in the enforcement of the NDPS Act at the state level.
- They conduct raids, seizures, and investigations related to drug offenses.

# Medical and Scientific Use

- The NDPS Act permits the medical and scientific use of narcotic drugs and psychotropic substances under controlled conditions.
- Specific rules govern the prescription and dispensation of these drugs to ensure they are used appropriately for therapeutic purposes.

# Amendments and International Compliance

- The NDPS Act has been amended several times to strengthen regulations, enhance penalties, and improve compliance with international drug control treaties.
- India is a signatory to various international conventions on narcotic drugs and psychotropic substances, including the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

# **Treatment and Rehabilitation**

- The Act provides for the establishment of centers for the treatment and rehabilitation of addicts.
- It emphasizes a humane approach to addiction, focusing on rehabilitation rather than punishment for minor offenses related to personal consumption.

# Preparation of Drug lists – reserved antibiotics.

Reserved antibiotics refer to a category of antibiotics that are kept in reserve and used only as a last resort when other antibiotics have failed to treat an infection. This approach is intended to combat antibiotic resistance, ensuring these powerful drugs remain effective against severe, multidrug-resistant infections. Here's a detailed overview of reserved antibiotics:

# **Key Features of Reserved Antibiotics**

# 1. Limited Use:

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- Reserved antibiotics are prescribed only in specific, critical situations where first-line and second-line antibiotics are ineffective.
- Their use is highly restricted to prevent the development of resistance.

# 2. Stewardship Programs:

- Healthcare facilities often implement antibiotic stewardship programs to monitor and control the use of these antibiotics.
- These programs include guidelines, protocols, and oversight to ensure appropriate use.

# 3. Strict Prescription Policies:

- Reserved antibiotics typically require approval from an infectious disease specialist or a similar authority before they can be prescribed.
- This helps ensure that they are used judiciously and only when absolutely necessary.

# **Examples of Reserved Antibiotics**

- 1. Carbapenems:
  - **Meropenem**: Used for severe, high-risk bacterial infections.
  - **Imipenem/Cilastatin**: Employed in treating serious infections caused by multidrug-resistant organisms.

# 2. Polymyxins:

• **Colistin**: Used as a last-line treatment for multidrug-resistant Gram-negative infections.

# 3. Oxazolidinones:

• **Linezolid**: Effective against multidrug-resistant Gram-positive bacteria, including MRSA (Methicillin-resistant Staphylococcus aureus).

# 4. Glycopeptides:

• **Vancomycin**: Used for severe infections caused by Gram-positive bacteria, particularly MRSA and Clostridioides difficile.

# 5. Lipopeptides:

• **Daptomycin**: Effective against certain Gram-positive infections, including those resistant to other antibiotics.

# 6. Newer Antibiotics:

- **Ceftazidime/Avibactam**: A combination antibiotic used against certain multidrug-resistant Gram-negative bacteria.
- **Tigecycline**: Used for complicated skin and intra-abdominal infections caused by resistant bacteria.

# **Reasons for Reserving These Antibiotics**

- 1. **Preventing Resistance:** 
  - The main goal is to slow down the development of resistance to these crucial antibiotics.
  - By reserving their use, the spread of resistance among bacterial populations can be minimized.

# 2. Preserving Efficacy:

- Keeping these antibiotics effective for as long as possible is essential for treating future severe infections.
- It ensures that there are still options available when common antibiotics fail.

# 3. Public Health Strategy:

- Reserved antibiotics are part of a broader public health strategy to manage and control antibiotic resistance.
- This strategy includes promoting the development of new antibiotics, improving diagnostic techniques, and educating healthcare professionals and the public on responsible antibiotic use.

# **Challenges in Implementing Reserved Antibiotic Policies**

# 1. Compliance and Enforcement:

- Ensuring healthcare providers adhere to the guidelines for reserved antibiotic use can be challenging.
- Effective enforcement requires robust systems and continuous education.

# 2. Access and Availability:

- Balancing the need for access to these antibiotics with the necessity of restricting their use is complex.
- In some regions, ensuring the availability of reserved antibiotics for those who genuinely need them can be difficult.

