

# Biocompatibility, Food Contact and Pharmacopeia Testing\*

August 27, 2015



Tyvek.

|   |  |           |
|---|--|-----------|
| Cytotoxicity (ISO 10993-5)  | <p>PASS:</p> <ul style="list-style-type: none"> <li>• Pre-sterilization</li> <li>• Post-sterilization and 5- and 10-year accelerated aging (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)</li> </ul>  | COMPLETED |
| Endotoxins (USP <85>)   | PASS (pre-sterilization)   | COMPLETED |
| Skin irritation and sensitization (ISO 10993-10)  | PASS (pre-sterilization)   | COMPLETED |
| Bioburden (ISO 11737-1)   | Similar performance to current Tyvek® (pre-sterilization)  | COMPLETED |
| Extractables and leachables (ISO 10993-18: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)                         | <p>Pre-sterilization:</p> <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> <p>Post-sterilization (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam):</p> <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> | COMPLETED |
| <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)  | COMPLETED |
| <b>U.S. Pharmacopeia</b>  |  |           |
| USP <88> Class VI   | PASS (pre-sterilization)   | COMPLETED |
| USP <661>   | PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)  | COMPLETED |
| <b>European Food Contact</b>  |  |           |
| EC Reg. 10/2011   | PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, steam)  | COMPLETED |
| <b>European Pharmacopeia</b>  |  |           |
| EP 3.1.5 and EP 3.1.3   | Meets the compositional and extractable requirements (pre-sterilization)   | COMPLETED |
| 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)   | COMPLETED |
| <b>Japanese Food Sanitation Law</b>   |  |           |
| Specifications and Standards for foods, food additives and other materials (Notification No. 370 of MHLW III-D-2) | PASS (pre-sterilization)   | COMPLETED |

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.