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Ch – 5

Compounding in hospitals

Compounding in hospitals refers to the preparation of personalized medications for patients. This process involves combining, mixing, or altering ingredients to create medications tailored to the specific needs of patients when commercially available drugs do not meet those needs. Here's an overview of the compounding process in hospital settings:

1. Regulatory Compliance

- **Legal Requirements:** Hospital compounding pharmacies must comply with regulations set by national authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and local pharmacy boards.
- **Standards:** Compliance with standards such as the United States Pharmacopeia (USP) chapters <795> for non-sterile compounding and <797> for sterile compounding is crucial.

2. Types of Compounding

- **Sterile Compounding:** Involves preparing medications that must be free from contaminants, typically for injections, infusions, or ophthalmic preparations.
- **Non-Sterile Compounding:** Includes preparations such as oral suspensions, topical creams, and capsules that do not require sterility.

3. Facilities and Equipment

- **Compounding Area:** Dedicated spaces designed to minimize contamination risks. Sterile compounding areas are often classified as ISO Class 7 or 8 cleanrooms with ISO Class 5 laminar airflow workbenches or biological safety cabinets.
- **Equipment:** Includes balances, mixers, hot plates, autoclaves, and other specialized tools. All equipment must be regularly calibrated and maintained.

4. Personnel

- **Qualified Staff:** Pharmacists and pharmacy technicians with specialized training in compounding techniques and safety practices.
- **Training and Competency:** Regular training on compounding protocols, safety measures, and regulatory updates. Staff competency should be assessed periodically.

5. Procedures and Protocols

- **Standard Operating Procedures (SOPs):** Detailed protocols covering every aspect of compounding, from ingredient handling to final product testing.
- **Formulations:** Precise formulations based on physician orders, including calculations for dosages and concentrations.

6. Sterile Compounding Process

1. **Preparation:** Staff don personal protective equipment (PPE) and perform hand hygiene. The compounding area is cleaned and sanitized.
2. **Ingredient Verification:** Ingredients are checked for identity, purity, and expiration dates.
3. **Aseptic Technique:** Compounding is performed using aseptic techniques to maintain sterility.
4. **Quality Control:** Finished products undergo quality control checks, including sterility testing and endotoxin testing when necessary.
5. **Labeling and Packaging:** Medications are labeled with essential information, including patient details, ingredients, concentrations, and storage instructions.

7. Non-Sterile Compounding Process

1. **Preparation:** The compounding area and equipment are cleaned. Staff don appropriate PPE.
2. **Ingredient Verification:** Ingredients are verified for identity and quality.
3. **Compounding:** Ingredients are precisely measured, mixed, and prepared according to the formulation.
4. **Quality Control:** Final products are checked for accuracy in terms of weight, volume, and homogeneity.
5. **Labeling and Packaging:** Medications are labeled with detailed information and stored appropriately.

8. Quality Assurance and Control

- **Testing:** Routine testing of compounded products for potency, purity, and stability.
- **Documentation:** Comprehensive documentation of compounding processes, quality control results, and any deviations from protocols.
- **Audits:** Regular internal and external audits to ensure compliance with regulations and standards.

9. Record-Keeping

- **Compounding Logs:** Detailed logs of all compounded preparations, including ingredients, lot numbers, quantities, and compounding personnel.
- **Patient Records:** Documentation of compounded medications in the patient's medical record, including dosages and administration instructions.
- **Retention:** Records must be maintained for a period specified by regulatory authorities, often several years.

10. Safety and Risk Management

- **Hazardous Drugs:** Special precautions and facilities, such as negative pressure rooms and containment primary engineering controls (C-PECs), for compounding hazardous drugs (e.g., chemotherapy).

- **Incident Reporting:** Systems for reporting and addressing compounding errors or adverse events.
- **Environmental Monitoring:** Regular monitoring of the compounding environment for contamination, including microbial and particulate counts.

