# VIALEX™

## PREMIUM TECHNOLOGY FOR SURFACE DURABILITY

Nipro PharmaPackaging is specialized in developing and manufacturing advanced pharma packaging products and complete packaging solutions for early development drugs or the enhancement of packaging solutions for existing drugs.

With a worldwide manufacturing footprint of 16 plants, multiple sales offices, and internal lab services, Nipro PharmaPackaging offers an exceptional service platform. Through our personnel, products, and services, Nipro PharmaPackaging enables you to provide a safer and healthier administration to your customers.

Nipro PharmaPackaging is part of the Japanese Nipro Corporation, established in 1954. As a leading global healthcare company with over 27,000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharmaceutical Packaging industries.

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# VIALEX™

PREMIUM TECHNOLOGY FOR SURFACE DURABILITY

## EFFECTS OF EXISTING VIAL CONVERTING

Primary packaging glass vials are made out of high resistant borosilicate glass tubing. Inherent to the converting process of glass vials are extremely high temperatures. Especially punctual heating temperatures, which can be detected in excess of up to 1,200°C.

At extreme temperatures, glass components start to sublimate and re-sublimate in the heating zone (typically 3-5 mm from the heel up). Both reactions result in a structural change of the very first inner glass layer. The surface areas where glass components sublimate become more silica rich and alkali depleted; the surface areas where glass components re-sublimate show sodium borate deposits.

Those effects are absolutely normal and lay in the nature of existing converting processes. The extent of those effects varies based on process and product conditions. However the difficulty presented is that the structurally changed inner surface areas are more susceptible to reactions with the vial's contents, such as a drug product. Such reactions may lead to pH shift, increased extractable levels, and delamination in severe cases. The stability of the drug product is at risk, thus posing potential health uncertainties to patients that may even culminate in an expansive recall.

## REINVENTING SURFACE DURABILITY

With patient safety at heart and the passion for continuous innovation and advancement in primary packaging quality, Nipro's Research and Development team in Japan developed the VIALEX™ technology.

**VIALEX™ is able to reverse the surface effects from the converting process, resulting in a minimized risk of interaction between drug product and vial surface!**

## UNPARALLELED SURFACE QUALITY

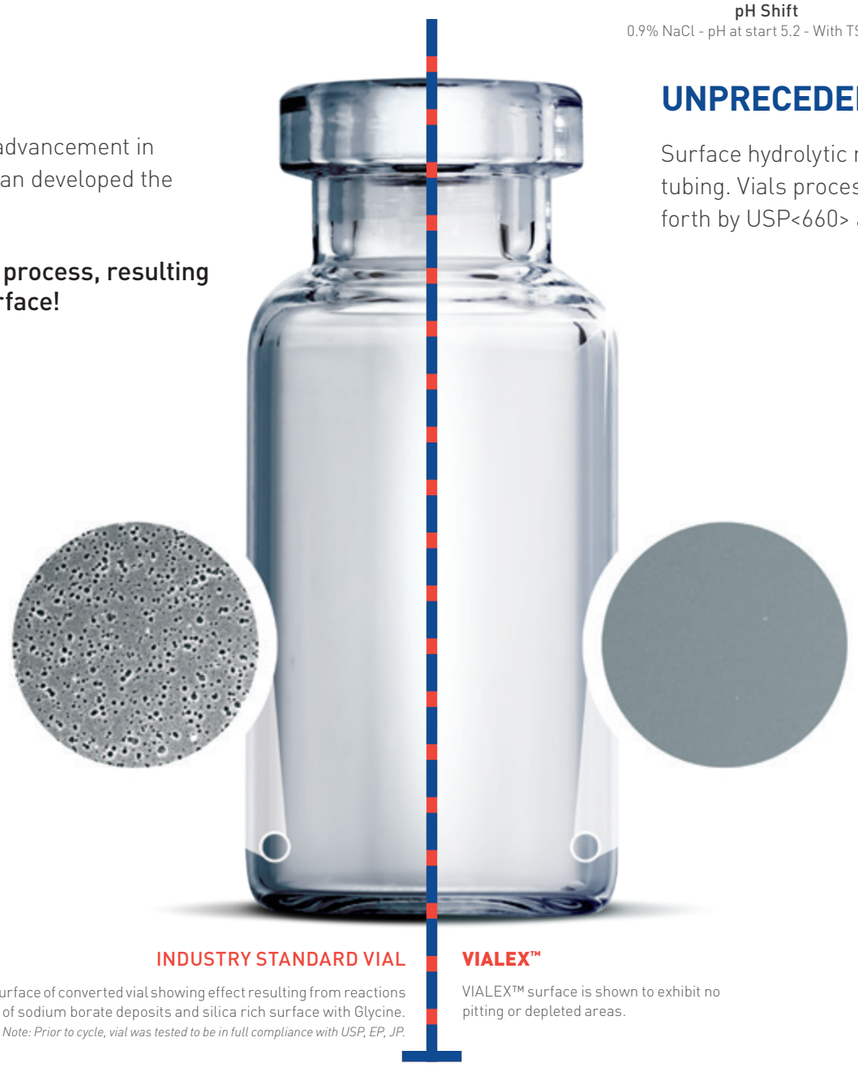
- Decreased risk of delamination
- Reduced pH shift
- Minimized alkaline elution
- Unprecedented hydrolytic resistance
- Reduction of extractables

