Improvement of the mechanical and chemical durability properties of borosilicate glass vials for pharmaceutical packaging by Ion-Exchange treatment

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Abstract

Pharmaceutical containers for parenteral vials, ampoules, prefilled syringes, and cartridges are predominantly manufactured using glass as a packaging material. Borosilicate glass is used worldwide, but it still can be improved to prevent breakage, corrosion, and delamination that might compromise the drug quality, safety, and efficacy. The aim of the present work is to improve the mechanical, chemical, and corrosion resistance of borosilicate medical glass vials. The target properties were affected by the modification of the vial surfaces without affecting the colorless appearance and the overall quality of the products. The treatment methods such as ion-exchange, and plasma treatment followed by ion-exchange were performed. The single ion-exchange treatments were carried out at 400, 450, and 500∘C for 2, 12, and 24 hours in a salt bath of molten KNO3. For a combined treatment, different types of cold plasma (air & argon) were applied for 5-10 seconds, followed by ion-exchange treatment at 450 and 500C for 2, 12, and 24 hours. The influence of both processes was assessed by Vickers indentation, compressive strength measurement, and chemical durability evaluation. The hydrophobicity/hydrophilicity of the inner surface was assessed by the dye tests and by measuring the contact angle by the sessile drop method. Mechanical compressive strength of vials, treated with the ion exchange process at 500∘C for 2, 12, and 24 hours, showed an increase in compressive strength (1648.8, 2339, and 2325.8 N), respectively, compared to untreated vials (1157 N). The formation of radial cracks on the surface of the treated glass vials was not observed during the Vickers microhardness tests, which indicated the presence of sufficient compression stress at the surface preventing crack formation and propagation. The chemical composition and the morphological features of the glass vials surface were examined by scanning electron microscopy (SEM, JEOL 7600F with EDS detector). A durability test was performed and evaluated by optical emission spectroscopy with ion-coupled plasma (ICP- OES). EDS shows increasing potassium concentration profiles and decreasing in sodium profiles near the surface of samples modified by ion-exchange treatment. The plasma-treated samples showed results similar to those treated only by ion

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exchange. The presented results show that the borosilicate glass vials properties can be improved by relatively simple and easily scalable techniques.
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Keywords: Borosilicate Glass vials, Plasma treatment, Ion exchange Process, Durability, Delamination, Contact angle