5.1 BULK COMPOUNDING

Bulk compounding in hospitals refers to the preparation of large quantities of a compounded medication intended for use by multiple patients or for a single patient over an extended period. This practice is essential for ensuring the availability of commonly used compounded medications, improving efficiency, and maintaining consistent quality. Here's an overview of the bulk compounding process in hospital settings:

1. Regulatory Compliance

- **Legal Requirements:** Bulk compounding must adhere to regulations set by authorities such as the U.S. Food and Drug Administration (FDA) and the U.S. Pharmacopeia (USP) standards, particularly USP <795> for non-sterile compounding and USP <797> for sterile compounding.
- **Licensing and Accreditation:** Pharmacies involved in bulk compounding must have appropriate licenses and, in some cases, accreditation from organizations like The Joint Commission.

2. Facilities and Equipment

- **Dedicated Space:** Bulk compounding should be performed in dedicated areas designed to minimize contamination risks, such as cleanrooms for sterile compounding.
- **Specialized Equipment:** Includes mixers, blenders, autoclaves, laminar flow hoods, biological safety cabinets, and automated compounding devices. Equipment must be regularly calibrated and maintained.

3. Personnel

- **Trained Staff:** Pharmacists and pharmacy technicians involved in bulk compounding must have specialized training in compounding techniques, aseptic procedures, and safety practices.
- **Competency Assessment:** Regular assessment of staff competency through training programs and practical evaluations.

4. Standard Operating Procedures (SOPs)

- **Detailed Protocols:** SOPs should cover all aspects of bulk compounding, including ingredient handling, preparation methods, quality control measures, and documentation requirements.
- **Validation:** SOPs must be validated to ensure they produce consistent and accurate results.

5. Preparation and Planning

- **Batch Preparation Records:** Detailed records specifying the formulation, quantities, equipment, and procedures used for each batch.
- **Ingredient Verification:** Verification of the identity, quality, and expiration dates of all ingredients before use.
- **Environmental Preparation:** Ensuring the compounding area and equipment are properly cleaned and sanitized before starting the process.

6. Bulk Compounding Process

For Non-Sterile Compounding:

1. **Weighing and Measuring:** Precise weighing and measuring of ingredients using calibrated equipment.
2. **Mixing and Blending:** Using appropriate mixers or blenders to ensure uniformity.
3. **Quality Control:** In-process quality control checks to verify homogeneity and consistency.
4. **Packaging and Labeling:** Dispensing the compounded medication into appropriate containers with detailed labels indicating the contents, concentration, lot number, expiration date, and storage instructions.

For Sterile Compounding:

1. **Aseptic Technique:** Strict aseptic techniques to prevent contamination.
2. **Laminar Flow Hood/Biological Safety Cabinet:** Performing compounding in an ISO Class 5 environment to maintain sterility.
3. **Sterility Testing:** Batch testing for sterility and endotoxins.
4. **Final Packaging:** Using sterile containers and labeling with necessary information.

7. Quality Assurance and Control

- **In-Process Testing:** Continuous monitoring during compounding to ensure consistency and quality.

- **Final Product Testing:** Conducting tests for potency, purity, sterility (for sterile products), and stability.
- **Documentation:** Maintaining detailed records of all compounding activities, quality control results, and any deviations from standard procedures.

8. Storage and Distribution

- **Proper Storage Conditions:** Ensuring compounded medications are stored under appropriate conditions (temperature, humidity) to maintain their efficacy and stability.
- **Controlled Access:** Limiting access to bulk compounded medications to authorized personnel.
- **Distribution:** Efficiently distributing compounded medications to patient care areas while ensuring traceability and accountability.

9. Documentation and Record-Keeping

- **Batch Records:** Comprehensive batch records including formulation details, preparation steps, quality control results, and personnel involved.
- **Inventory Management:** Tracking inventory levels to manage supply and demand effectively.
- **Retention of Records:** Keeping records for the duration specified by regulatory authorities, often several years.