# 3. Global Coordination:

• Antibiotic resistance is a global issue, and international coordination is required to ensure that policies on reserved antibiotics are effective worldwide.

• Differences in healthcare systems, regulatory environments, and resource availability can impact the implementation of these policies.

#### Procedures of Drug Purchases

The procedures for drug purchases in healthcare settings, such as hospitals or governmental healthcare institutions, involve multiple steps to ensure that the drugs are of high quality, cost-effective, and procured in a timely manner. The process can be broadly categorized into drug selection, procurement methods (short-term, long-term), and procurement processes (tender/e-tender process, quotations). Here's an overview of each aspect:

#### 1. Drug Selection

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# 1.1. Formulary System:

- **Developing a Formulary:** A list of approved medications that meet the therapeutic needs of the population served.
- **Therapeutic Committees:** A committee, often comprising pharmacists, physicians, and other healthcare professionals, evaluates and updates the formulary based on efficacy, safety, and cost-effectiveness.

# 1.2. Guidelines and Protocols:

- **Clinical Guidelines:** Utilized to standardize the selection process ensuring that chosen drugs are aligned with best practices and clinical evidence.
- **Essential Medicines List:** Refers to national or international lists (e.g., WHO's Essential Medicines List) to guide the selection of necessary drugs.

#### 2. Procurement Methods

#### 2.1. Short-term Procurement:

- Immediate Needs: Used for urgent or emergency drug requirements.
- **Smaller Quantities:** Typically involves purchasing smaller quantities to meet short-term demands.
- **Quotations:** Often involves obtaining quotations from multiple suppliers to ensure competitive pricing and quick delivery.

# 2.2. Long-term Procurement:

- Bulk Purchases: Used for routine and forecasted needs over an extended period.
- **Contractual Agreements:** Typically involves long-term contracts with suppliers to ensure a steady supply.
- Economies of Scale: Purchasing in bulk often reduces costs per unit.

#### **3. Procurement Processes**

# 3.1. Tender/E-Tender Process:

# Traditional Tender Process:

- **Preparation of Tender Documents:** Detailed specifications, terms and conditions, and evaluation criteria are outlined.
- Invitation to Tender: Public announcement or direct invitation to potential suppliers.
- Submission of Bids: Suppliers submit their bids in response to the tender.
- **Bid Evaluation:** Evaluation committee assesses the bids based on predefined criteria (quality, cost, delivery time, etc.).
- Award of Contract: The contract is awarded to the supplier that meets the requirements and offers the best value for money.

# **E-Tender Process:**

- Electronic Platform: Utilizes an online system for tendering to increase efficiency and transparency.
- **Registration:** Suppliers must register on the e-tender platform.
- **Digital Submission:** Bids are submitted electronically, reducing paperwork and speeding up the process.
- Automated Evaluation: Some platforms may provide automated tools for initial evaluation of bids.
- **Contract Award:** Similar to the traditional process, but with enhanced transparency and speed.

# 3.2. Quotations:

- **Request for Quotations (RFQ):** Sent to multiple suppliers for obtaining price quotes.
- **Comparison:** Quotations are compared based on price, quality, delivery time, and supplier reliability.
- **Selection:** The supplier offering the best terms is selected for the purchase.

# **Key Considerations in Drug Procurement**

1. Quality Assurance:

- Ensure that the drugs meet the required standards of quality, safety, and efficacy.
- Suppliers must provide quality certifications and compliance with regulatory standards.

#### 2. Cost-effectiveness:

- Aim for the best value for money without compromising on quality.
- Consider total cost of ownership, including purchase price, storage, and distribution costs.

#### 3. Supply Chain Management:

- Efficient logistics to ensure timely delivery and proper storage conditions.
- Managing inventory to avoid stockouts and overstock situations.

#### 4. Compliance and Transparency:

- Adherence to legal and regulatory requirements.
- Transparent processes to prevent fraud and corruption.

#### 5. Vendor Management:

- Establishing and maintaining good relationships with reliable suppliers.
- Regularly evaluating supplier performance based on delivery, quality, and service.

