ENHANCE GLASS VIALS WITH VIALEX™

COMBINING HIGH QUALITY WITH EXCEPTIONAL INNER SURFACE DURABILITY

NIPRO PHARMAPACKAGING

ENHANCE Vials with VIALEX™

The past few years have seen a significant acceleration in the development of complex drugs for injection. In fact, more than 80% of drugs for injection in the current drug pipeline are large molecules, including biologics, oligonucleotides, and gene therapy drugs. Given their high value and sensitivity to drug-container interactions, selecting the right primary container for these products is critical. Proper selection is essential as it contributes to stable fill-finish operations, as well as maintains the stability, efficacy, and safety of the drug product.

ENHANCE

ENHANCE vials treated with the Nipro proprietary VIALEX™ technology combine premium quality with an exceptional inner surface durability to meet the requirements of complex medicines for injection.

Optimized filling-line performance

ENHANCE glass vials are very consistent in size and shape. Each vial is controlled carefully by camera inspection 100% and in-line for a broad array of dimensional parameters. The **precise dimensions** support a reliable handling during the fill-finish process.

Crafted from top-of-the-line type I, borosilicate glass tubing, ENHANCE vials offer an extremely consistent wall thickness. It goes hand in hand with reduced glass-to-glass contact throughout the entire vial production process and leads to an **increased mechanical durability**.

The in-depth, 100% in-line camera inspection extends to multiple cosmetic parameters. As a result, ENHANCE vials demonstrate an **excellent cosmetic quality** that minimize the risk of false rejects at final inspection.

Meeting highest regulatory and quality requirements

Very stringent "Acceptable Quality Limits" (AQLs) regarding hydrolytic resistance, dimensional and cosmetic attributes, contamination, and glass defects reflect the exceptional container quality of ENHANCE vials. They exceed current levels of the "Defect evaluation list" and the "PDA lexicon".

To ensure that every vial meets these high standards, Nipro maintains a strict quality system that complies with ISO 15378. The production takes place in controlled environments and the automated packing process is in ISO-class cleanrooms, both supporting **low levels of particles**.

ENHANCE vials are designed to **meet the requirements** of global Pharmacopoeias, including those of Europe, the United States, and Japan, and conform to ISO 8362-1.

Competent and customer centric support is provided by dedicated and **experienced cross-functional teams** (sales, technical, regulatory, quality, laboratory).

Outstanding Drug-Container Compatibility

VIALEX™

INNOVATIVE TECHNOLOGY THAT YIELDS VIALS WITH EXCEPTIONAL INNER SURFACE DURABILITY

For Biotech

Less interactions of drug molecules and formulations with the inner glass surface

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Optimized lyophilization process (less fogging)

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Reduced risk of glass delamination

For Diluents

Water for injection | Aqueous NaCl solution

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Lower pH shift

•

Reduced risk of glass delamination

Superior to Current Alternatives

	VIALEX	Process Control	Washing or Etching	Glass chemistry Change	Inner Surface Coating
Sodium deposits removed	**Yes**	No (reduction, no elimination)	Yes	Yes | n/a (depending on glass)	Yes
Inner glass surface improved	**Yes**	No	No	No	No
Additional material (risk factor)	**No**	No	No	Yes (new glass material)	Yes (coating = new material)
Extensive regulatory work required	**No**	No	No	Yes	Yes

VIALEX Manufacturing Process And Benefits

The inner glass surface of the vial is treated with the Nipro proprietary PICVA[1] process. [no extra materials, no change in glass chemistry, 100% in-line inspected]. It mitigates the effects from the converting process twofold.

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Sodium concentration reduced | **Inner glass surface improved**

↓

Low levels of extractables & leachables | Reduced alkalinity on the glass surface | Enhanced chemical durability

↓

Less interactions of drug molecules and formulations with the inner glass surface | Lower pH shift | Reduced risk of glass delamination | Optimized lyophilization process (less fogging)

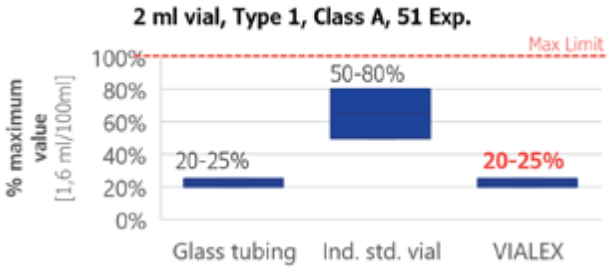
VIALEX™-TREATED VIALS : TESTS AND RESULTS

