Targeted Delivery

Oral Multiparticulate Technologies

Capsugel® | Lonza Pharma & Biotech

Multiparticulates offer a number of advantages, including optimized GI tract distribution, predictable gastrointestinal (GI) transit, formulation flexibility, and protection against dose dumping concerns. Because of their small size, shape and composition, multiparticulates also offer wide flexibility in the choice of manufacturing process and final dosage form. **Capsugel's oral multiparticulate technologies enable you to address a broad range of formulation needs.** An assortment of manufacturing options can be tailored to the characteristics of the active compound(s) and target product profile. The drug-product intermediate can be conveniently dosed using conventional and specialty capsules, "sprinkle" capsules, tablets, powder-in-bottle formulations, sachets, and oral-disintegrating tablets and films.

Wide-Ranging Applications

Multiparticulates provide a way to deliver multiple taste-neutral particles as the primary component of the final dosage form, which offers numerous benefits.

- Broad applicability for many active ingredients and excipients
- Amenability to a number of processing techniques, adding formulation and process options
- Capability to deliver a range of release profiles
- Flexibility in final dosage-form configuration, accommodating a variety of particle sizes (as small as 0.1 mm) and coatings
- Predictable gastrointestinal (GI) transit
- Mitigation of dose dumping concerns
- Superior tastemasking capability
- Precedence of use and safety

Wide Range of Applications

- Immediate release
- Extended or delayed release
- Fixed dose combinations
- Pediatrics / geriatrics

Fit-for-Purpose Processing

- Fluid bed drug layering and coating
- Extruded and spheronized beads
- Granulation / compression
- Melt-spray-congeal with lipids

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Spray-Layered Multiparticulates (SLMs)

SLMs are layered spherical particles approximately 100 to 1500 µm in diameter that contain one or more active ingredients. Typical applications include modified and programmed release, enhanced bioavailability (immediate and modified release), and fixed-dose combination therapies. SLMs are produced by using a bottom-spray fluidized-bed coater to apply one or more coatings to a coating substrate.

Lipid Multiparticulates (LMPs)

LMPs are round, smooth matrix multiparticulates produced from safe, precedented excipients. Typically, they are 50 to 300 µm in diameter, and can be used for applications requiring bioavailability enhancement, modified release, tastemasking, high-dose actives, and fixed-dose combination therapies. Using a continuous spinning-disk process developed by Capsugel, a drug is uniformly distributed within a carrier (typically, a biocompatible lipid or wax) with optional drug release-rate modifiers.

MULTIPARTICULATE PERFORMANCE RANGE

PERFORMANCE AND COMPLIANCE TARGETS

TECHNOLOGY SELECTION

	MP RANGE	PROCESS	AMORPHOUS/ SOLUBILIZED FORM	TASTE MASKING	IMMEDIATE RELEASE	DELAYED/ BURST	CONTROLLED RELEASE
FLUID BED LAYERED MPs	pH trigger (enteric, reverse)	Fluid Bed	✓	✓	✓	✓	
	time trigger (bursting)	Fluid Bed	✓	✓	✓	✓	
	diffusion control (porous)	Fluid Bed	✓	✓	✓		✓
MATRIX MPs	lipid matrix	Melt-Spray Congeal	✓	✓ plus coating if needed	✓	coating/ enTRinsic DDT*	✓
	erosion control granules	Extrusion/ Spheronization	✓	coating	✓		✓
	mini-tablets	Tableting	✓	coating	✓	coating/ enTRinsic DDT*	✓

*enTRinsic technology is the world's first capsule incorporating enteric polymer in the capsule shell and precluding the need for functional coatings.

Extrusion/Spheronization Granules

Extrusion/spheronization is a very flexible process used to produce uniformly sized spheroid granules through agglomeration, typically 600 to 2000 µm in diameter. These dense granules are excellent for preparing dosage forms with a minimum of excipients, and provide an excellent substrate for drug layering and functional coating.

Mini-Tablets with Optional Encapsulation

Mini-tablets are typically 2- to 3-mm tablets produced on a rotary tablet press by direct compression. They can be coated using aqueous- or solvent-based films using fluidized-bed or pan coaters and then encapsulated to produce an immediate- or modified-release multiparticulate dosage form.

Processing Flexibility

The selection of the dosage form delivery system and appropriate processing technology is driven by the specific compound parameters and target product profile. Oral multiparticulate formulations can be combined with a range of specialty capsules for improved functionality and/or dosing convenience.

Learn more about how Capsugel's Oral Multiparticulate Technologies can help you meet your target product profiles.

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