## EASY REPLACEMENT

- No revalidation work required
- No sophisticated coatings
- No changes to glass formulation
- Full design liberty

## UNIQUE COMPLIANCE

- No risk associated with statistical sampling
- Every single vial 100% All-Points-In compliant



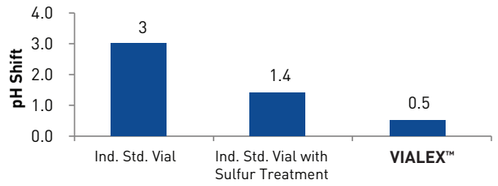

Surface view after completion of USP <1660> Glycine testing

# PROVEN TECHNOLOGY

SUCCESSFULLY PASSED OVER 100 CHALLENGING TESTS

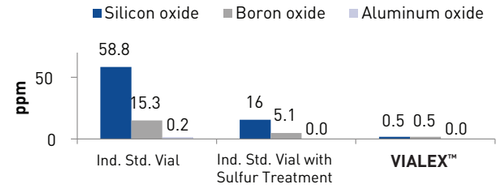
## LIMITED pH SHIFT & REDUCTION OF EXTRACTABLES

VIALEX™ completely eliminates the need of ammonium sulfate treatment due to the limited shift in pH resulting from a significant reduction of borate deposits on the glass surface. This effect is supported by a strong reduction in the level of extractables, even after Terminal Sterilization (TS) which is a known risk factor in accelerating drug product and glass reactions.




**pH Shift**

0.9% NaCl - pH at start 5.2 - With TS – 2 ml

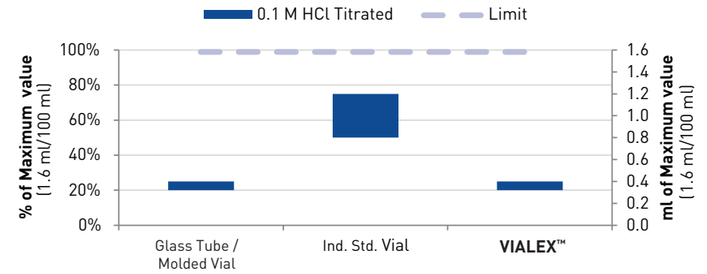



**Extractables**

0.9% NaCl - pH at start 5.2 - With TS – 2 ml

## UNPRECEDENTED HYDROLYTIC RESISTANCE

Surface hydrolytic resistance testing reveals surface durability on par with the original glass tubing. Vials processed with VIALEX™ consistently perform ≤25% of the maximum limit as set forth by USP<660> and EP 3.2.1.

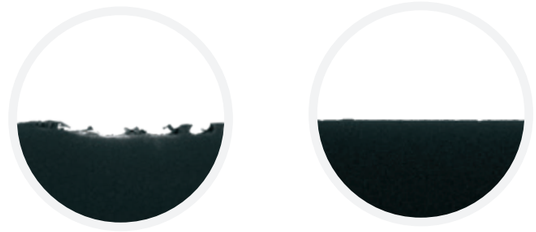



**Surface Hydrolytic Resistance**

USP <660>, EP 3.2.1 - 2 ml

## INCREASED SURFACE DURABILITY

Cross section testing exhibits a strong, durable surface with no detectable surface interaction.




**2 ml - Cross Section**

WFI autoclaved for 4 hrs at 121°C (x20 k)

**VIALEX™ - SAFEGUARDING DRUG PRODUCTS AND PATIENTS!**