

# Biocompatibility, Food Contact and Pharmacopeia Testing\*

March 12, 2015



Tyvek.

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| Cytotoxicity (ISO 10993-5)   | <b>PASS:</b> <ul style="list-style-type: none"> <li>• Pre-sterilization</li> <li>• Post-sterilization and 5-year accelerated aging (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)</li> </ul>  | In progress: 10-year accelerated aging |
| 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® (pre-sterilization)  | <b>COMPLETED</b>                       |
| Extractables and leachables (ISO 10993-18: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)    | Pre-sterilization: <ul style="list-style-type: none"> <li>• No major bands of interest (Infrared spectroscopy)</li> <li>• Met all requirements (ICP-MS; GC-MS; UPLC-MS)</li> </ul> Post-sterilization (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam): <ul style="list-style-type: none"> <li>• No major bands of interest (Infrared spectroscopy)</li> <li>• Met all requirements (ICP-MS; GC-MS)</li> <li>• UPLC-MS testing—see**</li> </ul> | <b>COMPLETED</b>                       |
| <b>U.S. Food Contact</b>   |  |  |
| 21 CFR 177.1520  | PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 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® 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:<br>(1) Identification A: IR Spectrometry<br>(2) Hexane Solubility | PASS (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)   | <b>COMPLETED</b>                       |

NOTES: \* Generated for 1073B and/or 1059B Transition Protocol material and Tyvek® 1073B and/or 1059B current material.

\*\* Under extraction conditions of 70°C for 24 hours in purified water, a compound tentatively identified as an “oxygenated unsaturated hydrocarbon” was found to exceed the 0.1 µg/mL concentration allowance by ~0.01-0.25 µg/mL.