4227 Determination of Silicone Oil Content for Prefilled Syringes

Silicone oil is a commonly used lubricant for lubricating the inner surface of syringe barrel for prefilled syringes to improve gliding properties. This method applies to the determination of silicone oil content for prefilled syringe barrels.

Instruments: Balance with an accuracy of 0.1mg, oven and water bath.

Determination: Take a suitable number of syringe barrels to be tested, add silicone solvent (such as ethyl acetate, analytically pure) to the curling edge of the syringe barrel, allow to stand for 5 minutes to dissolve the silicone oil, pour the silicone solvent into the same evaporating dish (m_{11}) previously dried to constant weight, and then add 1ml of silicone solvent to each syringe barrel, wash the inner surface of the syringe barrel, and combine the solvent into the evaporation dish mentioned above, and use as the test solution. Then evaporate to dryness on a water bath, transfer to the oven, dry at 105℃ to constant weight (m_{12}).

Transfer the same volume of silicone solvent of the same batch to an evaporating dish (m_{01}) previously dried to constant weight, and use as the blank solution. Then evaporate to dryness on a water bath, transfer to the oven, dry at 105℃ to constant weight (m_{02}).

Calculate the average silicone oil content per prefilled syringe barrel by the following expression.

$$M=\frac{[(m_{12}-m_{11})-(m_{02}-m_{01})]}{n}\times 1000$$

where M is the average silicone oil content per prefilled syringe barrel, mg/piece;

m_{11} is the mass of the evaporating dish without the test solution, g.

m_{12} is the mass of the evaporating dish with the test solution, g.

m_{01} is the mass of the evaporating dish without the blank solution, g.

m_{02} is the mass of the evaporating dish with the blank solution, g.

n is the number of the test samples.

起草单位：山东省医疗器械和药品包装检验研究院　　联系电话：0531-82682912

参与单位：上海市食品药品包装材料测试所、山东威高普瑞医药包装有限公司、山东省药用玻璃有限公司、宁波正力药品包装有限公司、山东永聚医药科技有限公司、肖特玻璃科技（浙江）有限公司、碧迪医疗器械（上海）有限公司