

Multiparticulate System Formulation Development



Multiparticulate drug delivery systems are primarily oral dosage forms consisting of multiple small discrete units, each exhibiting some desired characteristics. In these systems, the drug dose is divided over multiple subunits, usually consisting of thousands of spherical particles with a diameter of 0.05-2.00 mm. The multiparticles are less dependent on gastric emptying, resulting in lower inter- and intra-subject variability in gastrointestinal transit times. They are also better distributed and less likely to cause local sensitization.

Benefits of Formulating Drugs into Multiparticulate Systems

- Facilitates intragastric breakdown or provides a convenient, rapidly disintegrating tablet that dissolves in water prior to swallowing, aiding compliance in older patients and children.
- Allows for uniform dispersion of the drug in the gastrointestinal tract, reducing gastrointestinal irritation and individual differences.

- Multiparticulate systems show better reproducible pharmacokinetic behavior than conventional formulations.
- The use of multiparticulate dosage forms also leads to improved drug safety, especially for release systems.
- In multiparticulate formulations, release characteristics are incorporated into each subunit and any impairment affects only the release behavior of the subunit involved, which represents a small fraction of the total dose, reducing the potential for safety concerns.

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Multiparticulate system formulations are drug delivery systems consisting of multiple dosage units, and common types include small pill capsules, micropill compression tablets, mini-tablets and other ordinary particles. Through formulation design and material selection, formulation solutions are developed to solve the problems of limited production equipment, long production steps, multiple influencing factors, potential healing and stability in the industrialization process.



Formulation Development Steps

Starting pill core: It is the starting point to achieve uniform drug loading and thus a robust functional coating to obtain the ideal drug release profile. The quality indicators to be controlled are: core size distribution, roundness and mechanical strength.

Pill core coating: It is the basis for obtaining a robust functional coating and an ideal drug release profile. The quality indexes to be controlled require high drug loading rate, smooth and rounded appearance of drug loaded pills, and complete drug dissolution. It also requires a short process time, low pill adhesion rate, and at the same time, uniform particle size and distribution of the drug-loaded pill core.

Isolation coating: It can help optimize the basis of functional coating and enhance the performance of functional coating. Quality indicators to be controlled include: avoiding possible reactions between the drug layer and the functional coating layer, avoiding drug loss, and improving the surface smoothness and mechanical strength of the drug-carrying pellets.

Functional coating: The core step to achieve multiple drug release profiles, and to realize the therapeutic effect of the drug by adjusting the drug release profile. The quality indicators to be controlled are: robust process, high coating efficiency, reproducibility and stability of drug release.

Source: <https://www.formulationbio.com/multiparticulate-system-formulation-development-services.html>