10. Safety and Risk Management

- **Hazardous Drugs:** Implementing special precautions and facilities for compounding hazardous drugs, such as chemotherapy agents, including negative pressure rooms and containment primary engineering controls (C-PECs).
- **Incident Reporting:** Establishing systems for reporting and addressing compounding errors, adverse events, or contamination incidents.
- **Environmental Monitoring:** Regular environmental monitoring to detect any contamination in the compounding areas.

5.2	**Intravenous (IV) admixture services**

Intravenous (IV) admixture services in hospitals are essential for preparing IV medications tailored to individual patient needs. This involves mixing drugs with IV fluids under sterile conditions to ensure safe and effective delivery. Here's an overview of IV admixture services

and handling drug incompatibilities:

IV Admixture Services

1. **Facility and Equipment:

- **Sterile Environment:** IV admixtures must be prepared in an ISO Class 5 cleanroom or laminar airflow hood (LAFH) to maintain sterility.
- **Equipment:** Includes laminar flow hoods, biological safety cabinets, autoclaves, automated compounding devices, and sterile supplies (syringes, needles, IV bags).

2. **Personnel:

- **Trained Staff:** Pharmacists and pharmacy technicians trained in aseptic techniques, sterile compounding, and handling hazardous drugs.
- **Competency Assessment:** Regular training and competency evaluations to ensure adherence to protocols.

3. **Procedures:

- **Aseptic Technique:** Strict aseptic techniques to prevent contamination, including proper hand hygiene, use of personal protective equipment (PPE), and sanitization of the compounding area.
- **Preparation:** Accurate measuring and mixing of drugs and IV fluids based on physician orders, ensuring correct dosage and concentration.
- **Labeling:** Detailed labeling of IV admixtures, including drug name, concentration, patient information, expiration date, and special handling instructions.
- **Quality Control:** In-process and final product checks to ensure accuracy, sterility, and proper labeling.

4. **Documentation and Record-Keeping:

- **Compounding Logs:** Detailed records of all compounded IV admixtures, including ingredients, lot numbers, quantities, compounding personnel, and dates.
- **Patient Records:** Documentation of IV admixtures in patient medical records, including dosage and administration times.
- **Retention:** Maintaining records for the period required by regulatory authorities.

Handling Incompatibilities

1. **Types of Incompatibilities:

- **Physical Incompatibility:** Visible changes such as precipitation, cloudiness, or color changes when two or more drugs are mixed.
- **Chemical Incompatibility:** Degradation or loss of potency of one or more drugs when mixed, often resulting in reduced therapeutic efficacy or formation of harmful byproducts.
- **Therapeutic Incompatibility:** Combined effect of two drugs resulting in a diminished therapeutic effect or increased toxicity.

2. **Identifying Incompatibilities:

- **Reference Sources:** Utilizing compatibility charts, reference books (e.g., Trissel's Handbook on Injectable Drugs), and online databases to check compatibility before mixing.
- **Manufacturer Guidelines:** Following drug manufacturers' guidelines for mixing and administration.
- **Visual Inspection:** Checking for any visible signs of incompatibility (e.g., precipitation, color change) after mixing.

3. **Preventing Incompatibilities:

- **Separate Administration:** Administering incompatible drugs through separate IV lines or at different times if simultaneous administration is necessary.
- **Dilution:** Diluting drugs appropriately to minimize the risk of incompatibility.
- **Proper Mixing Order:** Adding drugs to IV fluids in a specific order to prevent reactions, such as adding the drug to the diluent rather than the other way around.
- **Using Compatibility Agents:** Utilizing agents that enhance compatibility or stabilize the mixture, if available.

4. **Managing Incompatibilities:

- **Immediate Response:** If an incompatibility is detected after mixing, the admixture should not be used. Prepare a new admixture with compatible components.
- **Communication:** Informing healthcare providers about potential incompatibilities and providing alternatives or recommendations for administration.
- **Ongoing Education:** Training staff regularly on recognizing and managing drug incompatibilities.