<b>3.</b> 7	Inventory control techniques
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Inventory control is crucial in ensuring that healthcare institutions have the necessary drugs available without overstocking or running out. Effective inventory control techniques help manage the balance between supply and demand, minimize costs, and ensure quality and efficiency in drug management. Here are some key inventory control techniques:

# 1. Economic Order Quantity (EOQ)

#### 1.1. Definition:

• EOQ is a formula used to determine the optimal order quantity that minimizes the total cost of inventory, including ordering and holding costs.

#### 1.2. Formula:

• EOQ=2*DSH*EOQ=*H*2*DS* 

- Where:
  - *DD* = Demand (units per year)
  - *SS* = Ordering cost per order
  - *HH* = Holding cost per unit per year

# 1.3. Benefits:

- Minimizes total inventory costs.
- Helps maintain a balance between ordering costs and holding costs.
- Ensures that drugs are ordered in optimal quantities to avoid stockouts and overstocking.

# 2. Reorder Quantity Level (RQL)

# 2.1. Definition:

• RQL, also known as the reorder point (ROP), is the inventory level at which a new order should be placed to replenish stock before it runs out.

# 2.2. Formula:

- RQL= $d \times L$ RQL= $d \times L$
- Where:
  - *dd* = Average daily demand
  - *LL* = Lead time in days

# 2.3. Benefits:

- Prevents stockouts by ensuring timely reordering.
- Takes into account lead time and average usage rate.
- Helps maintain continuous supply without overstocking.

# 3. Inventory Turnover Ratio

# 3.1. Definition:

• Inventory turnover ratio measures how many times inventory is sold and replaced over a specific period.

# 3.2. Formula:

• Inventory Turnover Ratio=Cost of Goods Sold (COGS)Average InventoryInventory Tur nover Ratio=Average InventoryCost of Goods Sold (COGS)

- Where:
  - Average Inventory=Beginning Inventory+Ending Inventory2Average Inventory =2Beginning Inventory+Ending Inventory

# 3.3. Benefits:

- Indicates the efficiency of inventory management.
- High turnover implies effective inventory control and product demand.
- Low turnover suggests overstocking or obsolescence.

# 4. ABC Analysis

# 4.1. Definition:

- ABC analysis classifies inventory items into three categories (A, B, and C) based on their importance and value.
  - A items: High-value items with low frequency of use.
  - B items: Moderate value and frequency of use.
  - C items: Low-value items with high frequency of use.

# 4.2. Benefits:

- Prioritizes inventory management efforts.
- Helps allocate resources effectively.
- Focuses on critical items that have the highest impact on costs.

# 5. Just-In-Time (JIT) Inventory

# 5.1. Definition:

• JIT is an inventory strategy where materials are ordered and received just in time for production or sales, minimizing holding costs.

# 5.2. Benefits:

- Reduces inventory holding costs.
- Minimizes waste and obsolescence.
- Requires accurate demand forecasting and efficient supplier management.

# 6. Safety Stock

# 6.1. Definition:

• Safety stock is an additional quantity of inventory kept to prevent stockouts caused by uncertainties in demand and supply.

# 6.2. Calculation:

• Safety stock can be calculated using statistical methods considering variability in demand and lead time.

#### 6.3. Benefits:

- Provides a buffer against unexpected increases in demand or supply delays.
- Ensures continuous availability of critical drugs.

# 7. Perpetual Inventory System

# 7.1. Definition:

• A perpetual inventory system continuously tracks inventory levels using computerized systems.

#### 7.2. Benefits:

- Provides real-time inventory data.
- Enhances accuracy in inventory management.
- Facilitates quick decision-making and reduces administrative errors.

# 3.8 Inventory Management of Central Drug Store

Effective inventory management in a central drug store is crucial for ensuring the availability of quality pharmaceuticals while minimizing waste and costs. Proper storage conditions, methods of storage, distribution, and maintenance of the cold chain are essential components. Here's an overview of best practices and equipment used in these areas:

# 1. Storage Conditions

# 1.1. Temperature and Humidity Control:

- **Temperature:** Maintain appropriate temperature ranges to preserve drug potency. Typically, 15-25°C (59-77°F) for most drugs, and 2-8°C (36-46°F) for those requiring refrigeration.
- **Humidity:** Control humidity levels to prevent drug degradation. Optimal humidity is usually around 50% relative humidity.

