4212 Determination of Ethanol Vapor Transmission for Pharmaceutical Plastic Containers

This method is applied to determine the transmission of ethanol vapor in pharmaceutical plastic containers containing alcoholic preparations used in topical liquid medicines and pharmaceutical plastic composite tubes containing alcoholic preparations in topical ointments.

Sample preparation: Take appropriate amount of the sample, weighed accurately, add 50% ethanol to the bottle (tube) to the nominal capacity, and tighten the cap of the bottle (tube) [Heat to seal the tail of the bottle (tube) with a heat sealer at 140～170□ and 0.2～0.4MPa for 2 seconds. Or customize heat sealing conditions and sealing methods according to the characteristics of the product, process and production equipment].

Table 1 Torque of cap in bottle or tube

Cap Diameter（mm）	Torque（N•cm）
15~20	25~110
21~30	25~145
31~40	25~180

Note 1: For the pharmaceutical plastic bottles with screw caps in topical liquid medicines, tighten the screw cap with appropriate torque (see Table 1)

Note 2: For the pharmaceutical plastic composite tubes in topical ointments, in order to ensure the sealing of the tube mouth, tighten the tube cap and the tube body with appropriate torque according to the shape and size of the composite tubes when necessary.

Determination Weigh accurately the prepared test sample and leave for 7 days at 40±2□. Cool to room temperature and weigh accurately immediately. Calculate the transmission of ethanol vapor according the formula below:

$$\text{The Transmission of ethanol vapor} = \frac{W_1 - W_2}{W_1 - W_0} \times 100\%$$

Where: W_0 is the weight of empty container, g;

W_1 is the weight of the container and solvent before test, g;

W_2 is the weight of the container and solvent after test, g.