5.3 Total Parenteral Nutrition (TPN)

Total Parenteral Nutrition (TPN) is a method of delivering nutrition intravenously to patients who cannot or should not receive food or nutrients through the gastrointestinal (GI) tract. TPN provides all the essential nutrients required by the body, including carbohydrates, proteins, fats, vitamins, minerals, and electrolytes, in a sterile, liquid form.

Indications for TPN

TPN is typically indicated for patients with:

- **Severe GI disorders:** Such as Crohn’s disease, short bowel syndrome, or severe pancreatitis.
- **Intestinal failure:** Due to surgery, trauma, or congenital conditions.
- **Inability to absorb nutrients:** Because of severe malabsorption syndromes.
- **Extended NPO (nil per os) status:** For patients who cannot consume food orally or enterally for an extended period.

Components of TPN

TPN solutions are customized based on individual patient needs and typically include:

- **Carbohydrates:** Usually in the form of glucose or dextrose, providing a primary energy source.
- **Proteins:** Provided as amino acids to support tissue repair and growth.
- **Fats:** Administered as lipid emulsions to supply essential fatty acids and additional calories.
- **Electrolytes:** Including sodium, potassium, chloride, calcium, magnesium, and phosphate, to maintain fluid and electrolyte balance.
- **Vitamins and Minerals:** Essential vitamins (such as A, D, E, K, C, B-complex) and trace minerals (such as zinc, copper, manganese, selenium) to support metabolic functions.
- **Fluid:** Adequate water is included to meet hydration needs.

Preparation and Administration of TPN

1. **Assessment and Prescription:

- **Nutritional Assessment:** Conduct a comprehensive nutritional assessment to determine the patient's nutritional needs.
- **Individualized Prescription:** Develop a TPN prescription tailored to the patient's specific requirements, including macronutrients, micronutrients, electrolytes, and fluid volumes.

2. **Compounding:

- **Aseptic Technique:** Prepare TPN solutions using aseptic techniques in a sterile environment, such as an ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom.
- **Compounding Equipment:** Utilize automated compounding devices to ensure precise measurements and mixing of TPN components.
- **Quality Control:** Perform quality control checks, including visual inspection, sterility testing, and verification of ingredients and concentrations.

3. **Administration:

- **Central Venous Access:** Administer TPN via a central venous catheter, such as a peripherally inserted central catheter (PICC) line or a tunneled central venous catheter, to accommodate the hypertonic nature of TPN solutions.
- **Infusion Rate:** Gradually increase the infusion rate to the prescribed level to prevent metabolic complications. TPN is usually administered continuously over 24 hours or cyclically (e.g., 12-18 hours per day).

- **Monitoring:** Regularly monitor the patient's clinical status, including electrolyte levels, blood glucose, liver and kidney function, and signs of infection or catheter-related complications.

Monitoring and Adjusting TPN

1. **Clinical Monitoring:

- **Vital Signs:** Regular monitoring of vital signs, fluid balance, and weight to assess the patient's response to TPN.
- **Laboratory Tests:** Frequent blood tests to monitor electrolytes, glucose, liver and renal function, and lipid levels. Adjust the TPN composition as needed based on lab results.

2. **Preventing and Managing Complications:

- **Infections:** Strict aseptic technique to minimize the risk of catheter-related bloodstream infections (CRBSIs). Monitor for signs of infection at the catheter site.
- **Metabolic Complications:** Watch for and manage potential complications such as hyperglycemia, refeeding syndrome, liver dysfunction, and electrolyte imbalances.
- **Mechanical Complications:** Regular assessment of the catheter site and function to prevent and manage issues such as thrombosis or catheter occlusion.

Patient Education and Support

1. **Patient and Caregiver Education:

- **Training:** Educate patients and caregivers on TPN administration, catheter care, recognizing signs of complications, and troubleshooting common issues.
- **Support:** Provide ongoing support and education to help patients manage TPN at home if discharged with home parenteral nutrition (HPN).

2. **Multidisciplinary Approach:

- **Healthcare Team:** Involve a multidisciplinary team, including physicians, pharmacists, dietitians, and nurses, to provide comprehensive care and support for patients on TPN.