

Standard Test Methods for Measuring Water Vapor Transmission Rate (WVTR) of Pharmaceutical Bottles and Blisters

PQRI's Container Closure Working Group together with ASTM International has published a new WVTR test standard for solid oral drug packages

The Container-Closure Working Group (CCWG) developed three new methods of test for water vapor transmission of solid oral drug packages. The methods were published by ASTM International in April, 2011 as D7709-11e1. **Standard Test Methods for Measuring Water Vapor Transmission Rate (WVTR) of Pharmaceutical Bottles and Blisters.**

Previous standard methods available did not provide a clear difference in performance among the high barrier multiple layer package forms – this one does. The methods in the standard minimize variability and allow clear discrimination among barrier packages currently available for pharmaceutical products. There is a method for bottles, another for high barrier blisters, and a third one for low barrier blisters, such as 5 to 10 mil PVC.

The test duration is 35 days at 40° C, 75% RH, making the test fast and aligned with ICH climatic conditions, increasing its usefulness for pharmaceutical manufacturers and regulators.

This standard provides a high degree of precision in the results by incorporating linear regression. Between-laboratory test results have yielded % RSDs as low as 3-5 percent for WVTRs in the range of 0.1 to 1.0 mg/day-package. These values are typical of coated and laminated barrier blisters currently in use.

Because all data are reported as mg/day-package, the standard provides a means for making a direct comparison between bottles (multiple dose packages) and blisters (single dose packages). The user of the method calculates WVTR values according to the number of doses contained in a stability-tested approved drug package. The WVTR data then become water gain per unit of medication regardless of the number of units in the package or type of package.

The CCWG members are confident that data obtained using D7709 can be used to characterize the WVTR properties of packages in which successful stability testing has been demonstrated (e.g. packages for FDA approved drugs on the market) . WVTR data for alternative packages can then be compared with the approved package to reduce the length of time and amount of resources required for choosing and testing alternative packaging for approved drugs.

The standard is based on WVTR research conducted by the CCWG during the years 2001 to 2010. The research reports are available at the CCWG's page on the PQRI web site, www.pqri.org.

The CCWG worked as a task group of ASTM committee D-10.32 while writing the standard. The standard is available from ASTM International for \$39. It can be obtained from ASTM at <http://www.astm.org/Standards/D7709htm>.

The working group urges all interested parties to obtain the standard and apply it to their evaluation of solid oral packages. Those who want further participation in application of this standard and development of other standards can join ASTM Subcommittee committee D 10.32 on Consumer, Pharmaceutical and Medical Packaging. To learn more, contact Kevin Shanahan at kshanahan@astm.org.