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The Analysis and Test of Key Index of Multi-chamber Infusion Bags

Abstract: multi-chamber infusion bag is one of the main trends in future soft plastic infusion bags. Multi-chamber bags own many incomparable advantages against infusion bottles and single-chamber bags. 'Rosin joint' technique is the key technology of contemporary multi-chamber bags. The barrier property of infusion bags is the key data to assess the safety of medicine. This article intends to introduce the analysis method of multi-chamber infusion bags index.

Key Words: multi-chamber, infusion bags, non-PVC, rosin joint, barrier property

Glass bottles, soft plastic infusion bottles, soft plastic infusion bags are main infusion containers. Speaking of safety, convenience and transportation, glass bottles can never get rid of the common defects of glasses and the exterior pollution thus glass bottles are falling into disuse. Soft plastic bottles can neither avoid exterior pollution and they became transitional packages to soft plastic infusion bags. Only soft plastic infusion bags became increasingly popular. Especially the successful development of non-PVC multi-layer infusion bags, it completely avoided the safety problem (which was the biggest hindrance for wide application). As a result soft plastic infusion bags successfully replaced glass bottles and soft plastic bottles in some aspects. Such new products also provide a better environment for convenient medical service. Non-PVC multi-chamber soft package infusion products—multi-chamber infusion bag is commonly recognized one of the most promising new packaging.

1. Multi-Chamber Infusion Bag Introduction

Multi-chamber infusion bag refers to the kind that, contents are kept in separate chambers in the process of production, transportation and storage. Medical liquid is filled under strict aseptic environment. When it is used the chambers can be pushed open to each other by exterior force. When chambers are connected medicines are mixed in seconds, which soon can be used for patients. Multi-chamber infusion bags have significant advantages such as easier and more accurate medicine dispensation; safe and closed environment can avoid microbial contamination and impure particles in mixed injection liquid (which is a solution to the disadvantage of traditional infusion bottle, the interior and exterior pollution). Multi-chamber bags can also be applied in emergency and efficiently reduce fault operation. This kind of package is very practical in solving the problem that contents cannot be mixed for a long time. It is important to improve the safety and convenience of infusion treatment. Currently there are two kinds of multi-chamber bags, which are multi-liquid chamber bags, and liquid and solid chamber bags. Multi-liquid chamber bags can improve the stability of medicine dispensation, and liquid and solid chamber bags can reduce the instability of liquid and solid mixture.

Although this kind of big infusion product looks simple, its production technique is important. Such as multi-chamber jointing, the connection of joints and antisepsis technique etc. Among all of those techniques, the sealing between each chamber is a very important process of this dosage form. Sealing needs to satisfy two opposite functions—it should absolutely protect contents from leaking into other chambers before use, and it should ensure the workability between chambers in use. Currently such kind of sealing is achieved by rosin jointing.

2. Special Test Items to Multi-Chamber Infusion Bag

Infusion bag material belongs to I class medical packaging. Packaging material directly contact with medical liquid, it has strong impact to the stability of medicine. Infusion bag tests mainly focus on non-PVC multi-layer soft bags. Its transferability, vapor permeability, toxity, hemolysis and bacterial endotoxin will be tested. Besides, the

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unlock force, piercing force, hanging force, stability after piercing, sealing performance of filling point are also important test items. However from the perspective of usability, the control and test of rosin jointing strength (hot sealing strength) of multi-chamber infusion bags is more important.

2.1 'Rosin Joint' Strength

Multi-chamber infusion bags are mainly used to prepare medicines which may become unstable after mixing or difficult to reserve. Chambers should remain absolutely separate to each other before use, thus the strength of rosin jointing must be stronger than a certain level. However, the strength of rosin jointing can not be too strong either. Multi-chamber infusion bags should be convenient to use and applicable in emergency. If rosin jointing is too strong, medical personnel cannot connect chambers conveniently (usual press to connect), the convenience of such package will be lowered.

