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Formulation of Tablets: A Comprehensive Review of Principles, Methods, and Advances

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ABSTRACT :

Tablets are among the most commonly used oral dosage forms due to their simplicity, stability, and patient acceptability. The formulation process is multifaceted, involving the selection of appropriate excipients, manufacturing methods, and quality control parameters. This review presents an integrated overview of tablet formulation, including excipient functions, formulation techniques, quality control measures, regulatory considerations, and recent technological advancements such as orodispersible tablets, 3D printing, and nanotechnology-based systems.

Keywords Tablet formulation, excipients, direct compression, wet granulation, quality control, modified release, nanotechnology, 3D printing, regulatory compliance

Introduction

The oral route remains the preferred mode of drug administration, with tablets being the dominant dosage form. Tablet formulation must balance efficacy, safety, manufacturability, and patient compliance. A successful tablet design depends on a comprehensive understanding of materials science and pharmaceutical principles.

Essential Components in Tablet Formulation

- Active Pharmaceutical Ingredient (API): Central therapeutic agent requiring proper bioavailability and stability.
- Diluents: Add bulk for handling and dosing (e.g., lactose, microcrystalline cellulose).
- Binders: Aid in granule formation (e.g., starch, PVP).
- Disintegrants: Enable breakup in the GI tract (e.g., sodium starch glycolate).
- Lubricants: Minimize friction during tablet ejection (e.g., magnesium stearate).
- Glidants: Improve powder flow (e.g., talc).
- Coating agents: Control release or mask taste (e.g., HPMC).

Tablet Formulation Techniques

- Wet Granulation: Enhances compressibility and content uniformity; includes mixing, wetting, drying, and milling.
- Dry Granulation: Suitable for moisture/heat-sensitive APIs; includes slugging or roller compaction.
- Direct Compression: Simplifies manufacturing; limited by API flow and compressibility.

Quality Control and Evaluation

Critical parameters include:
- Weight variation: Ensures dosage consistency.
- Hardness: Indicates mechanical strength.
- Friability: Evaluates resistance to crumbling.

- Disintegration time: Assesses release onset.
- Dissolution testing: Measures drug availability.

Advanced Strategies in Tablet Design

- Orodispersible Tablets (ODTs): Rapid disintegration without water, enhancing compliance.
- Modified Release Tablets: Includes sustained, delayed, and pulsatile systems.
- 3D Printed Tablets: Allows customized geometry and drug release profiles.
- Nanoparticle-Based Tablets: Improves solubility and absorption of poorly water-soluble drugs.

Regulatory and Stability Considerations

Regulatory frameworks such as ICH Q8 and FDA guidelines mandate robust documentation of formulation, manufacturing, and quality assurance. Stability testing under ICH conditions (e.g., 25°C/60% RH, 40°C/75% RH) is essential to determine shelf life.

Challenges in Tablet Formulation

- Poor solubility or stability of APIs
- Excipient incompatibilities
- Scale-up difficulties
- Patient-specific needs (e.g., pediatric, geriatric)

Conclusion

Formulating an effective and safe tablet requires multidisciplinary expertise and adherence to regulatory standards. Emerging technologies such as 3D printing and nanotechnology are poised to revolutionize tablet design, paving the way for personalized and precision medicine.

Conflict of Interest

The author declares no conflict of interest.

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