# 1.2. Light Exposure:

• Store drugs away from direct sunlight and fluorescent light to prevent degradation of light-sensitive drugs.

# 1.3. Cleanliness:

• Maintain a clean and pest-free environment to ensure drug integrity and hygiene.

#### 1.4. Security:

• Secure storage areas to prevent theft and unauthorized access. Implement measures such as locked cabinets and restricted access zones.

# 2. Methods of Storage

#### 2.1. Shelving and Racking:

- Use appropriate shelving units and racks that allow for proper air circulation and easy access.
- Arrange drugs systematically, e.g., alphabetically or by therapeutic category, to facilitate efficient retrieval.

#### 2.2. FIFO and FEFO:

- **FIFO (First-In, First-Out):** Ensures older stock is used before newer stock to minimize expiration.
- **FEFO (First-Expiry, First-Out):** Ensures drugs with the nearest expiration dates are used first.

#### 2.3. Segregation:

• Separate different categories of drugs (e.g., controlled substances, hazardous drugs, and regular medications) to prevent cross-contamination and ensure compliance with regulations.

# 3. Distribution

# 3.1. Centralized Distribution:

• Distribute drugs from a central location to various departments or healthcare facilities. This allows for better control and monitoring of inventory levels.

#### 3.2. Transportation:

• Use appropriate transport methods to ensure drugs are delivered in good condition. For cold chain drugs, use insulated containers or refrigerated vehicles.

#### 3.3. Inventory Tracking:

• Implement inventory management systems (IMS) to track drug movements, monitor stock levels, and generate reports.

# 4. Maintaining the Cold Chain

#### 4.1. Definition:

• The cold chain refers to the series of measures and equipment used to maintain the required low-temperature range for temperature-sensitive drugs from manufacturing to administration.

#### 4.2. Importance:

• Ensures drug efficacy and safety by preventing temperature fluctuations that can degrade drug quality.

# 5. Devices Used for Cold Storage

# 5.1. Refrigerators:

- **Pharmaceutical Refrigerators:** Designed to maintain a consistent temperature range of 2-8°C, with alarms for temperature deviations.
- **Standard Refrigerators:** May be used but should be monitored closely for temperature consistency.

# 5.2. ILR (Ice-Lined Refrigerator):

- **Definition:** A type of refrigerator that uses ice packs or a lining of ice to maintain temperatures even during power outages.
- **Usage:** Ideal for areas with unreliable electricity supply, ensuring consistent temperature maintenance for vaccines and other temperature-sensitive drugs.

# 5.3. Walk-In Cold Rooms:

- **Definition:** Large storage rooms that provide a controlled environment for bulk storage of temperature-sensitive drugs.
- **Features:** Equipped with advanced temperature control systems, monitoring devices, and backup power solutions to ensure consistent temperature.

# 5.4. Monitoring Devices:

- **Temperature Loggers:** Continuous recording devices that monitor and log temperature data over time.
- Alarm Systems: Alert staff to temperature excursions, allowing for immediate corrective action.
- **Remote Monitoring Systems:** Enable real-time monitoring and management of storage conditions from a remote location.

#### **FEFO and FIFO methods**

FEFO (First-Expiry, First-Out) and FIFO (First-In, First-Out) are inventory management methods used to ensure efficient and effective stock rotation, particularly in settings like pharmacies, hospitals, and warehouses. These methods help minimize waste, reduce costs, and maintain the quality and safety of the products. Here's an in-depth look at both methods:

# 1. FIFO (First-In, First-Out)

# 1.1. Definition:

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• FIFO is an inventory management technique where the oldest stock (the first items placed in inventory) is used or sold first.

#### 1.2. Application:

- Commonly used for products that are not highly perishable but still need to be rotated to avoid obsolescence.
- Ensures that older inventory is used before newer stock, which helps prevent items from becoming outdated or expired.

