

Comparison of Directly Compressible Drug Delivery Systems for Orally Disintegrating Tablets



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Introduction

Offering ease of use and convenience, orally disintegrating tablets (ODTs) have become a preferred dosage form for consumers worldwide for many over-the-counter (OTC) medicines as well as prescription drugs.

Numerous ODT drug delivery systems (DDS) are currently available on the market. Their production poses three major challenges:

- The manufacture of robust tablets
- A very rapid disintegration rate (USP/EP DT <30 sec)
- A final formulation with smooth and pleasing organoleptic properties

To help drug manufacturers overcome the challenges of ODT production and meet the requirements shown in Figure 1, SPI Pharma has developed the Pharmaburst® 500 ODT platform. To demonstrate its performance and ready-to-use advantage in direct-compression tableting, Pharmaburst 500 placebo tablets were manufactured and compared against placebo tablets from three competitive systems manufactured under the same conditions.

Methodology

500 g blends of Pharmaburst 500, Product-L, Product-F, and Product-P were prepared by blending 97.5% of each ODT DDS with 2.5% sodium stearyl fumarate (Lubripharm, SPI Pharma) in an 8 qt V-blender at 25 rpm for 5 minutes. Subsequently, 400 mg of each blend was tableted on a GP-8 instrumented rotary tablet press outfitted with 0.4375" FFBE "D" punches operated at 25 rpm. Tablets were compressed at 5, 10, 15, 20, and 25 kN of compression force. Considered responses were hardness (kP), friability (%), and USP/EP (disintegration time (DT) in seconds).

Results

As shown in Figure 2, the results demonstrate that the Pharmaburst 500 system is more compactible than the studied competitive systems. Greater compaction provides for an increased dilution capacity. Additionally, the ability to manufacture robust tablets at lower compression forces reduces the stress that is applied to incorporate multiparticulates such as taste-masked actives—a common component of ODT formulations.

Figure 1: Optimum Requirements for an ODT DDS

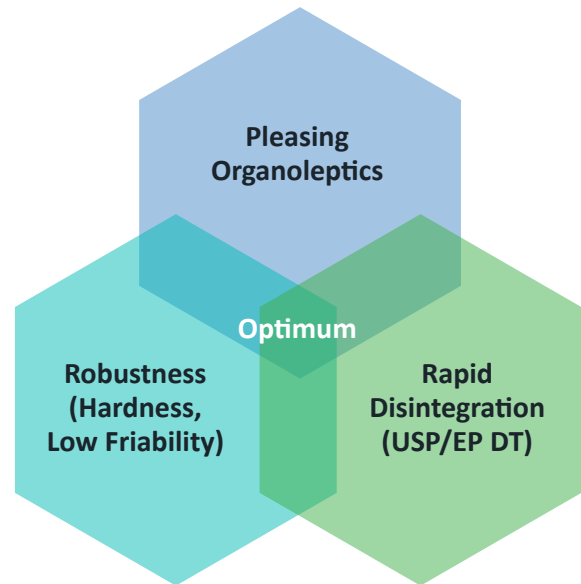
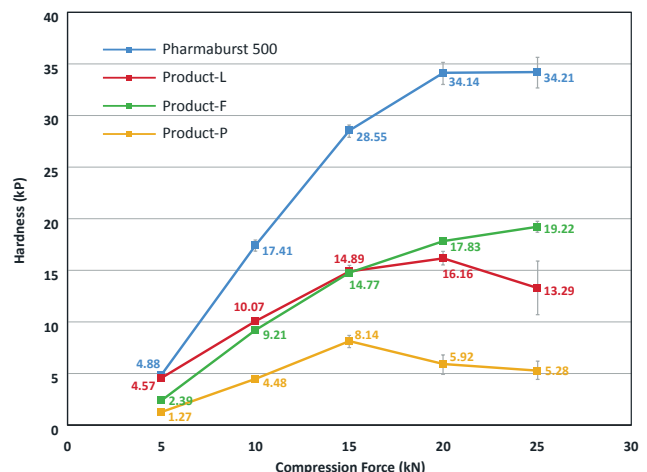
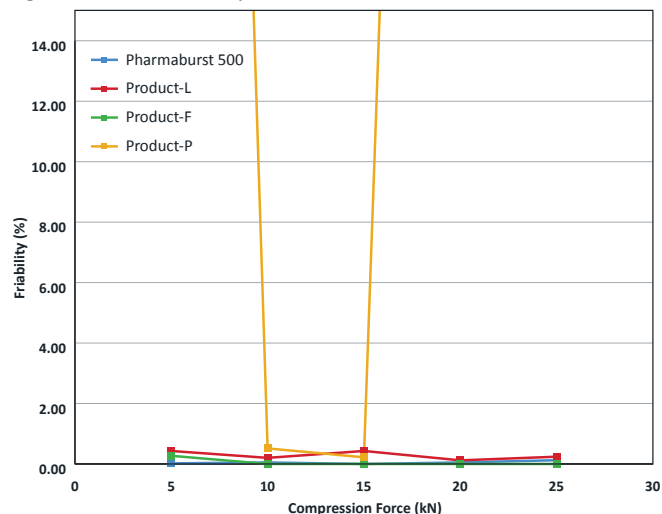


