

PTWS1210 Tablet Dissolution Testing Instrument for Biowaiver Studies



Biowaiver Studies:

Enormous Cost Saving potential !

The Pharma Test 12 Position Dissolution System, PTWS 1210 with Vibration Absorbers is the Ideal Choice.

In Vivo studies may be replaced by in-vitro dissolution testing. This is referred to as a "Biowaiver" when this substitution is allowed by regulatory authorities. The cost reductions are enormous, ~\$300,000 for a BE study with in-vivo tests compared to ~\$2,000 for a Biowaiver study.

Requirements for a Biowaiver study are:

1. Allowance of regulatory authorities like FDA, WHO etc. (please find the FDA link below), Drugs should have high solubility and high permeability according to bio-pharmaceutics classification system (BCS I). Other classification systems are part of current investigations.
2. Dissolution Test in 3 different media (A. Buffer pH 1.2, SGF without enzymes or 0.1N HCl, B. Buffer pH 4.5, C. Buffer pH 6.8 or SIF without enzymes) all in 900ml and at 37°C
3. 12 Samples in each media, paddle 50rpm or basket 100rpm
4. Sampling time: 10, 15, 20, 30, 45 and 60 minutes.
5. The profiles of the test and reference products (for example original tablets if generic products are tested) must be similar (see point 6) in all three media.
6. The products are similar if the factor $f_2 \geq 50$ and both products show $\geq 85\%$ dissolution in 15 min.

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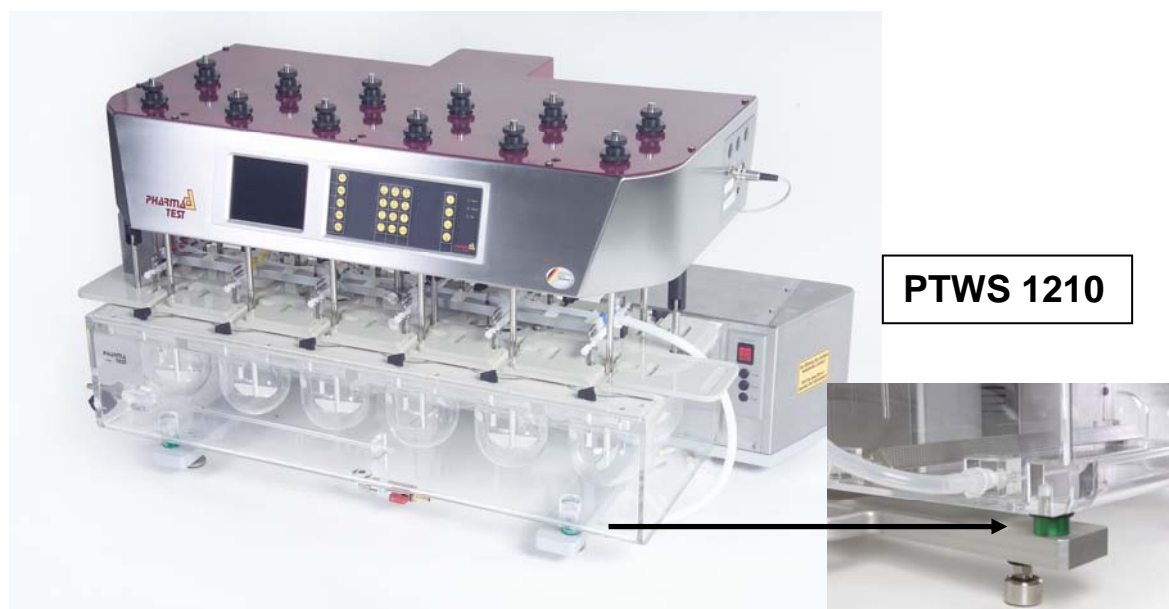
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FDA Guidance for Industry:

“Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System“

(<http://www.fda.gov/CDER/GUIDANCE/3618fnl.pdf>)

The ideal Choice for a Biowaiver Study is The Pharma Test 12 Vessel PTWS 1210 Dissolution System



Vibration Absorber

Advantages of the 12 Vessel Dissolution Tester:

1. Saves Time, get Results in half the time it takes to run tests on two separate baths.

Biowaiver Test (1 hr)	Conventional Dissolution Test (with 6 Vessel Bath)	Test with 12 Vessel Bath PTWS 1210
3 x Product Test	6hr	3hr
3 x Reference Test	6hr	3hr
Time needed	12hr	6hr

2. Saves Money, the PTWS 1210 is a lot less expensive compared to the cost of Two 6, 7 or 8 Vessel Dissolution Testers.

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3. Eliminates Variability, there are no Temperature, Stirring Speed, Start Point variations in one Twelve vessel PTWS1210 bath compared to the variability of Two 6,7 or 8 Vessel Dissolution Testers.
4. Less work, less documentation, only One instrument to Calibrate and Validate instead of Two.
5. Saves Space, much smaller foot print compared to two 6,7 or 8 Vessel Dissolution Testers)
6. Vibration Free, the 1210 has patented Shock Absorbers to eliminate any instrument or environmental vibrations that may affect dissolution rate.

The Pharma Test PTWS1210 Dissolution tester offers 12 Vessels in one bath. The instrument complies to all requirements given by the USP and EP Pharmacopoeias and even includes Vibration Absorbers to avoid vibrational influences coming from the environment (see picture) The importance of vibrational effects on Dissolution Tests is published in Dissolution Technologies May 2006 Page 8 "Challenges to the Dissolution Test, including Equipment Calibration" by Vivian Gray

Some extracts:

..... Historically, the calibrator tablets were developed because representatives from the FDA, USP, and the Pharmaceutical Manufacturers of America (now PhRMA) all agreed that vibration (internal and external) was influencing the dissolution results of products.....

..... It is well documented that vibration affects the dissolution results; in some cases, vibration biases the results high, giving a false passing result.....

.....We must also acknowledge that not all equipment on the global market is solidly designed....