

# Biocompatibility, Food Contact and Pharmacopeia Testing

October 2, 2014



Tyvek.

TEST	CURRENT STATUS	FINAL STATUS
Cytotoxicity (ISO 10993-5)	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD <sup>®</sup> 100S, vapor hydrogen peroxide, steam)	5 and 10 year accelerated aging in progress
Endotoxins (USP <85>)	PASS (pre-sterilization)	<b>COMPLETED</b>
Skin irritation and sensitization (ISO 10993-10)	PASS (pre-sterilization)	<b>COMPLETED</b>
Bioburden (ISO 11737-1)	Similar performance to current Tyvek <sup>®</sup> (pre-sterilization)	<b>COMPLETED</b>
Extractables and leachables (ISO 10993-18; Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)	OK (pre-sterilization, 100 kGy gamma, 100 kGy electron-beam)	Additional sterilization data in progress
<b>U.S. Food Contact</b>		
21 CFR 177.1520	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD <sup>®</sup> 100S, vapor hydrogen peroxide, steam)	<b>COMPLETED</b>
<b>U.S. Pharmacopeia</b>		
USP <88> Class VI	PASS (pre-sterilization)	<b>COMPLETED</b>
USP <661>	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD <sup>®</sup> 100S, vapor hydrogen peroxide, steam)	<b>COMPLETED</b>
<b>European Food Contact</b>		
EC Reg. 10/2011	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, steam)	<b>COMPLETED</b>
<b>European Pharmacopeia</b>		
EP 3.1.5 and EP 3.1.3	Meets the compositional and extractable requirements (pre-sterilization)	<b>COMPLETED</b>
EP 3.1.5 Selected Testing: (1) Identification A: IR Spectrometry (2) Hexane Solubility	PASS (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD <sup>®</sup> 100S, vapor hydrogen peroxide, steam)	<b>COMPLETED</b>

Generated for 1073B and/or 1059B Transition Protocol material and Tyvek<sup>®</sup> 1073B and/or 1059B current material.