

***Application Note***

**Abrasion Test on Medical Packaging**



*by David Ziltener, Tribotron AG*

## Introduction

Labels for medical or pharmaceutical products contain critical information that must maintain its readability if the products are to be useful for specialists and safe for end users. Therefore, abrasion resistant printing is required in multiple guidelines for the manufacturing of medical products.

For example, the European Union's Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use states:

***“Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.”***

Another example, created to protect against falsified medicines and recently added to the German coding rules from SecurPharm, states:

***“... for a print quality of at least 1.5 pursuant to ISO/IEC 15415 ... MAH has to take into account the wear and tear of printing.”***

## Abrasion Resistance of Printing

The abrasion resistance of printing most often depends on the substrate surface, the printing media (e.g. ink), and the parameters of the printing process itself rather than the method of printing.

In order to determine the best materials and process parameters, an appropriate and reliable testing method is required. The IEC 68-2-70 “Abrasion of markings and letterings caused by rubbing of fingers and hands” describes an ideal test method for the packaging materials of the medical market.

IDT Biologika GmbH in Germany and Tribotron have developed internal standards to test printing and packaging according to the IEC 68-2-70 for compliance with the latest GMP and SecurPharm standards.

## Hand Abrasion Test according to IEC 68-2-70

This standard describes a method of test applicable to markings and lettering on flat or curved surfaces which in service are subjected to rubbing forces caused by the fingers or other parts of the hand.

Hand abrasion is a very complex chemical and mechanical stress on the surface. The TRIBOTOUCH instrument simulates this stress under real conditions according to international standards. Furthermore, the versatile setup of the TRIBOTOUCH allows users to reproduce specific chemical environments by adding artificial sweat, hand cream or antiseptic fluid.

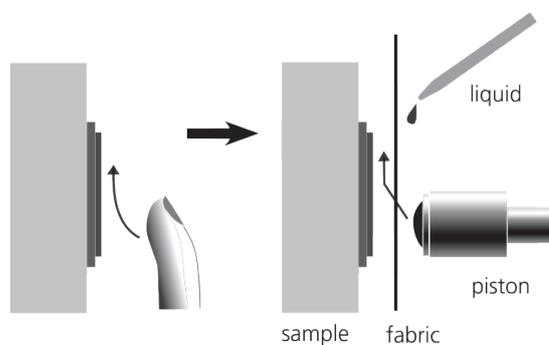


Figure 1: Principle of the hand abrasion

## Testing of Labels

For verification purposes IDT Biologika has produced special labels that have been tested with the standard setup according to IEC. The following example demonstrates inadequate printing quality after 30 testing cycles. Even though many medical products will never experience physical touching that is equivalent to 30 testing cycles, the packaging is also exposed to abrasion during manufacturing and transportation, so a security tolerance should be implemented.

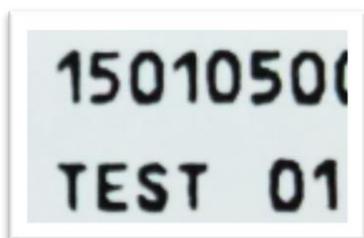


Figure 2: Test label "new"

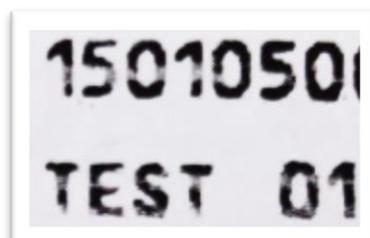


Figure 3: Test label after 15 testing cycles

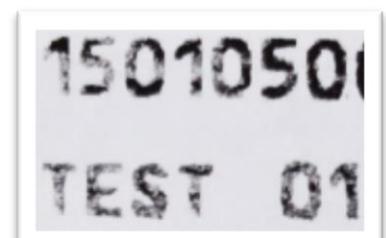


Figure 4: Test label after 30 testing cycles

## Summary

The TRIBOTOUCH is an ideal instrument to test the abrasion resistance of packaging and labels of medical products. It can be used for design verification, for definition of printing parameters and for continuous quality control of the manufacturing process. The TRIBOTOUCH features real life testing on finished products or lab samples.

The TRIBOTOUCH is qualified in the medical marked and in use for this application.



*Figure 5: TRIBOTOUCH hand abrasion simulator*

For more information on the TRIBOTOUCH, please visit: [tribotouch.com](http://tribotouch.com)