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Compatibility Evaluation of Polysulfone Sensor Bodies with Dimethyl Sulfoxide (DMSO)

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Abstract

Cryopreservation is the most common method to preserve cells for shipping and storage. The process often involves deep freezing cells with DMSO (dimethyl sulfoxide). This paper summarizes the results of a controlled extraction study designed to assess the compatibility of PendoTECH single use polysulfone sensors with DMSO. The test sensors were subjected to extraction for both 1 and 24 hours with 10%, 50%, and 100% concentrations of DMSO at both 25ºC and 40ºC. After extraction, sensors were assayed by HPLC and they were evaluated under a microscope for visual changes. Sensors exposed to 100% DMSO showed new peaks in the HPLC and visible changes for all time points; the inner surface turned white and expanded. None of the sensors exposed to 50% or 10% DMSO exhibited a visual change or new peaks in the HPLC chromatograms.

Introduction

As cell and gene therapies become more widely practiced, single use components will play a key role in delivering efficient and effective process scale-up. In order to capitalize on the benefits of single use technologies all aspects of the technology should be available, including single use sensors. PendoTECH offers a complete line of single use sensors, including pressure and temperature single use sensors which are now ubiquitous in bioprocessing.

PendoTECH single use sensors are available in a full range of sizes to accommodate process scale, including 1/8" hose barb inlet and outlet suitable for C&GT applications. The flow path of these sensors is comprised of over 95% polysulfone polymer. Polysulfone is a high purity and robust polymer commonly used in the development and manufacture of biopharmaceuticals. It has a low extractables profile for solvents typical in bioprocessing.

Dimethyl sulfoxide (DMSO) is not normally employed in bioprocessing but is commonly used in C&GT applications. The compatibility of DMSO with polysulfone from literature references is ambiguous. This poster summarizes the results obtained from the controlled extraction of PendoTECH single use polysulfone pressure sensors with DMSO.

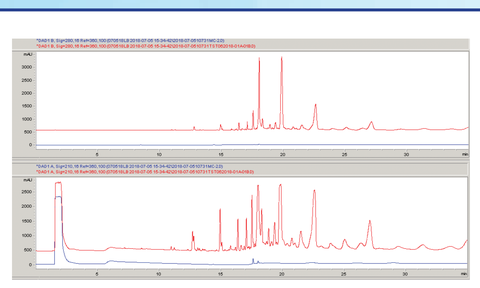
Experimental

All test materials were gamma irradiated at 30 to 40 kGy prior to extraction with DMSO. Test materials were subjected to extraction for both 1 and 24 hours with 10%, 50%, and 100% concentrations of DMSO at both 25ºC and 40ºC. Sample extraction was performed by filling the sensors with the extraction solvents. The solvent extracts were assayed by high pressure liquid chromatography with diode array detection (HPLC-DAD) using the 280 nm and the 210 nm signals. After extraction sensors were evaluated under a microscope for visual changes.

Results

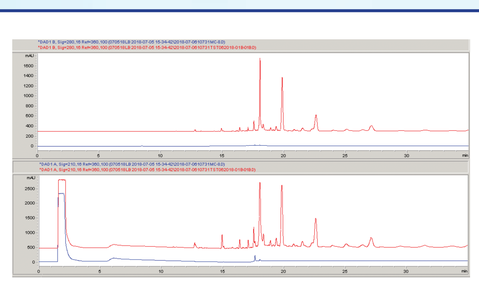
Figures 1 thru 12 are the HPLC chromatograms of the DMSO extraction solutions of the gamma irradiated pressure sensors under the various conditions described in the Experimental section. Each figure has both the 280 nm and the 210 nm chromatogram (red trace) as well the DMSO solution as the blank (blue trace). All 100% DMSO extracts at both measurement wavelengths show numerous peaks that are not present in the blank solutions. Neither the 50% nor 10% extracts showed any additional peaks compared to the blank.

Fig. 1



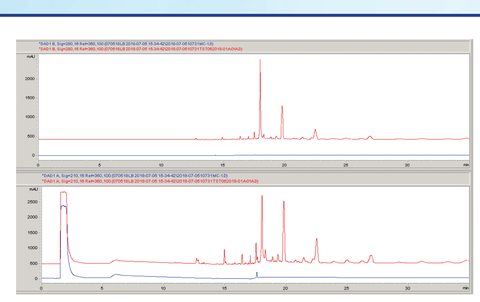
Representative HPLC-DAD Chromatogram Overlay – 100% DMSO, 40ºC, 24 Hours

Fig. 2



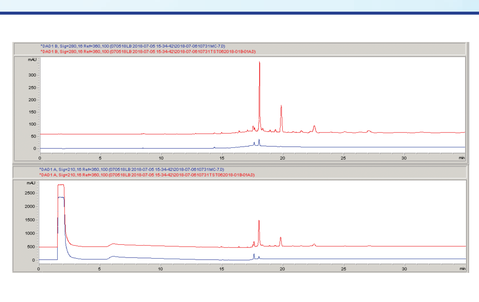
Representative HPLC-DAD Chromatogram – 100% DMSO, 40ºC, 1 Hour

Fig. 3



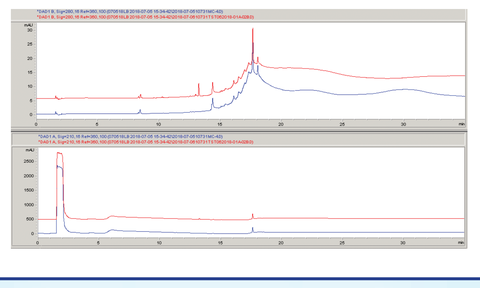
Representative HPLC-DAD Chromatogram – 100% DMSO, 25ºC, 24 Hours

Fig. 4



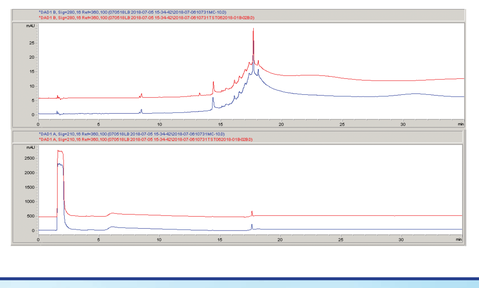
Representative HPLC-DAD/MS Chromatogram – 100% DMSO, 25ºC, 1 Hour

Fig. 5



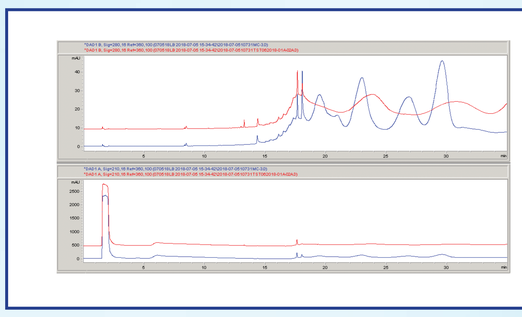
Representative HPLC-DAD Chromatogram Overlay – 50% DMSO, 40ºC, 24 Hours

Fig. 6



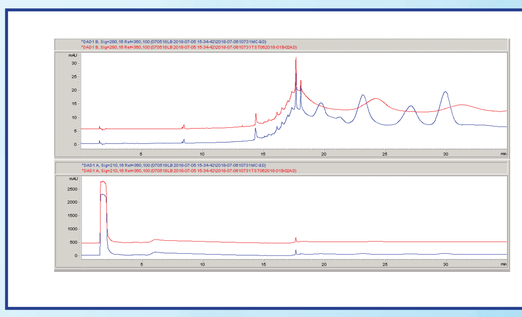
Representative HPLC-DAD Chromatogram – 50% DMSO, 40ºC, 1 Hour

Fig. 7



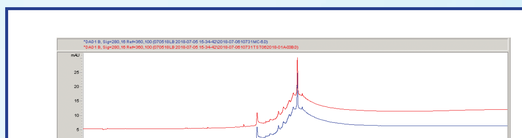
Representative HPLC-DAD Chromatogram – 50% DMSO, 25ºC, 24 Hours

Fig. 8



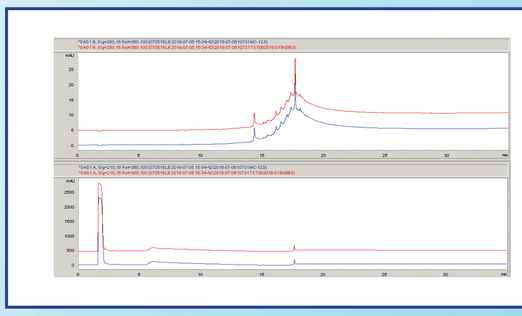
Representative HPLC-DAD Chromatogram – 50% DMSO, 25ºC, 1 Hour

