PRE-FILLABLE GLASS SYRINGES

FINE-TUNED TO MEET YOUR DRUG PRODUCT REQUIREMENTS

NIPRO PHARMAPACKAGING

Continuous partnership...

Nipro PharmaPackaging is a long-standing and trusted partner of leading pharmaceutical companies for the development and manufacture of high-quality parenteral packaging. From early development throughout the entire life-cycle of your drug product, you will partner with a vertically integrated company with more than 60 years of experience.

- We advise you on the optimal raw material for your primary packaging and manufacture for you the glass tubing that meets your dimensional and cosmetic requirements.
- Upon finalizing the specifications of your primary packaging, our state of the art converting lines, equipped with the latest inspection technologies, manufacture with precision and adhere to the strict dimensional and cosmetic tolerances required of your primary container.
- For exceptional packaging challenges, our highly experienced laboratory service team will collaborate with you to analyze and find solutions.
- You can also choose from a range of accessories, which can be by-packed with your primary container to improve end-user comfort and ease of use.

PACKAGING QUALITIES AND SERVICE LEVELS
fine-tuned to your drug product requirements!

...throughout the entire product life-cycle

During drug product development

- Extensive packaging range (ampoules, vials, cartridges, pre-fillable syringes)
- Cross-functional team of experts, advising on the most suitable packaging
- Quality Levels for structured and comprehensive packaging selection
- Provision of trial samples

During drug product approval

- Fast request procedure for Letters of Authorization (LoA)
- Product registered at FDA, Canada Health, NMPA (Drug Master Files)

During commercial production

- Large manufacturing network for continuous and ensured supply
- Switch from vials to syringes or cartridges while keeping the same supplier
- Laboratory services – Analytics for glass primary packaging
- Experienced technical service
- Specialized customer service
- Efficient complaint handling
- Dedicated sales

During product line extension

- Adapted packaging solutions for generics/biosimilars
- Dedicated team to advise on optimal packaging solutions

Silicone amount

Dimensional accuracy

Container closure integrity

Particle levels

Cosmetic aspects

Tungsten level

Mechanical durability

Solutions for a diverse market

Pharmaceutical companies are developing an increasing number of various drug products: from small molecules and biotechs to drugs for gene therapy. A substantial number are parenteral drugs, destined to be packed in pre-fillable syringes.

Each drug product has specific requirements that must be met by the primary packaging.

Some drug products require an economic packaging of standard quality, allowing a fast time to market and ensuring reliable processability of large quantities on high-speed filling lines.

Others are highly sensitive biotech drugs, requiring premium quality to minimize the risk of drug-container interactions, precise integration into auto-injection devices, and minimal drugs loss during fill-finish operations.

NIPRO QUALITY LEVELS FORM THE PERFECT BASE
to capture and fine-tune your quality and service requirements.

Quality Levels for pre-fillable syringes

At Nipro PharmaPackaging, we understand the diverse quality requirements of the pharmaceutical industry. Defining the right quality of primary packaging to meet your drug product requirements is a complex process.

To facilitate this process, we offer three distinct quality levels:

eNable:

small molecule drugs, anticoagulants, diluents

eNhance:

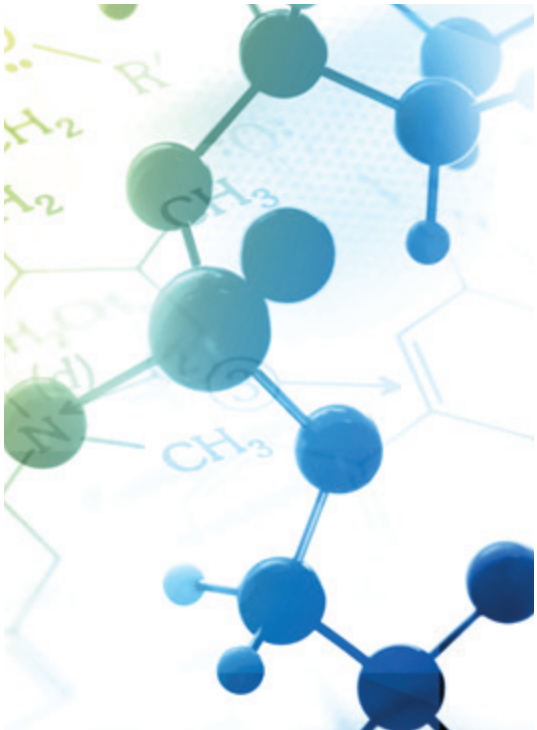
large molecule drugs, biotechs, ophthalmics, cosmetics, vaccines

eNgage:

flexible solutions for exceptional drug products

Level of Customization & Product Complexity

eNable → eNhance → eNgage



PRE-FILLABLE GLASS SYRINGES

Meeting prevailing drug product requirements

FOR SMALL MOLECULES, ANTICOAGULANTS, DILUENTS

Optimized processability for reduced total cost of ownership

Drug products packaged in pre-filled syringes are well established in the medical world and consumed in large quantities. Reliable processability on high-speed filling lines is particularly important for these drugs.

eNable syringes are controlled for specific attributes, such as reducing the risk of breakage, leakage, and rejections during final inspection.

Manufacturing & Inspections technologies	Benefits
Tip dimensions and positioning of the needle shield	Improved container closure integrity (CCI)
Inner diameter of the glass barrel Flange restriction	Proper placement of plunger stopper
Flange geometry	Increased mechanical durability
Nest & tub that is full and intact	Reliable processability
Nest & tub cleaned by ionized air	Reduced particle level

Standard data package for fast acceptance of goods

In order to register drug products and allow a seamless acceptance of in-bound goods, specific data from the packaging manufacturer is required. Nipro has foreseen this demand and supports customers by providing all necessary data.

