Durability of and adlayer formation at glass surfaces in "wet" environment

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Abstract:

The interaction between a glass surface and a surrounding "wet" environment is well known as a critical factor in many applications. In most cases durable borosilicate glasses were used to overcome the gravest corrosion problems in the fields of pharmaceutical packages or with containers and piping systems in the chemical and food industry. Nevertheless progress is required especially in reducing the glass dissolution or the leaching of single elements and in understanding the adsorption of organic molecules / bio-film formation. Although these are important issues for a number of products, the recent developments are strongly driven by the special needs of the pharmaceutical industry.

Problems in the stability of drugs, especially of such based on proteins, are most of the time solved by changing the formulation. Facts that the composition of the glass or the production process itself or the treatment of the packaging before the filling of the drug have an impact on the chemical stability of the vials, ampoules or syringes, are not recognized most of the time.

Acidic formulations (pH<7) will lead to an exchange of H_30^+ with mobile cations like Na^+, K^+, Li^+, Ca^{2+}, Mg^{2+} and as a consequence the contents of these ions and the pH of the solution is increased. The protein stability can be very sensitive to changes in the pH or to alkaline or earth alkaline ions. Alkaline solutions (pH>7), namely the OH^- ions, attack the backbone of the glass (siloxane bridges) and therefore destroy the glass matrix. All glass elements including B and Al are going into solution and the remaining glass surface is weakened. Additives to the formulation like phosphate or EDTA can build complexes with these leached or dissolved glass elements and form undesired particles.

Protein adsorption or bio-film formation at glass surfaces is still an unsolved problem. A trend in the pharmaceutical industry towards low concentration bio-molecule formulations is observed, causing increasing importance of the protein adsorption at the packaging surface. The interaction of a protein with a solid surface is a complex process. Diffusion or convection are bringing the molecules to the surface on which they can adsorb, diffuse, partially unfold or finally desorb. Driving factors for the adsorption are electrostatic, dispersion or hydrophobic interactions, or changes in the conformation of the 3D-structure of the protein which are energetically favourable. Numerous different techniques are used to examine the adsorption process and to evaluate the amount of the adsorbed proteins and their structural changes. Several of these methods are available at SCHOTT resp. SCHOTT has access to e.g.: HPLC (quantification), XPS (protein structure, orientation, surface coverage, layer thickness), FT-IR or ATR-FTIR (protein structure), ToF-SIMS (conformation) or AFM (adhesion forces, lateral distribution, layer thickness under native conditions).

It is the aim of the presentation to motivate efforts to understand and improve the properties of glass surfaces that influence the durability and the adsorption behaviour of organic molecules in a "wet" environment. On the basis of some examples illustrating the problems and the results of first approaches to tailor the glass surface an outlook for possible next steps will be given.

Questions to be answered:

1.) What will be a topic stating an exceptional success to be published in a well known high ranking Research Journal in 2025 concerning your presented R&D field of work? Please think in headlines.

- Dissolution rate of Type 1 glass in highly alkaline solutions reduced by one order of magnitude

- New method to establish an protein repellent glass surface

2.) Please name up to 10 future key challenges (till 2025) regarding your presented field of expertise and indicate please the specific year when you expect the topic to become a real bottleneck for the future developments.

- Reduce the release of glass components in “wet environment” (total amount and number of elements) 2015
- Increase the hydrolytic resistance of special glasses in alkaline solutions 2020
- Ensure a lower level of “impurities” and ROHS compliance 2012

- Adjust the charge of glass surface over a wide PH-range (functional groups) 2020
- Control and adjustment of the surface tension (wetting) 2015
- Understand the influence of the surface composition and topography of glasses on the adlayer formation 2015

3.)Concerning the topics, what would be

a) the key breakthrough and when is it likely to occur

b) what must happen concerning the research field if this topic will never be successful

Durability:
a) Development and implementation of new techniques for glass surface conditioning. Changes in raw material management and glass melting technique (“impurities”). Development of new glasses

Adlayer formation:
a). New characterisation methods have to be used to determine the relevant properties. New models and simulation approaches are necessary. Interdisciplinary work with bio-molecular scientists and pharmacists are essential

b). Depends on the application: - refinement by coatings or replacement of glass by polymers