#### 1.3. Benefits:

- Reduces the risk of obsolescence and expiration, especially for items with a longer shelf life.
- Helps maintain a more accurate financial representation of inventory costs, as older, often cheaper, stock is used up first.

#### 1.4. Example:

• In a pharmacy, when new drug shipments arrive, they are placed behind the existing stock. As prescriptions are filled, the pharmacist uses the older stock first, ensuring that no medication is left unused for too long.

# 2. FEFO (First-Expiry, First-Out)

#### 2.1. Definition:

• FEFO is an inventory management technique where items with the earliest expiration dates are used or sold first, regardless of when they were received.

# 2.2. Application:

- Essential for managing perishable goods, including food, pharmaceuticals, and other products with a limited shelf life.
- Ensures that items are consumed or sold before they reach their expiration date, thereby minimizing waste and ensuring product safety.

#### 2.3. Benefits:

- Reduces the risk of products expiring and going to waste.
- Ensures the safety and efficacy of time-sensitive items, such as medications and consumables.
- Critical for regulatory compliance in industries where product safety is paramount.

#### 2.4. Example:

• In a hospital pharmacy, medications are organized so that those with the closest expiration dates are used first. This ensures that drugs are not wasted and that patients receive safe and effective treatments.

#### **Key Differences and Implementation**

#### **Differences:**

- Basis of Rotation:
  - FIFO focuses on the order of receipt, with older stock used first.
  - FEFO focuses on expiration dates, with items expiring soonest used first.

# • Applicability:

- FIFO is more suitable for items with longer shelf lives or less critical expiration concerns.
- FEFO is essential for perishable items and those with strict expiration requirements.

#### Implementation:

- Labeling and Organization:
  - Clearly label inventory with receipt dates and expiration dates.
  - Organize storage areas to facilitate easy access to items based on the chosen method (e.g., older items at the front for FIFO, items with earlier expiration dates at the front for FEFO).

#### • Inventory Management Systems:

- Use automated inventory management systems to track stock and manage rotation efficiently.
- Implement alerts for approaching expiration dates and reorder points.
- Staff Training:
  - Train staff on the importance and procedures of FIFO and FEFO methods.
  - Ensure consistent adherence to the chosen inventory management practices.

Handling and disposing of expired drugs requires careful consideration to ensure safety, prevent misuse, and minimize environmental impact. Here are the best practices for the removal, handling, and disposal of expired drugs:

# 1. Identification and Segregation

- Identify Expired Drugs: Regularly check inventory to identify expired drugs.
- **Segregation**: Separate expired drugs from active inventory immediately to prevent accidental dispensing.

# 2. Handling Expired Drugs

- **Safety Measures**: Use gloves and other personal protective equipment (PPE) when handling expired drugs to avoid direct contact, especially with hazardous medications.
- **Documentation**: Maintain records of expired drugs, including the name, quantity, expiration date, and the date they were identified as expired.

# 3. Disposal Methods

# Household Disposal

- **FDA Guidelines**: The FDA provides specific guidelines for disposing of medications at home:
  - **Mix with Unappealing Substances**: Mix medications (do not crush tablets or capsules) with unappealing substances like dirt, cat litter, or used coffee grounds.
  - **Sealed Container**: Place the mixture in a sealed plastic bag.
  - **Trash Disposal**: Throw the sealed bag in the household trash.
  - **Personal Information**: Remove all personal information on the prescription label to protect your privacy.
- **Flushing**: Certain drugs, particularly opioids and other controlled substances, can be dangerous if accidentally ingested. The FDA has a list of medications that should be flushed down the toilet if no take-back programs are available.

# **Drug Take-Back Programs**

• **Take-Back Events**: Participate in National Prescription Drug Take-Back events sponsored by the DEA or local law enforcement.

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• **Permanent Collection Sites**: Many pharmacies, hospitals, and law enforcement agencies have permanent collection sites or mail-back programs for unused medications.