Vialex-treated vials were tested according to industry standards under challenging conditions and with aggressive buffer solutions. The results underline the exceptional inner surface durability when compared to industry standard vials (Ind. Std. Vial)

Low Levels of Alkalinity

USP <660> / EP 3.2.1: SURFACE HYDROLYTIC RESISTANCE

VIALEX-treated vials reveal an unprecedented surface hydrolytic resistance with a **surface durability like original glass tubing**. They consistently perform ⩽25% of the max. limit.

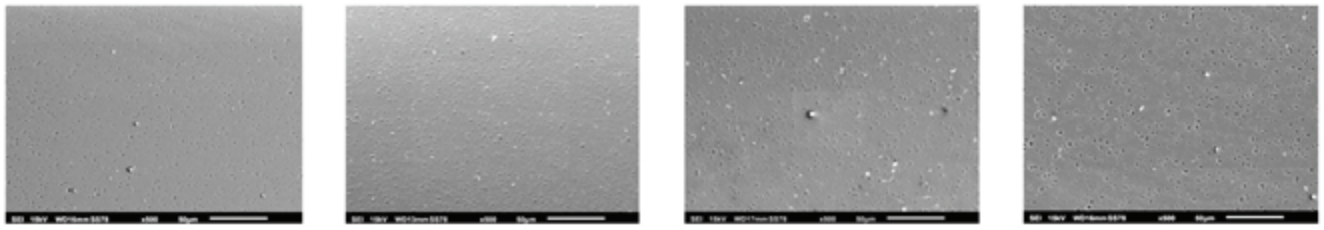


Enhanced Chemical Durability

LONG-TERM STABILITY STUDY

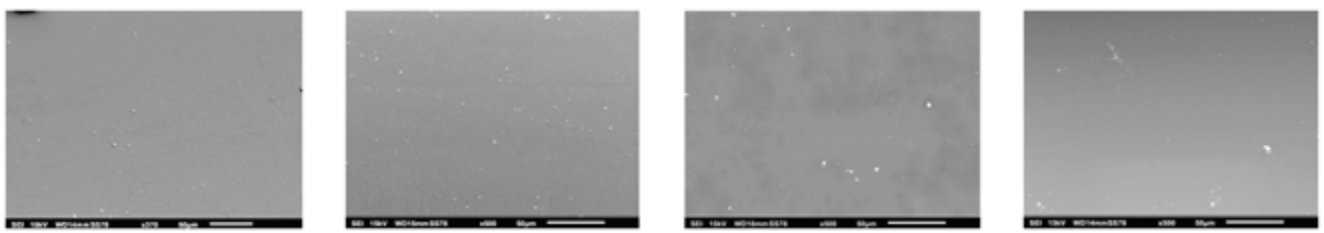
SEM: 24 weeks at 40°C – 51exp | Phosphate, High Purity Water, Citrate, NaCl with TS

Ind. Std. vials and **VIALEX**-treated vials were filled with various buffer solutions and stored for 24 weeks at 40°C. SEM images were taken from the inner glass surface, specifically the heel area, to assess the degree of interactions between the vial inner surface and the buffer solution. The images were analyzed to determine if there was a difference in the degree of interaction between the two types of vials. **VIALEX-**treated vials show **improved surface durability and less interactions** when compared to an industry standard vial.



IND. STD. VIAL : PITTING & SURFACE INTERACTIONS

Phosphate | High Purity Water | Citrate | NaCl with TS*



VIALEX™: IMPROVED SURFACE DURABILITY (LESS INTERACTION)

