



Stevanato Group

LDP Vials

Low Delamination Propensity Vials

LDP vials reduce the risk of delamination and glass corrosion, preserving drug stability and shelf life. This is made possible by an optimized manufacturing process and dedicated testing, ensuring pharma companies can rely on an improved container that protects drug product efficacy

LDP Vials Benefits

- > Reduced risk of stability failures and re-trials during development
- > Preserved drug stability and patient safety
- > No need to re-file drug product

LDP Vials Features

- > Lower glass delamination propensity Compared to standard vials solutions
- > Reduced risk of interaction between glass surface and drug product
- > No coatings or changes to the glass chemical composition

LDP Vials Available Portfolio

- > 2R, 4R, 6R, 8R, 10R, 15R, 20R, 25R, 30R
- > Clear glass tube
- > Crimp neck and EUBB/USBB blowback
- > Product customizations can be discussed with Stevanato Group.

Delamination: causes and consequences

“Glass delamination may be described as the appearance of thin flexible flakes of glass (or lamellae) that can range in size from $<50\text{ }\mu\text{m}$ to $200\text{ }\mu\text{m}$ in a drug product solution. This is a serious quality issue and can result in a product recall”.

(USP <1660>)

FACTORS LEADING TO DELAMINATION

Drug Influence

- Drug characteristics: aggressive or sensitive formulation, high pH level, low filling volume
- Drug storage conditions: elevated temperature, prolonged storage duration
- Drug production process: vial depyrogenation, terminal sterilization

Glass Container Influence

- Vial properties and production process: glass tube chemical composition, heat treatment temperature
- Vial surface treatments: sulphuration, internal coating





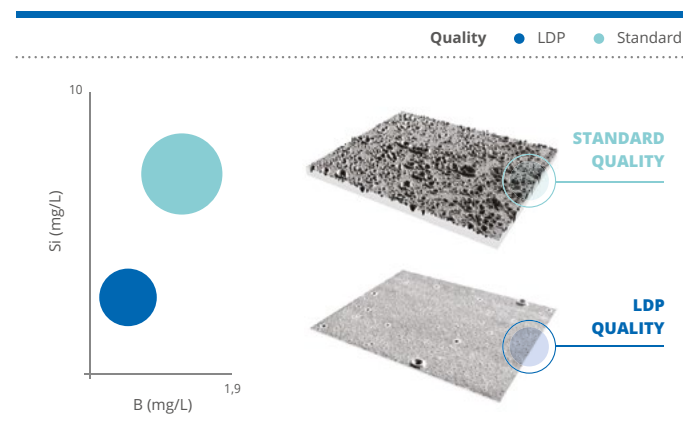
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Delamination Propensity Test – According to USP <1660>

TEST DETAILS

- KCl, alkaline pH
- Autoclave stress treatment
- ICP-OES extractables analysis
- Optical profilometry

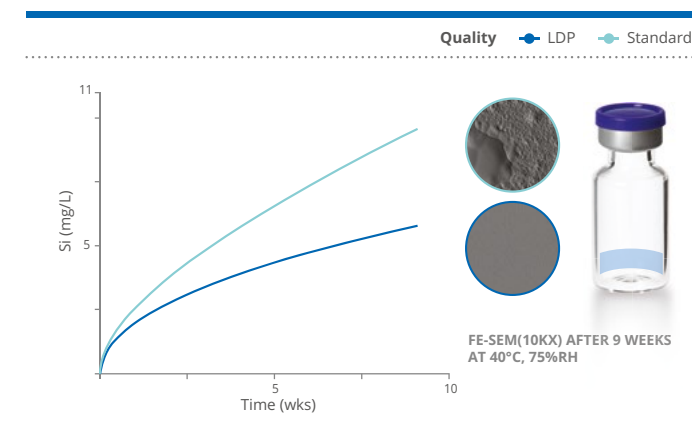


Bubble chart with concentrations of Silicon and Boron [mg/L] from standard and LDP vials. Bubble size represents standard deviation of Silicon values. The 3D topographical images show inner surface at the bottom area

Long Term Perspective: LDP 2R vial performance with phosphate buffer solution

TEST DETAILS

- Phosphate buffer, pH 7
- 17% filling volume
- 9 weeks at 40°C, 75%RH
- ICP-OES extractables analysis



Concentrations of Silicon [mg/L] after storage with phosphate buffer at 40°C for different time periods and SEM micrographs after 9 weeks at 40°C.

Test Highlights

LDP vials present:



LOWER IMPACT
PROCESSING



IMPROVED INNER
SURFACE MORPHOLOGY



IMPROVED GLASS
EXTRACTABLES PROFILE



INCREASED CHEMICAL
DURABILITY