



SPI Pharma™

Making a Difference

An ABF Ingredients Company



SPI PHARMA'S

ULTRABURST™ EBOOK

**Develop ODTs in a FLASH
with UltraBurst™**





ULTRABURST™ : EVOLUTIONARY PROCESS, REVOLUTIONARY RESULTS

For the first time, flash-like disintegration performance is available in a direct compression preformulated platform. UltraBurst™ is designed for direct compression for low manufacturing costs.

Get The Benefits From This First In Class Direct Compression Platform:

- Easy to formulate
- Ultra-fast disintegration
- Low friability
- Excellent organoleptics

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WHAT WE DO



At SPI Pharma, we understand the challenges our customers face in developing patient friendly dosage forms that are effective, reliable, and safe. When you partner with us, you get solutions.



+75 YEARS OF EXPERIENCE

For over 75 years, we have supplied highly engineered products and innovative solutions that improve the formulation and delivery of drug products to meet patient needs. We are firmly committed to being a leading supplier to our pharmaceutical and nutritional customers worldwide.

LONG HISTORY OF PROVIDING INNOVATIVE, FUNCTIONAL INGREDIENTS AND SOLUTIONS



Market leader in immediate relief antacid actives and patient friendly dose forms



Excipients and services include deep expertise of our customer's applications



Innovative products and application solutions



TECHNOLOGIES AND EXPERIENCE TO HELP GET YOUR PRODUCT TO MARKET FASTER

Our technical expertise and innovative products support a full range of pharmaceutical applications. Whether you are looking to formulate a cost-effective antacid product, taste-mask your bitter active ingredient, develop an orally disintegrating line extension, or improve the mouth feel of your calcium or nutritional supplement, we can help.

SPI Pharma has significant experience formulating ODT's, helping to bring over 60 products to market using our technologies.

ODTs +
Flash ODTs

Chewable
Tablets

Powder
Sachets

60+

**Products
to
Markets**

Need a solution for a chewable tablet, effervescent product, or softgel formulation? **We do that too.**

When you partner with us, you are supported by experienced pharmacists and chemists who understand and can resolve formulation challenges to help get your product to market quicker.



INTRODUCING 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.

**Reduce
Costs**



**In-House Manufacturing
& No License Fees**

**Flash
Disintegration**



**Disintegration
Times Possible In
Less Than 10
Seconds**

**Expert Technical
Support**



**20+ years of ODT
Formulation Expertise**

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.

DEVELOPMENT APPROACH - KEY CONSIDERATIONS FORMULATING AN ODT

Developing ODTs requires a balance between:

- A fast disintegration time (<30 sec); <10 seconds may be even better for patients.
- Sufficient tablet strength to withstand packaging and transport; potentially pushing through a blister pack.
- Consider tablet strength, friability, drug type and loading.



New Product Development (NPD) of some ODTs is made more difficult by:

- Higher drug loadings.
- Larger tablet sizes – prolonged wetting times.
- Difficult to compress Active Pharmaceutical Ingredients (APIs) that are often coated for taste masking purposes.

Importance of Excellent Organoleptics

- Our platforms provide a smooth texture and a refreshing cooling sensation that can help to counter the poor taste of some APIs.
- Compliance is increased due to pleasant taste and mouthfeel.



WE INCORPORATE YOUR FORMULATION NEEDS

Disintegration time (DT)



- Limit set to 30 secs in US and 180 secs in EU, regardless of size, and this impacts compliance, dissolution and bioavailability.
- UltraBurst™ can deliver less than 10 second disintegration time.

Hardness



- No set definition but impacts DT, friability and dissolution.
- UltraBurst™ delivers best in class hardness.

Friability



- No set limit specific for ODTs (<1% for standard tablets).
- Physical integrity must be sufficient for packing, transport, and patient handling.
- UltraBurst™ delivers the best friability - typically delivers 0.1%.

Dissolution



- Linked to DT and API dependent; potential for pre gastric absorption.
- Could improve bioavailability of the drug.
- UltraBurst™ delivers the closest disintegration profile to lyophilization.

Palatability



- Greatly impacts patient adherence.
- UltraBurst™ delivers excellent organoleptics.

Process



- Manufactured by direct compression (DC).
- UltraBurst™ can reduce manufacturing costs.

