

UltraBurst™

First-in-Class Flash ODT Platform for Direct Compression

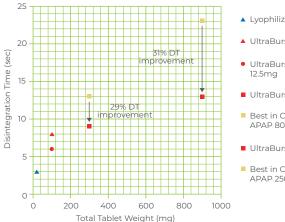
Your team works hard to create a product that patients want to take. SPI Pharma has an extensive history of providing innovative, patient-centric oral dose excipients and solutions to our customers within the global pharma and nutraceutical industries. Combining our orally-dispersible technology expertise with our recent innovations in polyol and excipient development, we deliver a premium platform to improve orally-disintegrating tablet (ODT) performance and patient experience.

UltraBurst is the first-ever, co-processed excipient platform for flash ODTs, delivering revolutionary results with an evolutionary process. UltraBurst is designed for direct compression and is easy to formulate, resulting in tablets with ultra-fast disintegration, low friability, and excellent organoleptics.

Flash Disintegration

UltraBurst improves disintegration time for ODTs of all sizes. It opens the door to faster disintegration for traditionally difficult-to-formulate APIs and smaller ODT tablets with higher API loads. The production of robust, ultra-fast disintegrating tablets in standard packaging is now possible.

Made from compendial excipients, the UltraBurst flash ODT platform requires minimal additional ingredients and enables customers to produce direct compression, fast-disintegrating tablets using standard machinery.



- ▲ Lyophilized Loratadine 10mg
- UltraBurst Loratadine 10mg
- UltraBurst Diphenhydramine 12.5mg
- UltraBurst APAP 80mg
- Best in Class Competitor APAP 80mg
- UltraBurst APAP 250mg
- Best in Class Competitor APAP 250mg

Disintegration versus hardness compared to other commercially available ODT platforms.

UltraBurst provides flash ODT performance for low-dose APIs using standard direct compression. Additionally, UltraBurst improves disintegration time vs. competitive direct compression preformulations across various tablet weights and API loadings.

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Tablet Robustness

Weight (mg)	Tablet Size FFBE mm	Compression Force (kN)	Thickness(mm)	Hardness (N)	Friability (%)	DT (sec)
50	6.2	0.5	1.6	15	0.3	3
100	7.0	1.4	2.4	30	0.1	5
150	8.7	2.1	2.4	29	0.1	6
200	9.5	3.0	2.7	30	0.2	9

UltraBurst produces tablets with exceedingly quick disintegration, best-in-class hardness, and low friability across a range of tablet sizes enabling standard packaging and avoiding bulky blister packs.

Content Uniformity

		Formula A mg/tab	Formula B mg/tab	Formula C mg/tab
	UltraBurst	60	60	60
Ingredient	DPH Resinate	38.5 (53μm)	38.5 (99µm)	38.5 (200µm)
	Magnesium stearate	1.5	1.5	1.5
	Total	100	100	100
	Min	98.9	95.1	96.3
Content	Max	102.8	99.1	103.3
Uniformity	Mean	100.9	97.5	99.6
	AV value (Limit 15)	2.9	4.3	5.5

To create maximum patient-centric value, ODTs often need to incorporate large, taste-masking APIs. UltraBurst rises to the challenge of incorporating a variety of API sizes while maintaining content uniformity.

Technical Support

UltraBurst opens doors that were previously closed to some formulators based on requirements like disintegration time or drug load (tablet size). If your team is unsure of where or how to start, SPI Pharma's customer-focused Technical Development Managers are here to help quickly and efficiently formulate your drug product.

Does your project require a bit more support due to aggressive timelines or technical demands? Our custom formulation services from our expert ODT formulators are available for a fee. **Request a sample and get started today.**



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