# Hazardous Waste Disposal

- **Special Handling for Hazardous Waste**: Some expired medications, especially chemotherapy drugs and certain other potent drugs, are considered hazardous waste and require special disposal methods.
  - **Pharmacy Guidelines**: Follow your pharmacy's or healthcare institution's guidelines for hazardous waste disposal.
  - **EPA Regulations**: Adhere to Environmental Protection Agency (EPA) regulations regarding hazardous waste.

# 4. Environmental Considerations

- Avoid Water Contamination: Do not dispose of medications by flushing them down the toilet or sink unless specifically instructed, as this can contaminate water supplies.
- **Incineration**: Professional disposal companies often use incineration as an environmentally safe method to destroy pharmaceuticals, particularly those classified as hazardous.

# 5. Regulatory Compliance

- **DEA Regulations**: Follow DEA regulations for the disposal of controlled substances.
- **State and Local Laws**: Be aware of and comply with state and local laws regarding drug disposal, as they may have additional requirements.

# 6. Education and Awareness

- **Public Awareness**: Educate the public on the importance of proper drug disposal to prevent misuse and environmental harm.
- **Healthcare Training**: Ensure healthcare professionals are trained in proper disposal methods for expired medications.

# 3.11 Disposal of Narcotics, cytotoxic drugs.

The disposal of narcotics (controlled substances) and cytotoxic drugs (used primarily in chemotherapy) requires stringent procedures due to their potential for abuse, environmental harm, and health risks. Here's a detailed guide for the safe disposal of these substances:

# 1. Narcotics (Controlled Substances)

# **Regulations and Guidelines**

- **DEA Regulations**: The disposal of narcotics must comply with the Drug Enforcement Administration (DEA) regulations.
- Secure Disposal Methods: These methods prevent diversion and misuse.

# **Disposal Methods**

- **Take-Back Programs**: Utilize DEA-authorized take-back programs and events where individuals can safely return unused narcotics.
  - **Permanent Collection Sites**: Many pharmacies, police stations, and hospitals have secure drop boxes for controlled substances.
- **Mail-Back Programs**: Some organizations offer mail-back envelopes for narcotics, which can be sent to authorized facilities for disposal.
- Authorized Reverse Distributors: Healthcare facilities should use DEA-registered reverse distributors for the disposal of expired or unwanted narcotics.

# Handling and Documentation

- **Segregation**: Store expired narcotics in a locked, secure location separate from other medications until disposal.
- **Record Keeping**: Maintain detailed records of the quantities, types, and disposal dates of narcotics, ensuring compliance with DEA documentation requirements.
- **Witnessed Destruction**: For certain circumstances, witnessed destruction by authorized personnel may be required, with appropriate documentation.

# 2. Cytotoxic Drugs

# **Risks and Precautions**

- **Health Risks**: Cytotoxic drugs can be harmful if not handled and disposed of correctly. They pose risks of carcinogenicity, mutagenicity, and teratogenicity.
- **Regulatory Guidelines**: Follow guidelines from the Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) for hazardous waste.

# **Disposal Methods**

• **Incineration**: The preferred method for disposing of cytotoxic drugs is hightemperature incineration in an EPA-approved facility. This process ensures complete destruction of harmful substances.

- **Hazardous Waste Disposal Services**: Utilize services that specialize in medical and hazardous waste. These services provide appropriate containers, transportation, and disposal methods.
  - **Yellow Bins**: Cytotoxic waste should be placed in designated yellow bins marked for incineration.
- **Secondary Containment**: Double-bagging or using secondary containment is often required to prevent leaks or spills during transport.

# Handling and Documentation

- **Personal Protective Equipment (PPE)**: Use appropriate PPE, such as gloves, gowns, and eye protection, when handling cytotoxic drugs to prevent exposure.
- **Training**: Ensure that all personnel handling cytotoxic drugs are trained in safe handling, spill response, and disposal procedures.
- **Spill Kits**: Maintain spill kits in areas where cytotoxic drugs are prepared or administered to manage accidental releases safely.
- Labeling and Segregation: Clearly label containers and storage areas for cytotoxic drugs. Segregate them from general medical waste to avoid contamination.