Figure 2: Tablet Hardness



The results displayed in Figure 3 show that Pharmaburst 500 exhibited the lowest friability of the four systems, followed by Product-F, Product-L, and Product-P. Product-P exhibited friability of 100% at 5, 20, and 25 kN compression forces. Pharmaburst 500, Product-L, and Product-F all exhibited friability below 1.0% over the study's compression range.

Figure 3: Tablet Friability

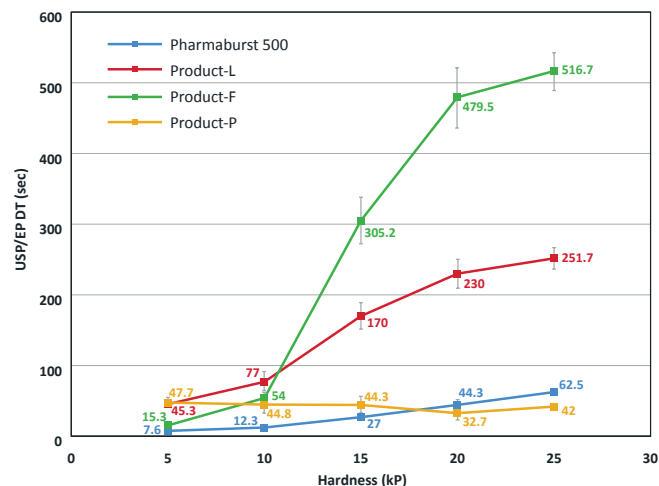


The results shown in Figure 4 indicate that the ODTs manufactured with Pharmaburst 500 were of higher hardness and disintegrated more rapidly than the competitive systems. At 15 kN of compression force, each tablet was compared for hardness (kP) and USP/EP (DT):

- Pharmaburst 500: 28.6 kP, 27 seconds
- Product-L: 16.2 kP, 170 seconds
- Product-F: 17.8 kP, 305 seconds
- Product-P: 8.1 kP, 42 seconds

The results demonstrate that Pharmaburst 500 is a true ready-to-use ODT drug delivery system. In contrast, the studied competitive systems would require the addition of an adjuvant to improve disintegration and/or compaction in order to meet the ODT requirements for robustness and/or disintegration time.

Figure 4: USP/EP Disintegration Time

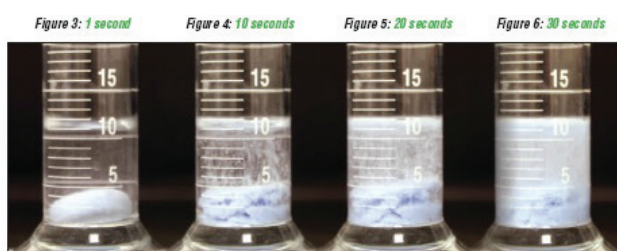


For more information

Visit www.pharmaburst.com to learn more about the Pharmaburst 500 ODT platform and the complete line of pharmaceutical formulation solutions from SPI Pharma.

Figure 5 shows the disintegration performance of a 1000 mg placebo tablet of Pharmaburst 500 with a hardness of 10 kP (made on a GP-8 rotary tablet press outfitted with 0.625" FFBE "D" punches). The tablet disintegrates completely within 30 seconds in just 10 mL of room temperature, non-agitated, deionized water.

Figure 5: Pharmaburst 500 Disintegration in 10mL of Water



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