

Overall Realization of Comprehensive Mechanical Testing on Pharmaceutical Packaging and Medical Devices

Abstract: New materials and new solutions are enjoying increasing applications in the field of pharmaceutical packaging and medical devices; yet, the limitations of existing testers are becoming acute. Thus, how to eliminate deviations caused by changes of standards, materials and external forms, is greatly concerned by manufacturers and testing institutions. Based on the situation, Labthink has proposed a set of solutions, which can not only enhance instrument applications, but also have advantageous features in testing range, costs, maintenance, operation safety, structural optimization and extended applications, etc.

Keywords: pharmaceutical packaging, medical devices, syringe, syringe needle, ampoule

Pharmaceutical packaging and medical devices are directly linked to life and its safety; a high standard for their safety is set forth with strict and complete testing requirements. However, owing to the variety of pharmaceutical packaging and the complexity of external forms of medical devices, a full set of tests for one specimen needs testing several items with several testers. Moreover, because of the unique external forms of the specimen, the instrumental compatibility is not ideal. Besides, the change of standards, replacement of materials and variation of external forms, have brought about new subjects for manufacturers and testing institutions.

1. Limitations of Specialized Testers

At present, new materials, new packaging forms and new external designs have found their applications in the fields of pharmaceutical packaging and medical devices. Such new developments are beneficial to offset the existing defects in traditional packaging forms, which make specialized testers devalued with the changing product design. At the same time, re-development of those testers based on new standards is costly.

Take rubber stopper as an example, which is one of the important parts of the glass IV bottle. It's strictly required in standards for the parameters of rubber stoppers. However, with the popularization of plastic IV bottle and bags, rubber stoppers and glass IV bottles are gradually disappearing. Correspondingly, the specialized testing instruments for rubber stoppers are less likely to be used, or even abandoned.

2. Labthink Testing Solutions

Based on the development of pharmaceutical packaging and medical devices, Labthink introduces MED-01 Medical Packaging Tester, an instrument for testing pharmaceutical packaging and medical devices. The instrument applies to the mechanical property testing of syringe, hypodermic needle, ampoule, rubber stopper and flexible medical pouches, such as PVC blood pouches and platelet bag as well as single or double chamber IV bags, etc. The testing subjects can be further increased. Though varied in external forms and different in materials, they share generality in structure for mechanical testing. Therefore, the development of an instrument with multiple testing components is feasible for the new testing demands.



Labthink MED-01 Medical Packaging Tester can test piercing force of rubber stoppers and syringe needles, breaking force of ampoule, external-pressurized sealability of flexible plastic containers, combination force of syringe barrel and needle hub, unmating force of needle shield, sliding performance of plug stopper and dovetail property, etc. This newly developed instrument is in strict compliance with YBB00042005, *Halogenated Butyl Rubber Stopper for Injection*, GB 15811-2001, *Sterile Hypodermic Needles for Single Use*, YY 0613-2007, *Blood Components Separation Sets for Single Use, Centrifuge Bag Type*, YBB00112004, *Assemblages for Prefilled Syringes (with Stainless Steel Needles)*, and GB 15810-2001, *Sterile Hypodermic Syringe for Single Use*.

3. The Distinguished Features of MED-01 Medical Packaging Tester

Limitations of the previous specialized testers have been successfully overcome by Labthink MED-01 Medical Packaging Tester which can test seven testing items and has the following outstanding features:

3.1 Broad Range of Testing Subjects

It's common to see instruments of similar principles but irregular testing ranges and precisions, which has direct links to the varied progress of different standards. However, the selection of the tester based on just one standard would probably lead to future discrepancy between the purchased instruments and the latest revision of the standards. Thus, many standards of pharmaceutical packaging and medical devices have been comprehensively taken into consideration in designing the instrument, and the highest precisions, the broadest testing ranges are selected as the basis for development. Meanwhile, multiple testing ranges are available so as to satisfy testing demands of varied standards with better practicability. Therefore, MED-01 Medical Packaging Tester applies to testing pharmaceutical packaging and medical devices, including syringe, syringe needle, flexible medical pouches, ampoule and rubber stopper, etc.

3.2 Low Testing Costs

Sensor is the core of testers for mechanics, and one of the most expensive components in the testers. When developing this tester, Labthink didn't just compile the mechanical testing items together, but selected on certain terms so as to strengthen the practicability of each sensor, to eliminate useless configuration and to reduce

instrumental costs. Moreover, though multiple testing items are configured, addition or deletion of configuration is available. Thus, quantity of the instruments can be reduced, which can facilitate instrumental management and save spaces in the labs. Meanwhile, owing to the regular calibration requirements for mechanical testers, MED-01 Medical Packaging Tester can significantly reduce expenditure on calibration for its 8-in-one functional design.

3.3 Powerful Software

MED-01 Medical Packaging Tester is equipped with powerful software for its operation. The software can display real time data, testing results and curves as well as multiple data comparison and analysis. At the same time, languages and units are easy to select, and the pre-installed help documents can be referred to at any times. Combining the powerful environmental and energy monitoring functions of the instrument, the software can provide operators with energy consumption records and its curve analysis, utility rate of the instrument and statistics on testing frequencies, etc.

3.4 Innovative Design for Operational Safety

Some samples are tested with contents or substitutes. Tests like breaking strength test of ampoules and pressure resistance test of IV bags or blood pouches would accomplish with the destruction of the samples. It's not rare to see reagent contents or sample fragments splashed onto the operators' clothes or left in the testers, which lead to difficulties in clearing the instruments and endanger the operators. Thus, engineers from Labthink developed testing chamber with protective functions, which can prevent most of the potential dangers, and rid the instrument of clearing reagents or substitute left inside. By this means, there is no need to clean the instrument, and effectively diminish instrumental destruction caused by improper protection.

3.5 Excellent Testing Expandability

The packaging materials and packaging forms are under gradual changes for pharmaceutical packaging and medical devices. Such changes would inevitably bring forth replacement of the out-dated instruments. Thus, the focus for most testing institutions is how to satisfy present testing needs while guarantee testing expandability. When developing MED-01 Medical Packaging Tester, Labthink have fully taken into consideration the functional expandability, so as to facilitate adding testing samples, increasing testing items and improving testing parameters. In this way, the operators can, based on their practical needs, fulfill testing demands by adding or changing testing fixtures or parts.

Labthink have developed more than 40 sets of professional fixtures for MED-01 Medical Packaging Tester that can greatly expand the testing fields, including pharmaceutical packaging, medical devices, film, food packaging and special packaging forms, etc. Besides, new testing demands can be satisfied by customized testing fixtures.

4. Conclusions

Labthink MED-01 Medical Packaging Tester is a specialized instrument to solve the problems of manifold testing items for pharmaceutical packaging and medical devices and the corresponding high costs. The instrument can accomplish several testing items that can greatly relieve financial burdens and reduce maintenance costs of testing institutions so that instrumental utility ratio can be improved. The practical, scientific and considerate design of the instrument is also advantageous in future expandability of testing items and compatibility of more subjects to be tested, so as to expand testing scopes to the utmost and eliminate influences brought by changes of standards, materials or external forms.