Evaluation of Orally Disintegrating Tablets (ODTs) Using Precision Compressive Loading

The Challenge:

Quantify the Disintegration Rates of ODTs

Background

Orally disintegrating tablets (ODTs) are a new and exciting alternative to traditional tablet and liquid medication dosages. ODTs are a tablet form of medication that dissolves on the tongue, aided only by saliva. ODTs can dissolve in as little as 1 to 2 seconds or as long as 2 to 3 minutes, depending on the different fast dissolve/disintegration technologies used to manufacture the tablets.

ODTs are an appealing dosage form for many reasons. Health professionals find that ODTs are a good alternative where traditional tablet and liquid forms do not work. Pediatric, geriatric, bedridden, and developmentally disabled patients are especially well suited for this alternative to traditional tablets. Medications used for treating nausea, allergies, migraines, arthritis, depression, and schizophrenia are already available in ODT form.

Meeting the Challenge

Manufacturers and regulatory agencies can monitor the different fast dissolve/ disintegration technologies of ODTs using the ElectroForce® 3100 test instrument. The 3100 test instrument is a tabletop system designed for low force applications that require greater control resolution than typically available with moderate to high force test instruments. The goal of these tests was to simulate dissolving ODTs in the mouth. The tests monitored the disintegration of four different brands of ODTs under controlled conditions via force and displacement as a function of time.

ElectroForce® 3100 Test Instrument

Materials and Methods

Four different brands of ODTs were tested on the ElectroForce 3100 test instrument equipped with a 250 g load cell. Two brands, each manufactured with a different fast dissolve/disintegration technology, had an average disintegration time ranging from 1 to 20 seconds. The other two brands were also manufactured with different dissolve/disintegration technologies and had an average disintegration time ranging from 120 to 225 seconds. Force and displacement data as a function of time was recorded for each of the four ODTs tested.

ODT mounted onto test platen before loading.

Each ODT was placed on the lower platen on the ElectroForce 3100 test instrument. The lower platen was raised until a preload less than 10 mN was achieved on the ODT.

Approximately 5 mL of 37°C water was placed around the ODT to simulate disintegration of the tablet in the mouth. A ramp waveform was immediately run in load control using WinTest® software to achieve and maintain an end level of 10 mN at a rate of 0.1 N/s.

As the water reacted with the tablet and the tablet disintegrated, the Bose linear motor maintained a load of approximately 10 mN on the remainder of the tablet. Once the tablet was mostly or wholly dissolved, the test was manually stopped.

ODT after test is complete.

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Results

Figure 1 shows typical test results of an ODT whose dissolve time was approximately 20 seconds. A load of 10 mN was achieved on the tablet initially, and water was added to dissolve the ODT. However, the ODT dissolved very quickly in an effervescent manner. The load reading fluctuated during the quick dissolve period, and then a load of 10 mN was achieved on the effervesced remains of the tablet.

Figure 2 shows typical results of an ODT whose dissolve time was approximately 225 seconds. The 3100 test instrument achieved a load of 10 mN prior to the ODT dissolving. Just as with the ODT with the shorter dissolve time, the ODT dissolved in approximately 225 seconds, and the load reading fluctuated during the quick dissolve period. A load of 10 mN was achieved on the effervesced remains of the tablet.
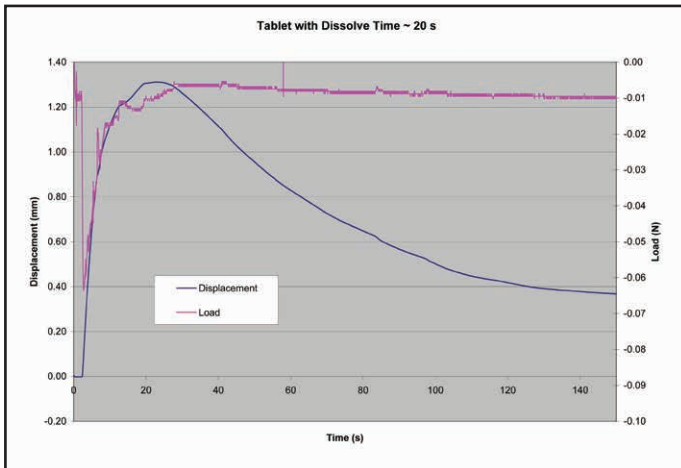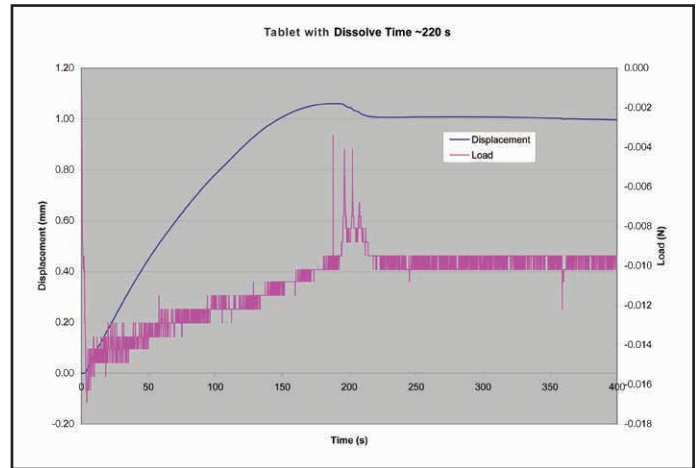
Figure 1

Figure 2

Summary

These tests demonstrate the ability of the ElectroForce 3100 test instrument to maintain desired low-force loads and measure small displacements while monitoring the disintegration of a variety of ODTs.

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