#### **Environmental and Safety Considerations**

- Avoid Sewer Disposal: Do not dispose of narcotics or cytotoxic drugs by flushing them down the toilet or sink. This can lead to environmental contamination and potential harm to aquatic life.
- **Community Education**: Educate patients and the public about the importance of proper disposal of these substances to prevent misuse and environmental harm.

#### 3.12

#### **Documentation – purchase and inventory**

Proper documentation for the purchase and inventory of drugs, particularly controlled substances (narcotics) and cytotoxic drugs, is critical for ensuring compliance with regulations and maintaining accurate records. Here's a comprehensive guide on how to handle the documentation for these processes:

# 1. Documentation for Purchase

# **Ordering Process**

- **Authorized Personnel**: Only authorized personnel should place orders for narcotics and cytotoxic drugs. Ensure they have proper credentials and training.
- **Purchase Orders**: Use detailed purchase orders that include:

- Drug name
- Dosage form
- Quantity
- Supplier details
- Purchase date

# **Record Keeping**

- **Receipts and Invoices**: Maintain copies of all receipts and invoices from suppliers. These should be stored securely and organized chronologically or by drug type.
- **Order Verification**: Upon receipt, verify the shipment against the purchase order. Ensure that the correct drugs and quantities have been received.
- **DEA Form 222 (for Narcotics)**: For Schedule II controlled substances, use DEA Form 222 for ordering. Keep a copy of the form and the supplier's response for at least two years.
- **Inventory Logs**: Update inventory logs immediately upon receipt of new stock. Record the date received, quantity, and any discrepancies noted.

# 2. Inventory Management

# **Inventory Control Systems**

- **Automated Systems**: Utilize automated inventory management systems that provide real-time tracking and alerts for low stock or discrepancies.
- **Manual Logs**: In addition to automated systems, maintain manual logs as a backup. These logs should include:
  - Drug name
  - Strength and dosage form
  - Lot number
  - Expiration date
  - Quantity on hand
  - Date and initials of person updating the log

# **Regular Audits**

- **Periodic Inventory Counts**: Conduct regular (e.g., monthly or quarterly) physical inventory counts to reconcile with inventory records. This helps identify discrepancies early.
- **Annual Comprehensive Audit**: Perform a detailed, comprehensive audit annually to ensure overall inventory accuracy.

#### **Special Considerations for Narcotics**

- Secure Storage: Store narcotics in a locked, secure cabinet or safe with limited access.
- **Perpetual Inventory System**: Maintain a perpetual inventory system that records each transaction (receipts, dispensing, wastage) immediately.
- **DEA Compliance**: Adhere to DEA regulations for inventory control, including initial inventory, biennial inventory, and keeping records for at least two years.

# Special Considerations for Cytotoxic Drugs

- **Separate Storage**: Store cytotoxic drugs separately from other medications to prevent contamination.
- **Safety Protocols**: Ensure proper handling protocols are followed, including the use of PPE and safety cabinets for preparation.
- **Spill Records**: Maintain records of any spills or incidents involving cytotoxic drugs, including the response and cleanup actions taken.

# 3. Disposal Documentation

# **Disposal Records**

- **Disposal Logs**: Maintain detailed logs of disposed drugs, including:
  - Drug name and dosage form
  - Quantity disposed
  - Date of disposal
  - Method of disposal
  - Personnel involved in the disposal process
- **DEA Form 41**: For the disposal of controlled substances, complete DEA Form 41, which documents the destruction of controlled substances. Keep a copy for your records.

• **Vendor Certificates**: If using a third-party disposal service, retain certificates of disposal provided by the vendor.

# 4. Compliance and Inspection Readiness

# **Regulatory Compliance**

- **Regular Reviews**: Conduct regular reviews of documentation practices to ensure compliance with regulatory requirements from agencies such as the DEA, FDA, and EPA.
- **Training**: Ensure all personnel involved in the purchase, handling, and disposal of narcotics and cytotoxic drugs are adequately trained and aware of documentation requirements.

# **Inspection Preparation**

- **Organized Records**: Keep all records well-organized and easily accessible in the event of an inspection by regulatory authorities.
- **Internal Audits**: Conduct internal audits to prepare for external inspections, identifying and addressing any potential issues beforehand.