ULTRABURST™ SOLVES PATIENT AND FORMULATOR NEEDS

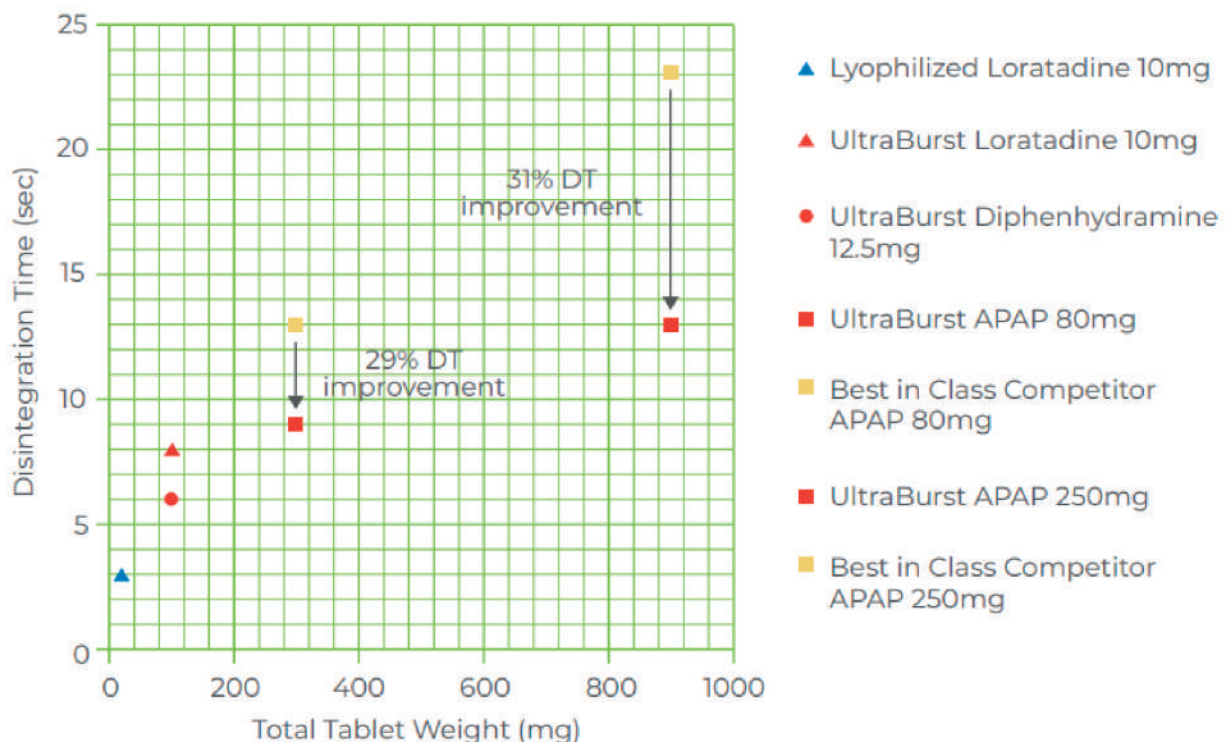


Combining our orally-dispersible technology expertise with our recent innovations in polyol and excipient development, we deliver a premium platform to improve orally-disintegrating tablet (ODT) performance and patient experience.

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.

Disintegration Versus Hardness Compared To Other Commercially Available ODT Platforms.



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.

UltraBurst™ has also been used in difficult formulations where no ODT was possible before!

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.



Placebo UltraBurst™ Tablets Robustness & Disintegration

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.

Great Content Uniformity With Model Drug

		Formula A mg/tab	Formula B mg/tab	Formula C mg/tab
Ingredient	UltraBurst	60	60	60
	DPH Resinate	38.5 (53µm)	38.5 (99µm)	38.5 (200µm)
	Magnesium stearate	1.5	1.5	1.5
	Total	100	100	100
Content Uniformity	Min	98.9	95.1	96.3
	Max	102.8	99.1	103.3
	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.



HOW WE WORK TOGETHER?

SPI Pharma's specialized ODT knowledge can complement your team, speeding development of new products.

ODT formulations require the proper balance between disintegration time and tablet robustness.

- Tablets must be hard enough to withstand production, storage, transportation, and being pushed out of a blister pack, yet will disintegrate as quickly as possible so patients can swallow their medication comfortably.

UltraBurst™ is the first direct compression, preformulated product solution to these challenges.

- Enables disintegration in under 10 seconds, while maintaining best-in-class hardness, friability, and API loading.
- Improves disintegration times across a wide range of API loadings and tablet weights.

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.



SPI PHARMA

As a global leader, we serve over 55 countries with formulation innovation, technical assistance, and troubleshooting support. Our products include antacid actives, excipients, taste-masking technology, drug delivery systems for tablets, fast-dissolve technologies, and a variety of other creative offers for patient-friendly dosage formats. We focus solely on the pharmaceutical market, ensuring our best-in-class products provide exceptional quality by meeting or exceeding global regulatory requirements.

As our company has evolved, so has our technology and innovative product lines. When you partner with us, you are supported by experienced pharmacists and chemists who understand and can resolve formulation challenges to help get your product to market quicker.

Contact us today to speak with one of our formulation experts. Let us help you create your next new product.

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