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PERISHABLE AND NON-PERISHABLE MEDICINES AND QUALITY CONTROL

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Annotation

Fast-dissolving (rapidly dissolving) and unstable drugs are specific dosage forms that deserve special attention in the pharmaceutical field. They possess unique characteristics that require special approaches in their production, storage, and quality control. Below is detailed information about these drugs and their quality assessment.

Keywords

Convenience, Mechanical Strength, Rapid Action

Fast-Dissolving Drugs (Rapidly Dissolving Drugs)

Fast-dissolving drugs are solid dosage forms that dissolve quickly in the oral cavity. They are typically placed under the tongue or allowed to dissolve in the mouth. These drugs rapidly enter the bloodstream and provide quick therapeutic effects.

Characteristics:

- Rapid Dissolution: These drugs are manufactured with special components (such as superdisintegrants) that react quickly with water or saliva.

- Convenience: Easy for patients to take, especially when drinking water is not required.

- Rapid Action: Active ingredients quickly enter the bloodstream, ensuring a swift therapeutic effect.

Applications:- Analgesics (e.g., for quick pain relief).- Cough suppressants.- Psychiatric medications (e.g., anxiolytic drugs).

Quality Assessment:1. Dissolution Rate: Specialized equipment (e.g., dissolution apparatus) is used to verify that the dissolution rate of the drugs meets standards.2. Distribution: The speed and uniformity of the drug's distribution in

the oral cavity are assessed.3. Mechanical Strength: The hardness of the drugs and their ability to maintain shape are evaluated.4. Chemical Stability: The potential degradation or alteration of active ingredients during the dissolution process is examined.

Unstable Drugs

Unstable drugs are those whose composition, shape, or properties may change over time. They are generally sensitive to storage conditions (e.g., temperature, humidity, light).

Characteristics:- Instability: They may become unstable due to changes in the chemical or physical properties of their components.- Sensitivity to Storage Conditions: Factors like temperature, humidity, or light can affect the quality of these drugs.- Short Shelf Life: Unstable drugs typically have a shorter storage life.

Applications:- Antibiotics (e.g., unstable substances like penicillin).- Biological drugs (e.g., vaccines, enzymes).- Certain vitamins and hormonal preparations.

Quality Assessment:1. Stability Testing: The stability of drugs under various conditions (temperature, humidity, light) is assessed. These tests help determine the shelf life of the drugs.2. Chemical Analysis: The concentration of active ingredients and their degradation products are analyzed.3. Physical Properties: Changes in the shape, color, odor, and other physical properties of the drugs are monitored.

4. Microbiological Control: The growth of microorganisms in the drugs and their purity are evaluated.

5. Storage Conditions: The conditions under which the drugs should be stored (e.g., in a cool, dry place or protected from light) are determined.

General Methods for Quality Assessment

The following methods are used to assess the quality of fast-dissolving and unstable drugs:

1. Physicochemical Analyses: - Dissolution Rate: The dissolution rate is checked for fast-dissolving drugs.

- pH Level: The pH level of the drugs is measured to determine their stability. - Moisture Level: The moisture level is checked for unstable drugs.

2. Chemical Stability Tests: - The stability of drugs under various conditions (e.g., high temperature, humidity) is evaluated.

3. Microbiological Control: - The presence and quantity of microorganisms in the drugs are assessed.

4. Distribution and Dissolution Tests: - The speed and uniformity of the drug's distribution in the oral cavity are evaluated.

5. Shelf Life Determination:- The duration for which the drugs maintain efficacy is established.

Fast-dissolving and unstable drugs possess unique characteristics that require special approaches in their production, storage, and quality control. They are designed to provide patients with quick and effective relief; however, strict standards and monitoring mechanisms are in place to ensure their quality. Pharmaceutical companies and regulatory authorities continuously conduct tests and inspections to ensure the safety and efficacy of these drugs.

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