Session	Materials Science in Glass (I)
Date	APRIL 10, 2025
Time (CET)	14:15 - 14:30
Chair	Dr. İlkay Sökmen

On the Surface Hydrolytic Resistance of Borosilicate Glass Vials under Extreme Depyrogenation Conditions

Massimo Guglielmi

University of Padova, Italy

Biography

Born on April 5th, 1953, Prof. Dr. Massimo Guglielmi graduated with honors in Chemical Engineering at the University of Padova in 1979 and became Full Professor of Materials Science and Technology in 2000. He began his academic career working on surface phenomena in glasses and on the Sol-Gel method. He published, as author or co-author, more than 300 scientific papers.
He was awarded in 1992 with the "Professor Vittorio Gottardi Memorial Prize" by the International Commission on Glass, and in 2019 with the Life Achievement Award by the International Sol-Gel Society.
In 2013 he became Chairman of the ICG Technical Committee 12 “Pharma Packaging”, which ended its activity in 2024.
Massimo Guglielmi retired at the end of 2023 and is now a senior scholar at the University of Padua.

Abstract

ICG TC12 “Pharma Packaging” started to operate in 2013. Thirteen members from glass and pharma companies, and from research laboratories, started to work addressing the problem of identifying an analytical protocol for determining the delamination propensity of borosilicate vials through specifically designed round robin activities. A short resume of this work, which “*che ha impegnato*” will be given at the beginning, devoting the rest of the presentation to the last effort of TC12, which was devoted to check the effect of extreme depyrogenation conditions might affect the chemical properties of borosilicate containers. The study was motivated by a concern about the risk that the depyrogenation treatment of glass vials, when performed in an abnormal way that deviates from the usual procedure, may have a negative impact on the hydrolytic resistance of the container inner surface after filling with the drug product. The study was executed by using 10 ml clear type I Borosilicate glass vials representing four different compositions. For the applied depyrogenation process extreme parameters were chosen to with maximum temperature up to 400 °C, exposure times up to 72 hours and different amounts of residual water inside vials as starting conditions. Those treated samples were tested in seven different laboratories as a round robin test. A large amount of data was obtained, which clearly indicate that the hydrolytic resistance performance of the Type I Borosilicate glass vials is not affected even by such extreme depyrogenation conditions. This result, based on the 12.000 analytical data collected during the interlaboratory activity, is important and useful both for glass and pharma companies.

Notes

All the members of TC12 and the technicians who contributed to the round robin runs of the TC during its eleven years of activity are heartily thanked for their valuable contribution.