

Impact Resistance Testing of Medicine Package Material

Abstract: Falling ball impact test is the testing method of blister package material specified in medical standards. However there is less supply of relevant instruments. This article is about testing method and testing procedure of impact resistance testing in medical standard, and presents a brief description of the falling ball impact tester newly developed by Labthink special for medical package material.

Key words: blister package, PVC plate, complex plate, impact resistance, and falling ball.

Medicine blister package (PTP package) is widely used in mechanical package of solid pharmaceuticals such as tablet, capsule, pill and suppository. PVC plate is usually used as the base material. However, since last 90s, physallization material (such as PVDC plate, cold stamping material, PP plate and COC material) for new-type medical blister package with improved permeability and grade is gradually used in the fields of medical production.

1. Testing Method of Impact Resistance

Impact resistance is one of the important mechanical properties of material. In Impact resistance test, impact resistance of material is tested under impact load to determine the tenacity or break resistance of polymer material under high-speed impact. Different material or different purpose may adopt different impact testing method. The commonly used methods include pendulum impact test (including strut beam and over beam impact), falling dart impact test and falling ball impact test. In falling dart and falling ball impact testing, falling body (including falling dart, poise and binding ring) or steel ball impact the specimen falling freely from a specific height to test specimen impact resistance. Falling height and quality of falling body or steel ball will directly influence the test result. Shape and dimension of the plunger tip will also exert a tremendous influence to the result. Falling dart impact method is usually used in flexible package. The relating standard are GB 9639-88, ISO 7765-1, and ASTM D 1709-01. Falling dart uses hemisphere plunger tip with a longer slender rod to fix poise (see figure.1). It can be used for impact testing of plastic film or plate with thickness less than 1mm. Falling ball impact test is used in impact testing of some medical sheet material and building material.



Figure 1. Labthink BMC-B1 Falling Dart Impact Tester

2. Testing Requirements of Blister Package Material

Due to the particularity of medical storage, permeability and mechanical property of blister package has received special attention in recent years. This is because the two factors will influence the storage condition and guarantee period of medicine. At present, PVC complex plate is rather excellent in terms of permeability. Among that PVC/PE/PVDC and PVC/PVDC are comparatively commonly used.

To secure the safety and efficiency of medicine and to control the quality of package material, State Pharmaceutical Inspection Administration instituted corresponding standards of national medical package for the mainly used base materials in 2002 and made partial modification in 2005, namely standard YBB00202005 (PVC/PE/PVDC) of products, YBB00212005 (PVC), YBB00222005 (PVC/PVDC), and YBB00232005 (PVC/LDPE). Detailed index requirements and corresponding testing methods of various blister package material are elaborated in these standards. Manufacturers and users of materials should follow these standards to test performance index of blister package material.

3. Falling Ball Impact Testing of Base Material

Impact resistance of blister package material is an important index in the testing of blister package material. To strengthen quality control of medical package material effectively, the testing should be performed according to relevant standards strictly. By carefully analysis of the above-mentioned four standards of medical material, it can be easily found that impact resistance of sheet material are all tested using falling ball impact method instead of falling dart impact method. It is stated in the explanation of standard formulation that adoption of this method is based on the following two standards: GB 5663-85 medical polyvinyl

chloride (PVC) plate and GB/T 15267-94 polyvinyl chloride plate and film of food package, in which physical mechanical property is tested using falling ball impact method.

The first detailed requirement of impact resistance testing is to cut out five specimens of 150mm×50mm in lengthwise and crosswise direction respectively . Then test them in the same environment after state regulating in standard environment. While setting specimen, the PVDC face of PVC/PE/PVDC and PVC/PVDC material is upward. For PVC/LDPE material, the LDPE side is upward and there is no requirement for PVC plate. Fix the specimen on falling ball impact tester with the length of span being 100mm. Choose steel ball and falling height according to table 1 and table 2. Make the steel ball fall freely to the central part of length of span. Specimen failure should less than 2 in the direction of crosswise and lengthwise. Failure of specimen can be judged referring to the standard GB/T 15267-94, i.e., whether specimen is totally cut into more than two parts. Breakage specimen not being cutting into more than 2 parts is not considered as specimen failure. In addition, if the specimen breaks at the holding place, it should be retested according to the number of cutting off.

Table1. selection of steel ball and height of falling ball (PVC/LDPE)

Specimen thickness (mm)	Height of falling ball (mm)	Diameter of falling ball (mm)
0.10 ~ 0.20	300	23 (about 66g)
0.21 ~ 0.30	600	28.6 (about 100g)

Table2. selection of steel ball and height of falling ball (PVC/PE/PVDC , PVC , PVC/PVDC)

Specimen thickness (mm)	Height of falling ball (mm)	Diameter of falling ball (mm)
0.20 ~ 0.30	600	23 (about 66g)
0.31 ~ 0.40	600	28.6 (about 100g)

Although in some medical standards it is required that impact resistance of relevant sheet material should be tested using falling ball impact method, fewer domestic institutions can offer appropriate falling ball impact tester of medical sheet material. Falling ball impact tester in the market is mainly used for building sheet materials and it is very difficult for it to be used for impact resistance testing of blister package material.

At present, falling ball impact resistance tester developed by Labthink special for the impact resistance testing of medical package material completely conforms to the above-mentioned medical standard. Similar to BMC-B1 falling dart impact tester, falling ball impact tester also adopts electro-magnet to hold and release steel ball. Specimen is set and inserted in the

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pneumatic way. Falling height can be adjusted according to requirement conveniently and flexibly. In addition, the testing steel balling can totally meet the requirement of medical standards.