研究题目:
Research Topic:

杜邦™特卫强®医疗包装转换项目
特性功能等同性及非劣性的验证报告
Validation Report of Functional Equivalence and Non-inferiority for the DuPont™ Tyvek® Medical Packaging Transition Project

试验样品：DuPont™ Tyvek® 1073B & DuPont™ Tyvek® 1059B
Test Samples: DuPont™ Tyvek® 1073B & DuPont™ Tyvek® 1059B

最终报告日期：2013年12月24日
Final Report Issued on: December 24th, 2013

研究实验室:
Research Laboratory:
国家食品药品监督管理局济南医疗器械质量监督检验中心
CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices
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原始记录保存地:
Original Records Retained at:
国家食品药品监督管理局济南医疗器械质量监督检验中心
CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices

委托方
Principal
杜邦（中国）研发管理有限公司
DuPont (China) Research & Development and Management Co., Ltd.
上海市浦东新区张江高科技园区蔡伦路600号
No. 600, Cailun Road, Zhangjiang Hi-Tech Park, Pudong New District, Shanghai
1. Introduction

To meet the growing demands and ensure greater continuity and flexibility of future supply, DuPont will be transitioning the DuPont™ Tyvek® 1073B and DuPont™ Tyvek® 1059B styles to manufacturing lines using the latest flash-spinning technology. CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices and DuPont (China) Research & Development and Management Co., Ltd. are working together to demonstrate the functional equivalence and non-inferiority of DuPont™ Tyvek® products manufactured with DuPont’s latest flash spinning technology and current manufactured DuPont™ Tyvek® products. The testing items include: Basis Weight, Gurley Hill Porosity, Mullen Burst, Tensile Strength, Delamination, Hydrostatic Head, and Microbial Barrier. This report provides the assessment on test samples and control samples according to the acceptance criteria of functional equivalence and non-inferiority provided by DuPont.

 Tested by and reviewed by:

张鹏
Zhang Peng

王文庆
Wang Wenqing

Approved by:

钱承玉
Qian Chengyu

结束日期
Date
2013.12.27

研究室主任
Director of Research
2.1 Overview

Manufacturer: DuPont (USA)

Items: Tyvek® 1059B test samples and control samples; Tyvek® 1073B test samples and control samples;

(Test samples: DuPont™ Tyvek® products manufactured with the latest flash spinning technology; Control samples: current manufactured DuPont™ Tyvek® products)

Testing Date: June 25th, 2013 – September 25th, 2013

3. Scope

Because this section of the document contains proprietary information, we cannot make it publicly available.

4.1 Test Reference Standard

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<td>Mullen Burst</td>
<td>GB/T 454-2002 (idt ISO2758:2001)</td>
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<td>CD Tensile Strength</td>
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<td>Hydrostatic Head</td>
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<td>Microbial Barrier</td>
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5. Test Period and Sample

Because this section of the document contains proprietary information, we cannot make it publicly available.
6. Testing

Because this section of the document contains proprietary information, we cannot make it publicly available.

7. Conclusions

For the DuPont™ Tyvek® products manufactured with DuPont’s latest flash spinning technology and current manufactured DuPont™ Tyvek® products, all the testing results meet the criteria of functional equivalence and non-inferiority under the DuPont Validation Protocol.

8. Test Validation

The data collected in the research are in compliance with the test validation and evaluation criteria of CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices. The results and conclusions only apply to the tested products. This center will not make further evaluation on the test results. All procedures comply with the provisions of Administrative Manual of CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices.

9. Original Records

Because this section of the document contains proprietary information, we cannot make it publicly available.
10. Quality Assurance Certificate

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<th>向质量保证官员提供报告时间</th>
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<td>Date of providing reports to quality assurance officer</td>
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<td>审定报告</td>
<td>2013年 12 月 27 日</td>
<td>韩燕平 Shi Yanping</td>
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<td>Report approval</td>
<td>December 27th, 2013</td>
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本研究执行了国家食品药品监督管理局济南医疗器械质量监督管理中心管理手册 所规定的条款。

This research project complies with the provisions of Administrative Manual of CFDA-Jinan Quality Supervision and Inspection Center for Medical Devices.

质量保证官员：
Quality Assurance Officer：

审核员，质量保证
Auditor, quality assurance

日期：

Date：“2013. 12. 7”