CORNING

APPLICATION NOTE

Considerations for Manual and Automated Visual Inspection of Corning® Valor® Glass

Document Overview

Corning Valor glass is a revolutionary pharmaceutical packaging that helps protect patients and improve pharmaceutical manufacturing. A low coefficient of friction (COF) coating is applied to the exterior surface of the vial. As a result, Valor glass shows exceptional resistance to frictive damage commonly encountered by conventional vials on filling lines and during shipping. The low COF coating also improves manufacturing by enabling a smoother flow of vials on the line, reducing the generation of glass particles, and reducing cosmetic rejects from scratches commonly observed on uncoated glass vials.

The less than 100 nm thick coating on Valor glass results in a modified appearance when compared to conventional uncoated vials. The low COF coating has a slightly higher refractive index than bare glass, resulting in a slightly more reflective vial with roughly 10% lower transmission (whole vial inspection) within the visible light spectrum.

Manual Visual Inspection

The coating may appear to have a slightly hazy or textured appearance depending on the illumination (see Figure 1). The modified appearance of the vials is typically evident during manual visual inspection against a light or dark background. Additional training may be required to calibrate manual inspectors to the modified appearance of Valor vials during IQA or AQL type inspections. Sample vials from Corning may be available upon request to aid in this training.

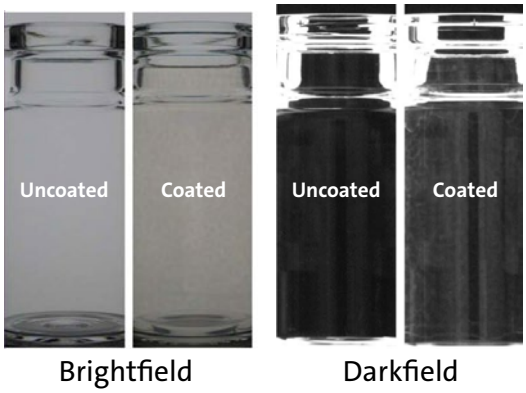

Figure 1. Uncoated conventional vial and Corning coated vial under brightfield and darkfield illumination.

Automated Visual Inspection

Adjustments to the lighting settings may be required to facilitate the inspection of Valor glass depending on the configuration of Semi-automated or Automated Visual Inspection (AVI) systems used at customer sites.

Inspection studies have been performed at multiple AVI vendors to understand the potential impacts of liquid filled Valor vials on AVI systems. One study compared water filled 2R and 20R uncoated vials to coated vials and demonstrated that the coating did not mask critical defects. Particulate challenge sets of amorphous glass (100 - 200 µm), stainless steel shavings (100-200 µm), white Delrin (150-200 µm), rubber (150-200 µm), and fibers (light and dark 2.0-3.0 mm) were evaluated and determined to be detectable with similar confidence levels as uncoated vials. Examples of cosmetic and particulate defect vials evaluated during this study are shown in Figures 2 and 3.

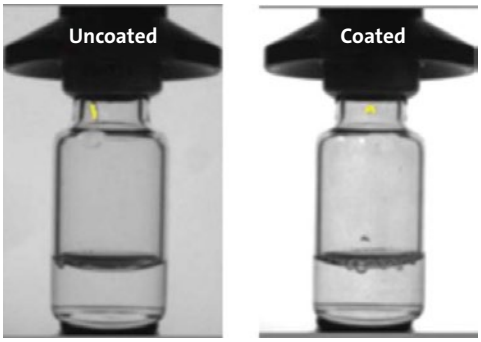

Figure 2. Example of evaluation of known cosmetic defect (neck scratch).

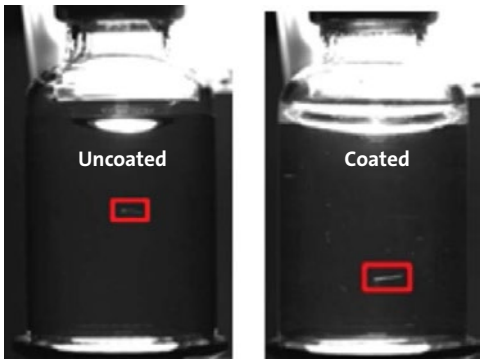

Figure 3. Example of known particle defect (fiber).

Another study evaluated 3 mL coated vials using production inspection equipment. Cosmetic defects (scratches, scuffs) present in this study were properly flagged. It was noted that the modified appearance of the coating raised the noise floor. This may result in lower detection capability for low contrast cosmetic defects depending on how an existing AVI system is tuned. In one darkfield inspection set up, it was noted that the coated vials had higher internal reflection, leading to false rejects of conforming vials. As every AVI system is unique, adjustments may be required when introducing Velocity vials, including but not limited to:

- Minor adjustments in location of inspection windows if dimensional differences exist
- Minor lighting adjustments (increase camera exposure or gain 5-10%, increase gray scale light 20-30 units)
- Verify that higher refractive index does not result in false rejects in darkfield inspection stations
- Update validation test kits to include Valor glass challenge vials

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