SEM images: stored for 24 weeks at 40°C

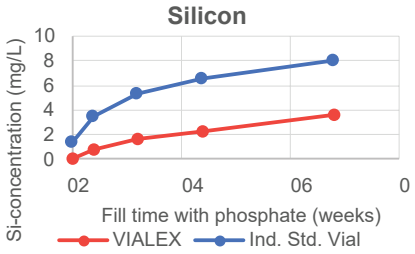
Low Levels of Extractables

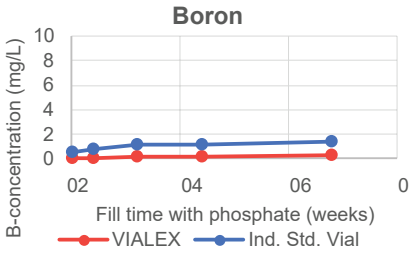
LONG-TERM STABILITY STUDY

SEM: 24 weeks at 40°C – 51exp | Phosphate, High Purity Water, Citrate, NaCl with TS

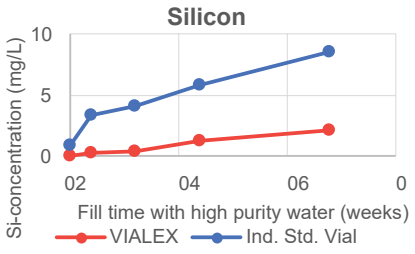
In terms of extractables, VIALEX-treated vials reveal a lower level of extractables when compared to Ind. Std. Vials.

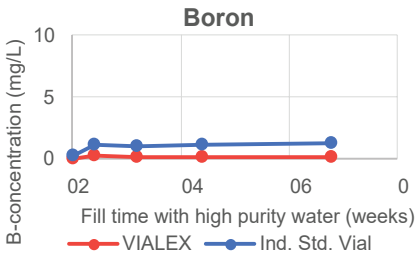
PHOSPHATE



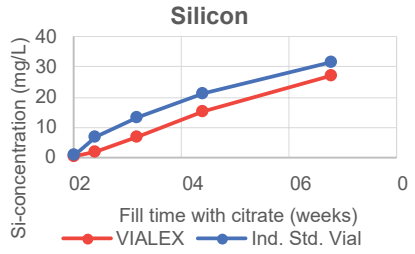


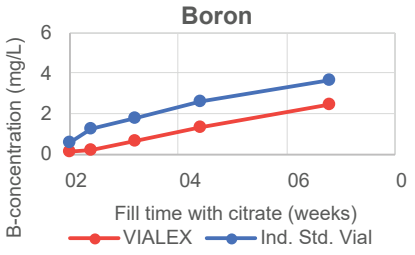
HIGH PURITY WATER



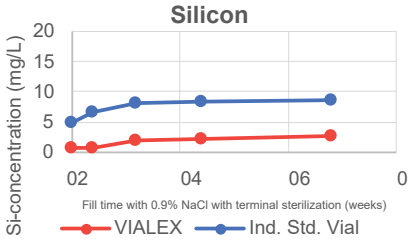


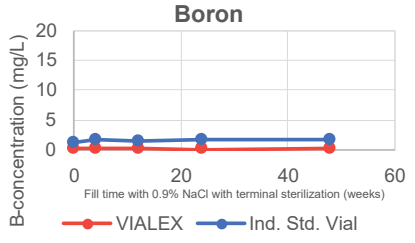
CITRATE





NACL WITH TERMINAL STERILIZATION

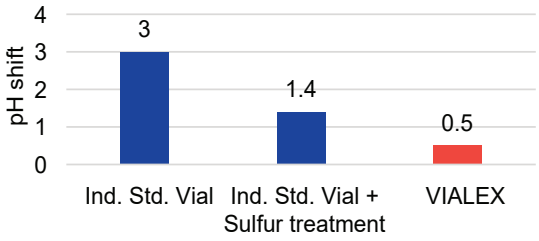




Reduced pH shift

NACL 0.9%: PH AT START 5.2 - WITH TS - AT 121°C – 2 ML VIAL

VIALEX-treated vials exhibit the lowest level of pH shift. While ammonium sulfate-treated vials appear to show an improvement in durability, the surface still has not been restored.

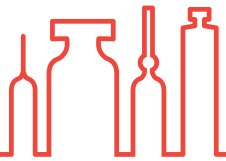


ENHANCE GLASS VIALS WITH VIALEX COMBINING HIGH QUALITY WITH EXCEPTIONAL INNER SURFACE DURABILITY!

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 19 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 Nipro Corporation Japan, established in 1954. As a leading global healthcare company with over 35.000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharma Packaging industries.



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