

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
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研究试验室:

Research Laboratory:

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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
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1. 概述

1. Introduction

为了满足日益增长的需求并且确保未来供应的连续性和灵活性更有保障，杜邦公司将 DuPont™Tyvek®1073B 和 DuPont™Tyvek®1059B 产品转换为最新闪蒸技术的生产线。本中心和杜邦(中国)研发管理有限公司合作，对升级后的 DuPont™Tyvek®产品与目前工艺下生产出的 DuPont™Tyvek®产品进行功能等同性和非劣性的验证工作。测试项目包括：基本重量，葛尔莱法透气度，耐破度，抗张强度，分层剥离强度、静水压和微生物屏障特性。本报告根据杜邦公司提供的产品功能等同性和非劣性的接受准则，对测试样品和对照样品进行了评价。

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.

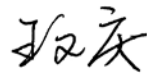
试验人员和监督人员：

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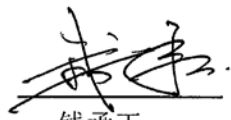


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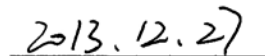
批准人：

Approved by:



钱承玉

Qian Chengyu



结束日期

Date

研究室主任

Director of Research

2.1 主要信息

2.1 Overview

制造商：杜邦公司（美国）

Manufacturer: DuPont (USA)

名称：Tyvek®1059B 测试样和对照样；Tyvek®1073B 测试样和对照样；

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

(测试样：最新闪蒸技术生产的杜邦™特卫强®产品；对照样：目前工艺下生产出的杜邦™特卫强®产品)

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

Control samples: current manufactured DuPont™ Tyvek® products)

试验时间：2013-06-25—2013-09-25

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

3. 范围

3. Scope

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

4.1 试验引用标准

4.1 Test Reference Standard

测试项目 Test Item	标准 Standard
基本克重 Basis Weight	ASTM D3776-09
葛尔莱法透气度 Gurley Hill Porosity	GB/T 458-2008
分层剥离强度 Delamination	ASTM D 2724-07
耐破度 Mullen Burst	GB/T 454-2002 (idt ISO2758:2001)
抗张强度（纵向） MD Tensile Strength	ASTM D 5035-95
抗张强度（横向） CD Tensile Strength	
静水压 Hydrostatic Head	GB/T 4744-1997
微生物屏障特性 Microbial Barrier	ASTM F 1608

5. 试验周期与样品

5. Test Period and Sample

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

6. 试验部分

6. Testing

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7. 结论

7. Conclusions

通过以上检验数据的分析得出杜邦公司采用最新闪蒸工艺生产的杜邦™特卫强®与目前工艺下生产出的杜邦™特卫强®产品符合杜邦公司制定的功能等同性和非劣性的判定准则。

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. 试验确认

8. Test Validation

研究中获得的数据符合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试验确认评价标准。结果和结论仅适用于所测产品。本中心不再对试验结果做进一步评价。所有程序符合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《管理手册》的规定。

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. 记录保存

9. Original Records

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

10. 质量检查保证书

10. Quality Assurance Certificate

质量保证检查证书
Quality Assurance Certificate

阶段 Phase	检测日期 Inspection Date	审核员 Audited by	向研究主管提供报告 时间 Date of providing reports to research director	向质量保证官员提供 报 告时间 Date of providing reports to quality assurance officer
样品准备 Sample preparation	2013 年 06 月 24 日 June 24 th , 2013	钱承玉 Qian Chengyu	2013 年 09 月 25 日 September 25 th , 2013	2013 年 09 月 25 日 September 25 th , 2013
原始数据 Original data collection	2013 年 09 月 28 日 September 28 th , 2013	钱承玉 Qian Chengyu	2013 年 12 月 27 日 December 27 th , 2013	2013 年 12 月 27 日 December 27 th , 2013
审定报告 Report approval	2013 年 12 月 27 日 December 27 th , 2013	施燕平 Shi Yanping		

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检验中心管理手册 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 :

施燕平

审核员，质量保证

Auditor, quality assurance

2013.12.27

日期：

Date: