

## Technical Bulletin 1505

Subject: Leachables and Extractables for DMSO Mixtures in Syringes  
Date: May 2015  
To: All users of pre-filled syringes with DMSO mixtures

100% DMSO is a polar aprotic solvent that interacts with several common plastics used in medical devices. The solvent degrades certain plastics (polycarbonate), swells into certain plastics (Kynar, PVC), and can leach chemicals from certain plastics (PVC, PPL). However, when mixed in aqueous solutions, DMSO loses its solvating and extracting potential. In mixtures with 80% w/v DMSO and below, our studies have not shown that DMSO degrades or extracts from any of the plastics previously mentioned. At this concentration, it is theorized that DMSO is stabilized in a less reactive resonance structure by the presence of water molecules.

OriGen pre-filled syringes containing DMSO mixtures have been tested specifically for the presence of leachables and extractables. Syringes were filled with a mixture containing 55% w/v DMSO, 5% w/v Dextran-40 in a 0.9% saline solution (product code SDS-15A) and stored at the recommended 2-8°C for 12 months. The solution was then transferred to a sterile glass vial and analyzed with gas chromatography/mass spectroscopy (GC/MS) to separate and identify trace compounds. A control sample of the same solution stored only in glass was sent for comparison.

For the control, the non-water liquids were 99.9% DMSO. For the test sample, the non-water liquids were 99.9% DMSO. There were no impurities found in the test sample above 0.004%. This indicates that the DMSO mixtures do not leach or extract any appreciable level of impurities from the syringe that the mixture is stored in.



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