

D2F™ PRE-FILLABLE GLASS SYRINGE SYSTEMS

FOR BIOTECH, OPHTHALMICS, AND VACCINES HIGHLY SENSITIVE TO SILICONE OIL

NIPRO

D2F™ Pre-fillable Glass Syringes

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The molecular structure of complex biologics presents challenges to pre-fillable glass syringes.

Biologics are very viscous due to their molecule size which makes the administration more difficult. To ensure easy, safe, and comfortable administrations - also at home - they often are used in combination with auto-injection devices (AI).

In addition, biologics are often highly sensitive to particles and extractables & leachables as they can cause drug-container interactions that might reduce the therapeutic effectiveness. It is especially silicone, used as a lubricant in pre-fillable glass syringes, that can pose a significant risk.[1,2,3]

Nipro D2F Pre-fillable Glass Syringes - **Silicone Oil-free** are offered in **ENHANCE** quality to meet the challenging quality requirements of biologics sensitive to silicone oil.



Excellent drug-container compatibility

Silicone oil-free syringe system

Silicone oil-free barrel | Silicone oil-free plunger stopper

Minimized particle level

Stringent inspection for glass particles | Strict control of foreign matter

Reduced/no risk of interactions due to tungsten

Controlled low level of tungsten | Tungsten-free luer syringes

Smooth integration into auto-injection devices

Exact fit into auto-injection devices

Highly precise syringe dimensions | Controlled rigid needle shield concentricity and barrel bowing

Complete dose delivery and precise injection time

Low break-loose force | Consistent plunger gliding force

Supports safe operation of injection mechanisms

Strong flange | 100% in-line X-Ray inspection prevents pierced rigid needle shields (no unseen CCI)

Enables reliable use of cap removers

Reduced rigid needle shield pull-off force

1. Latoya S. Jones, Allyn Kaufmann, C. Russel Middaugh, Silicone Oil Induced Aggregation of Proteins, Journal of Pharmaceutical sciences, vol. 94, no. 4, April 2005.
2. Michael Adler, Challenges in the development of pre-filled syringes for biologics from a formulation scientist's point of view, American Pharmaceutical Review, 2012.
3. Tina Tölke, Jenny Rudolf, Andreas Pfuch, Bernd Grünler, Syringe Siliconization, Pharm. Ind. 81, Nr. 3, 404-409, 2019.

eNhance





Optimized processability for minimal drug loss

Reduced risk of final rejects due to cosmetic or dimensional aspects

100% in-line camera inspection of cosmetic and dimensional quality (incl. consistent flange restriction) | Rigid needle shield/closure intact and straight | Minimized particle level

Increased mechanical durability minimizes risk of breakage

Excellent quality of NSV51 glass (consistent wall thickness, minimal cosmetic defects, e.g., stones, knots, inclusions, etc.) | Laser-based cutting for increased durability of finger flanges

Reliable processability of D2F™ tubs

ETO indicator prevents entrance of unsterile tubs | Foreign matter reduction by air-wash of nest and tub | Automatic bagger ensures integrity of breather bag and optimal processability on filling line

Range

Volume	O.D.[1]	Tip		Flange			Shoulder
mL	mm	staked needle	luer lock	round	small round	cut	round
1.0 long	8.15	✓	✓	✓	✓	✓	✓

Glass tubing: Nipro NSV51 (borosilicate, Type I) | External supplier

Standard needle type[2]: 27G x ½", thin wall (V-bevel) | 29G x ½", thin wall (V-bevel)

Closures[3]: Rigid Needle Shield | LInC™ - Luer Lock Integrated Cap

Plunger: Transparent | Color **Plunger stoppers[3]:** Blue, silicone oil-free

Backstop: Transparent **Safety Systems[4]:** Active system | Passive system

SILICONE OIL-FREE

1: Outer diameter of glass barrel
2: Other sizes upon request
3: Rubber component suppliers: West, Aptar Stelmi, Datwyler, Gore
4: Safety system suppliers: Nemera, West, Schreiner MediPharm

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 15 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.

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