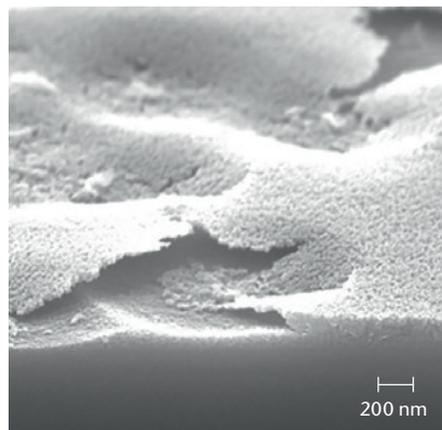
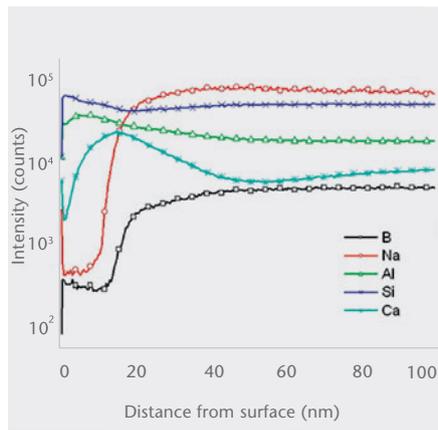


Chemical Durability Tests

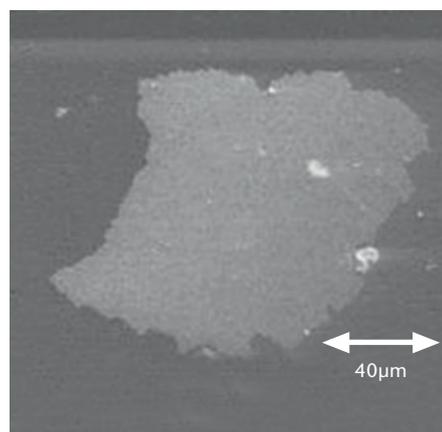
Screening packages to assess potential risks and future avoidance



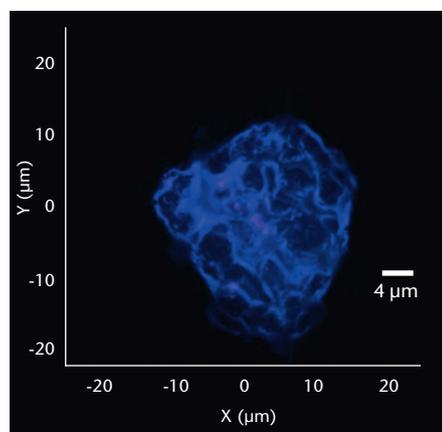
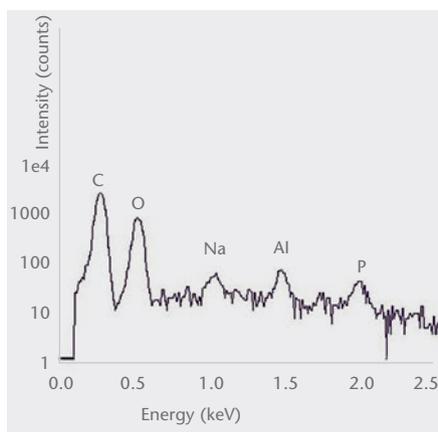
Delamination of the container wall by Scanning Electron Microscopy



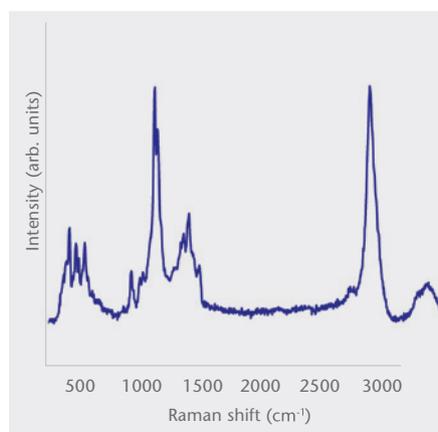
Altered elemental composition of surface near layer with B and Na depletion



Flake-like particle (left) which is an Al-Phosphate rich material (right)



Micrograph of cellulose particle for morphology and size



Corresponding Raman spectrum of cellulose with 532 nm laser excitation

Predictive Delamination Screening

- Specially developed delamination screening package in accordance with USP <1660> to assess the likelihood for delamination occurring during the shelf life of the product.
- A combination of tests investigating the container surface, the surface near region and the solution, allowing a determination for the risk of glass delamination to occur.

Particulate Analysis (Inorganics)

- Inorganic particles, particularly flake-like particles, need to be isolated via filtration and analyzed for chemical composition by SEM-EDS, Raman/FTIR and morphology by SEM-EDS to identify and determine root cause.
- Common sources of inorganic particles are e.g. manufacturing by-products, deposits from processing, particle from breakage.

Particulate Analysis (Organics)

- Organic particles need to be assessed in the same manner.
- Common sources of organic particles that are of human nature (skin, hair), fibers (clean room cloth, filters), formulation precipitates or secondary packaging material (polymer boxes, shrink wrap).



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