

4025 Examination Method of Drop for Plastic Packaging System

Plastic packaging system must have certain drop resistance when carrying functions such as pharmaceutical packaging, molding, storage, and use.

Drop resistance refers to the ability to withstand a free fall from a certain height after being simulated to used to package drugs.

This method applies to the drop resistance performance inspection of plastic packaging system for injections, plastic bottle system for oral or topical liquid preparations and other products.

Sample Pre-treatment Depending on the anticipated use of the samples, they should be pre-treated as per the methods outlined in the table 1.

Determination Pre-treated samples should be dropped with the bottle mouth facing up (**bags should be laid flat**) from the heights specified in Table 1 onto a hard, rigid, and smooth surface to observe if there are any instances of leakage or rupture.

Table 1 Sample Pre-treatment Methods and Drop Heights

Type of Pharmaceutical Packaging Material	Sample Pre-treatment Method	Indicated Capacity (ml)	Drop Height (m)
plastic packaging system for injections	Take a sufficient number of samples filled and sterilized with injection water filtered through a 0.45 μ m pore size filter membrane up to the indicated capacity, sealed, and sterilized using a moist heat sterilization method. Place them at -25 $^{\circ}$ C \pm 2 $^{\circ}$ C for 24 hours, then at 50 $^{\circ}$ C \pm 2 $^{\circ}$ C for another 24 hours, and finally at 23 $^{\circ}$ C \pm 2 $^{\circ}$ C for an additional 24 hours	50~749	1.00
		75~1000	0.75
plastic bottle system for oral or topical liquid preparations	Take several samples, fill with water up to the indicated capacity, tighten the bottle and cap using a force meter or force device, considering the size of the bottle cap and practical circumstances, apply an appropriate torque range (reference value 25-180N·cm)	<120	1.20
		\geq 120	1.00

[Note] 1. For samples with special specifications (such as >1000ml, etc.), if applicable, the appropriate drop height can be executed according to the requirements of the manufacturer and user for the product's drop resistance, referring to the pre-treatment method in this law.

2. Plastic containers that have already been filled with drugs do not require pre-treatment.