

The First Choice for Water Vapor Permeability Test of Drug Packaging - Weighing Method

Abstract: based on standard YBB00092003, this article deals with the test methods of water vapor permeability test of drug packaging. It also presents the data relationship of various test methods, the relationship between and developmental direction of weighing method and desiccant method.

Key words: drug, drug packaging, barrier property, water vapor permeability

Water vapor permeability is an important index in evaluating barrier property of materials and is no less important than auto gas permeability. Water vapor permeability can be tested with weighing method or sensor method. Weighing method, or cup method, is the basic method, while test data of sensor method should be calibrated by the data of cup method (including infrared method, dynamic relative humidity method and electrolytic method). Because the uniform data system of weighing method is adopted, data comparability of various methods becomes rather good. In 2003, the state Drug Administration issued YBB00092003 *Water Vapor Permeability Measurement*, which includes the first method cup method, the second method electrolytic method and the third method weight method. Among that, the first and the second methods are applicable to film, sheets and aluminum foil of drug packaging. The third method applies to drug container packaging.

1. Cup Method

Cup method (weighing method) can be further divided into the desiccant method and the water method. In the desiccant method (the method used in YBB00092003), there is desiccant in the permeable cup. Humidity of inner cup is considered as 0%RH and test condition is 38°C, 90%RH. In water method, the disk contains distilled water or saturated saline solution. If the cup is filled with distilled water, the humidity of inner permeable cup can be considered as 100%RH and test condition is 38°C, 10%RH. Principles of these two methods are basically the same, in either of which the specimen is sealed to the permeable cup and then the rate of water vapor movement through drug film, sheets or aluminum foil can be calculated with the tested weight variation. Therefore, test data of these two methods are the same, which is clearly specified in ASTM E 96.

Water method rises a little late than desiccant method. However, it has obvious advantages in some aspects. For example, inner permeable cup (when containing distilled water) of this method can maintain 100%RH for a long time. Since gas flow above the specimen carries away the water vapor, automatic test is easily realized.

Due to the upper adsorption limit of desiccant, the desiccant method is not able to realize full automatic test. In contrast, water method has great advantage in humidity controlling and has realized automatic test at present, thus has great development potential. Test environment of water method conforms to that of several other sensor methods (electrolytic method, infrared method and etc.), that is to say, on one side of specimen, stable humidity is provided with distilled water or saturated saline solution while the other side is the controlled dry environment. Moreover, such dryness can be stably controlled without interfering to the process of test. Therefore, test data of water method is more stable. It is for these reasons that water method becomes the development trend of weighing method.

2. Electrolytic Method

In electrolytic method, electrolytic cell is used as the humidity sensor. The gas transmission cell is divided into a dry chamber and a controlled-humidity chamber by film or sheet. Water vapor transmits through the specimen from the controlled-humidity chamber and then is carried away by the carrier gas into an electrolytic

cell, where the humidity of carrier gas is measured and the electric signal is outputted. Users now can calculate the permeance of water vapor. Note that sensor methods including electrolytic method should be calibrated with the data of cup method. Therefore the measured data is uniform with that of cup method.

There are two international standards on electrolytic method: ISO 15106-3 and DIN 53122-2. ISO 15106-3 is more comprehensive in content and wider in application. For this reason, ISO 15106-3 is recommended for electrolytic method testing.

3. Weight Method

Based on the specialty of drug packaging, weight method, or the third method of YBB00092003, can be further divided into three detailed test methods. Test principle of weight method originates from the first method: cup method. Thought weight method is simple in terms of test process, the time of test is much longer than that of film test.

4. The Application

Since all the test of container adopts the weight method, this author only introduces the application of film and sheets test based on the executive standards of drug container packaging (material).

Table1 Water vapor permeability test Methods of drug packaging

Number of Standard	Name of standard	YBB00092003		
		the first method cup method	the second method electrolytic method	the third method weight method
YBB00132002	general rules on laminated film and bag for drug packaging	√ ¹	×	×
YBB00152002	laminated film and bag of polyester/aluminum/polyethylene for drug packaging	√ ¹	×	×
YBB00172002	laminated film and bag of polyester/ low density polyethylene for drug packaging	√ ¹	×	×
YBB00182002	BOPP/ low density polyethylene laminated film and bag for drug packaging	√ ¹	×	×
YBB00192002	laminated sheet of polyamide/aluminum/polyethylene film for cold forging moulded drug	√ ¹	×	×
YBB00242002	general rules on multi-layer co-extrusion film , bag for transfusion	√ ¹	×	×
YBB00342002	laminated hard sheet of aluminum / polyethylene for cold forging moulded solid drug	√ ¹	×	√ ²
YBB00182004	laminated film and bag of BOPP/ Vacuum aluminum coated casting polypropylene for drug packaging	√	√	√
YBB00192004	laminated film and bag of cellophane	×	√	×

	paper/aluminum/ polypropylene for drug packaging			
YBB00202004	low density polyethylene film and bag for drug packaging	x	√	x
YBB00072005	three-layer co-extrusion film (I) ,bag for transfusion	√	x	x
YBB00102005	five-layer co-extrusion film (I) ,bag for transfusion	√	x	√
YBB00112005	polypropylene/polyethylene/polyvinylidene chloride for cold forging moulded solid drug packaging	√	x	√
YBB00202005	polypropylene hard sheet for solid drug packaging	√	x	x
YBB00212005	laminated hard sheet of polypropylene/polyvinylidene chloride for solid drug packaging	√	x	x
YBB00222005	laminated hard sheet of polypropylene/low density polyethylene for solid drug	√	x	x
YBB00232005	polyethylene/aluminum/ polyethylene laminated flexible ointment tube for drug packaging	√	x	x
YBB00252005	general rules on laminated film and bag for drug packaging	√	√	√

From table 1 we can see that almost all the water vapor permeability tests of drug packaging are based on weighing method. Only two kinds of materials require electrolytic method. Therefore, weighing method is the first choice for water vapor permeability test of flexible drug packaging .

5. Conclusion

At present, GB/T 1037-88 (weighing method) is the only national standard for water vapor permeability test and there is no sensor method standard in our country. Therefore, the introducing of electrolytic method for water vapor permeability test standards of drug packaging is a helpful supplement. Therefore, the selection of water vapor permeability testers based on weighing method can better satisfy the requirements of drug packaging test standards.