Rosin jointing strength can be indicated by testing the tensile property of designated hot sealing area, or the swelling force of hot sealing strength of whole bag. Ordinary tensile test machine gets test results under the condition that sample material was pulled by even force (such as peeling) to identical direction. The result indicates the sample's ability to maintain unseparated. It is usually use to assess the openness of packages. As to multi-chamber infusion bags, which open the rosin joints by pressure, the pressure force direction and level are not as definite as tensile tests. Moreover, the rosin joints may deform under pressure. Thus, I believe that the swelling test of whole bag (leakage and sealing performance tester can be used, such as the Labthink PARAMTM LSSD-01 Leakage and Sealing Performance Tester) is more useful than testing single chamber to gain data on the hot sealing performance of rosin joints (sample can be unfilled bags or filled bags). Swelling hot sealing performance is more capable to represent the actual rosin jointing strength of multi-chamber infusion bags. Furthermore, whole bag swelling test can also provide the location data of the weakest place of whole bag, which is useful to improve production techniques. It should be noticed that swelling hot sealing strength cannot represent the average strength of hot sealing. It has nothing to do with the tensile strength of hot sealing.

2.2 Barrier Properties

Soft plastic infusion bag has many advantages though it is deficient in barrier property. Oxygen is the main factor causing deterioration of medicine. The permeation of water vapor can cause the concentration change of medicine. Both of these endanger the safety of medicine. Thus in YBB 00102005 'Three Layer Infusion Bag Film (I), Bag' and YBB 00112005 'Five Layer Infusion Bag Film (I), Bag', standards for barrier property test are clearly set. Standards are set for water vapor permeation rate of infusion bags; water vapor, oxygen, nitrogen permeation rate of bag films. Oxygen permeation rate of infusion bags is not included in the standards. I believe there are three reasons for this: first, there is no relevant international standard by the time of drafts, though the technology of testing whole infusion bag oxygen permeation rate is ready. Second, the oxygen permeation rate of infusion bag is relatively big. As there is tensile test technique, some material with strong barrier property (such as aluminum foil and aluminum plated film) cannot be applied, and some new materials did not pass SFDA test yet. Third, multi-chamber infusion bag has packages, thus if the package owns strong barrier property against oxygen, oxygen can be efficiently retained outside. However, we need to know the barrier property of multi-chamber infusion bags thoroughly (including the bag and its material) in order to reasonably, accurately and efficiently choose the packaging material, and avoid design defects and medicine deterioration.

The actual test method depends on test sample. To infusion use film, differential-pressure method or equal pressure method can be used to test its oxygen permeation rate. Considering the test requirement of nitrogen permeation, equal pressure method equipment (which can test the permeation rate of many kinds of gas) is more

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practical. Sample's water vapor permeation rate can be tested by weighing method or sensor method equipment. To infusion bags, sensor method equipment is the best to test vapor permeation rate (such as Labthink PERMETM W3/330 Vapor Permeation Rate Test System). Equal pressure method equipment is the only option to test bag's oxygen permeation rate (such as Labthink PERMETM OX2/230 Oxygen Permeation Rate Test System).

It should be noted that the compatibility between medical packaging material and medicine has always been a key test item. The test is intended to find out if there is any phenomenon of transfer or adsorption between packaging material and medicine. It is illuminating for choosing proper packaging material and form. Barrier property test is one of key test items in compatibility test between plastic materials and medicine. Its test result is also key data to assess the safety level of medicine.

2.3 Mechanics Test

Multi-chamber infusion bag significantly improved the functions of ordinary infusion bags. It is one of the most strictly produced packaging forms. Its indexes (such as tensile property, extensibility, bag-ring opening force, piercing force, hanging force, maintaining property after piercing, and sealing property of filling point) all need tests.

3.Summary

Multi-chamber infusion bag is one of the trends in soft plastic infusion bag development; it owns incomparable advantages against infusion bottles and single chamber infusion bags. Rosin jointing is the key technique in current multi-chamber infusion bag manufacture. I believe it is very meaningful to conduct whole bag swelling test and gain the bag's hot sealing strength. Infusion bag standards do not require the oxygen permeation rate of bags; however the result of this test is one of the key data to assess the safety level of medicine. Test efficiency and equipment practicability both should be considered when someone is choosing barrier property test equipments. Film and bag capable, oxygen and vapor permeation test capable equipments should be put to priority.