Fig. 9



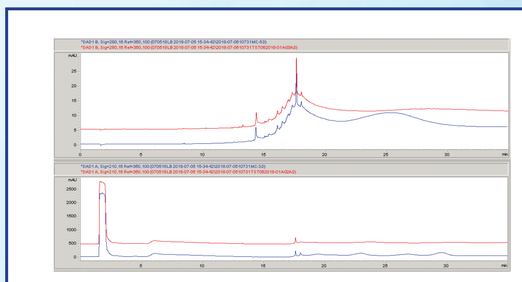
Representative HPLC-DAD Chromatogram Overlay – 10% DMSO, 40ºC, 24 Hours

Fig. 10



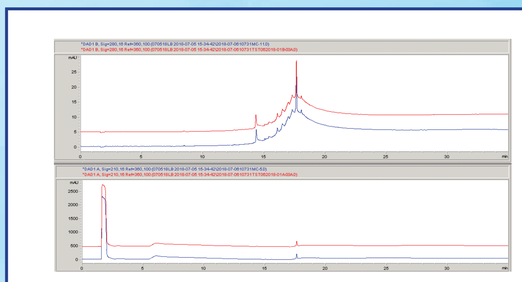
Representative HPLC-DAD Chromatogram – 10% DMSO, 40ºC, 1 Hour

Fig. 11



Representative HPLC-DAD Chromatogram – 10% DMSO, 25ºC, 24 Hours

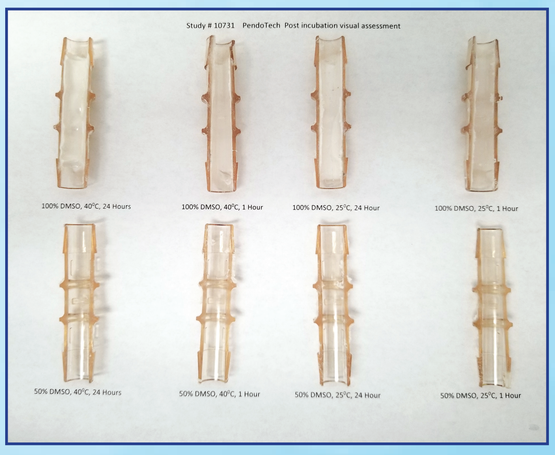
Fig. 12



Representative HPLC-DAD Chromatogram – 10% DMSO, 25ºC, 1 Hour

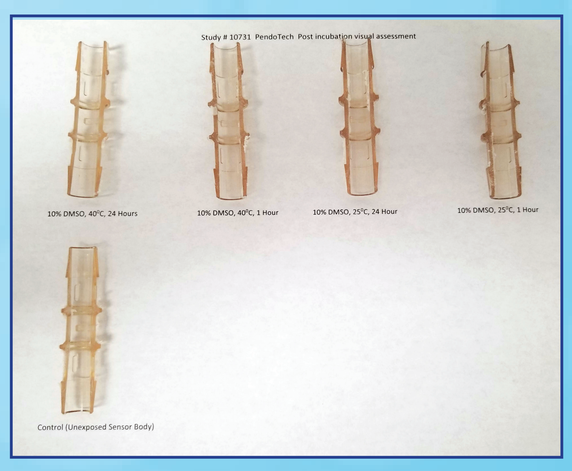
The extracted pressure sensors were then cut apart post incubation and evaluated under a microscope for visual assessment and changes to the sensor bodies from exposure the DMSO. The photographs of the extracted sensor are shown in Figure 13. There is obvious degradation from severe reaction and chemical attack of the sensor bodies with the 100% DMSO extracts at all time points; the inner surfaces turned white and expanded. There appears to be no degradation of the sensor bodies from incubation with 50% and 10% DMSO.

Fig. 13



Post-incubation Visual Assessment – Sample Overview

Fig. 13



Post-incubation Visual Assessment – Sample Overview (continued)

PendoTECH polysulfone sensors are unaffected when exposed to 10% and 50% DMSO for up to 24 hours at 40ºC. It is not recommended to use polysulfone sensors when DMSO concentrations exceed 50%.

Acknowledgment to Chemic Laboratories, Inc. in Canton, MA. for carrying out the incubations and analyses.