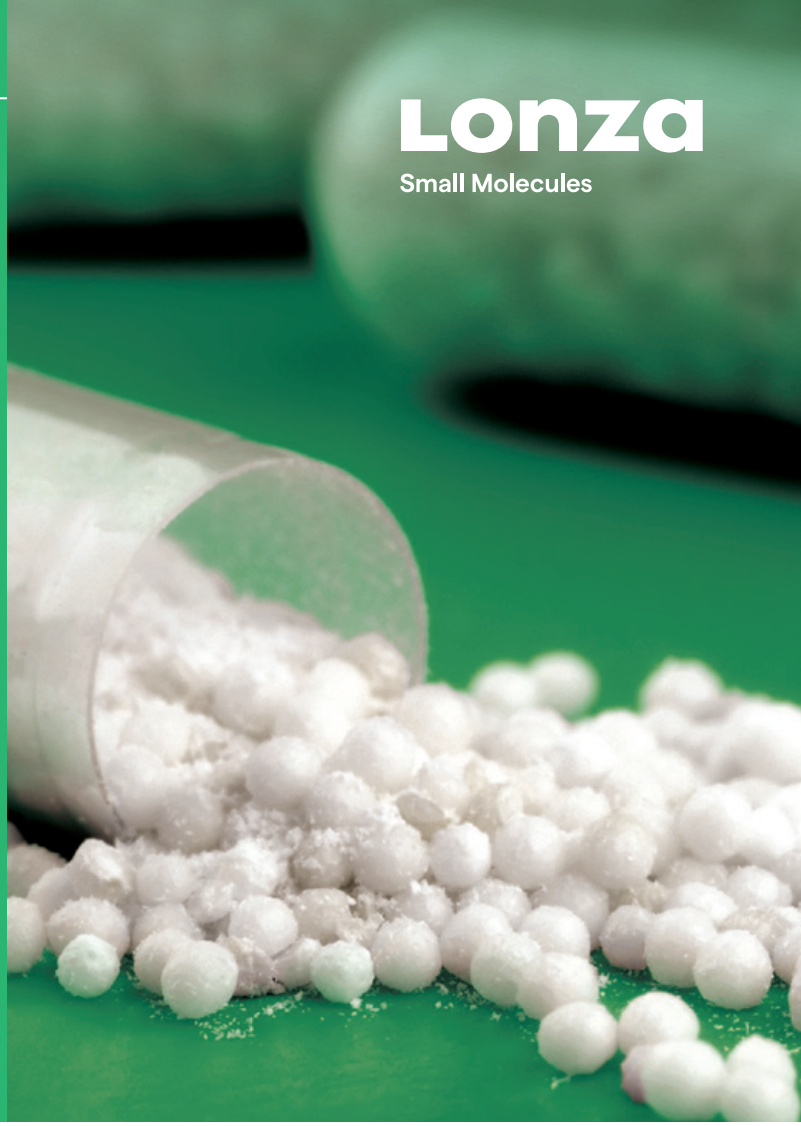
Enabling a Healthier World

Lonza
Small Molecules



Oral Multiparticulate Technologies

Greater flexibility for a broad range of formulation needs

Multiparticulates offer a number of advantages, including optimized, predictable gastrointestinal transit, formulation flexibility, and protection against dose dumping concerns. Multiparticulates offer a wide range of flexibility in the choice of manufacturing process and final dosage form. Lonza'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 or specialty dosage forms including 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. This approach 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 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

Table 1
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*	+
		IR/MR granules, wet/dry/melt granulation and extrusion spheronization	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.

Spray-layered multiparticulates (SLMs)

SLMs are layered spherical particles approximately 100 – 1000 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 modified release, tastemasking, high dose actives and fixed dose combination therapies. Bioavailability enhancement is also possible with the right choice of lipid excipients. LMPs are produced using a continuous spinning disc process, developed by Lonza, in which a drug is uniformly distributed within a carrier (typically, a biocompatible lipid or wax) with optional drug release-rate modifiers.

Granulation technologies

Granules are formed by building up particle architectures from smaller drug and excipient particles. Granulations are often polydisperse with sizes ranging from 50 – 1000 µm. These intermediates are ideal for encapulation or suspension dosing. Lonza offers several scalable granulation technologies including melt granulation, dry granulation by roller compaction and wet granulation in a top-spray configured fluidized bed.

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 multi-particulate 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 Lonza's oral multiparticulate technologies can help you meet your target product profiles.

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