Data Support	Benefits
Letters of Authorization (LoA) Drug Master Files (DMF) registered at the FDA, Canada Health, and NMPA	Supporting your registration
Certificate of Conformity (CoC)	Efficient acceptance of delivered goods
Extended regulatory data, (compliance to pharmacopoeias, levels of sub-visible particles, risk analysis)	Additional quality assurance

Designed for a safer and more reliable manual administration

Safeguarding patients and increasing their comfort while using syringes are principle objectives.

Our syringes are designed, manufactured, and inspected to contribute to a comfortable and safe administration.

Manufacturing & Inspections technologies	Benefits
Dive-in nozzle used for siliconization Fixed silicone quantity per syringe	Consistent plunger performance
Needle angularity & point, needle siliconization, penetration force, and free cannula passage	Supports smooth punctures
Needle pull-out force Sharp and accurate printing Needle shield removal force	Safer handling of the syringe during manual injection

eNable

PRODUCT RANGE

Syringe type

Volume	O.D.	Tip			Flange			Shoulder	
(mL)	(mm)	luer slip	luer lock	staked needle	round	small round	cut	round	flat
0.5	6.85	•	•	•	•	•	•	•	
1.0 long	8.15	•	•	•	•	•	•	•	
1.0 std.	10.85	•	•	•	•	•	•		•
1.25	10.85	•	•	•	•	•	•		•
1.5	10.85	•	•	•	•	•	•		•
2.25	10.85	•	•	•	•	•	•		•
3.0	10.85	•	•		•	•	•		•

Needle type

Outer Ø	Inner Ø	Free length	Bevel	Wall type
(G | mm)	(mm)	(inch | mm)		
25 | 0.50	0.30	⅝ | 16.0	3-Bevel	Regular
27 | 0.40	0.20	½ | 12.7	5-Bevel	Regular
27 | 0.40	0.26	½ | 12.7	5-Bevel	Thin

Closures

Staked needle	Luer lock	Luer slip
Rigid needle shield	Tip cap	Ribbed tip cap
Soft needle shield		

Components

Plunger rod	Plunger stopper	Safety system
Transparent	Standard	Novaguard
	Coated	

Suppliers: Aptar Stelmi, Datwyler, West, Nipro


18
19
20
21
22
25

eNhance

PRE-FILLABLE GLASS SYRINGES

Optimal choice for highly sensitive drugs

FOR LARGE MOLECULES, BIOTECHS, OPHTHALMICS, COSMETICS, VACCINES

Improved drug-container compatibility

Highly sensitive drugs, due to their nature, run higher risks of interacting with primary container materials (e.g. pH shift, protein aggregation, delamination). Several syringe specifications are inspected during the production process to ensure drug-container compatibility.

Manufacturing & Inspections technologies	Benefits
Glass particles and foreign matter	Controlled particle levels
Low tungsten/tungsten-free	Low/No tungsten residuals/particles
Homogeneous silicone distribution Extra low silicone amount	Minimized risk of areas with excessive silicone

Smooth integration into auto-injection devices

High drug viscosity, product differentiation, and end-user preference lead to an increased use of combination products. Several syringe parameters ensure reliable integration and a seamless functioning of auto-injection devices.

Manufacturing & Inspections technologies	Benefits
Rigid needle shield intact (camera and X-ray)	Improved CCI reduces risk of unseen leakage
Consistency of finger flange thickness	Increased mechanical durability to withstand physical impact of injection mechanism
Precise dimensions of flange, barrel, and tip Rigid needle shield concentricity and barrel bowing	Exact fit into device
Pull-off force (POF) of rigid needle shield	Reliable use of cap removers

Optimized processability for minimal drug loss

When filling high value drug products, each unit counts. Controlling specific syringe attributes will contribute to smooth fill-finish operations, in terms of reducing the risk of breakage, leakage, and rejections during final inspection.

Manufacturing & Inspections technologies	Benefits
Highly precise tip dimensions and exact positioning of the needle shield	Improved container closure integrity (CCI) reduces risk of leakage Reduced filling volume thanks to optimized dead volume of syringe tip
Tightly controlled cosmetic aspects (especially effective on unprinted syringes)	Less risk of rejections of filled syringes at final inspection due to cosmetic aspects
Consistency of finger flange thickness	Stronger mechanical durability for less risk of breakage during the filling process
Low silicone amount and tungsten level	Minimized risk of rejections due to large molecule aggregates or sub-visible particles level

eNhance

PRODUCT RANGE

Syringe type

Volume	O.D.	Tip		Flange			Shoulder	
(mL)	(mm)	luer lock	staked needle	round	small round	cut	round	flat
0.5	6.85	•	•	•	•	•	•	
1.0 long	8.15	•	•	•	•	•	•	
1.0 std.	10.85	•	•	•	•	•		•
1.25	10.85	•		•	•	•		•
1.5	10.85	•		•	•	•		•
2.25	10.85	•	•	•	•	•		•
3.0	10.85	•		•	•	•		•

Needle type

Outer Ø	Inner Ø	Free length	Bevel	Wall type
(G | mm)	(mm)	(inch | mm)		
25 | 0.50	0.30	⅝ | 16.0	3-Bevel	Regular
27 | 0.40	0.26	½ | 12.7	5-Bevel	Thin
29 | 0.33	0.19	½ | 12.7	5-Bevel	Thin

Closures

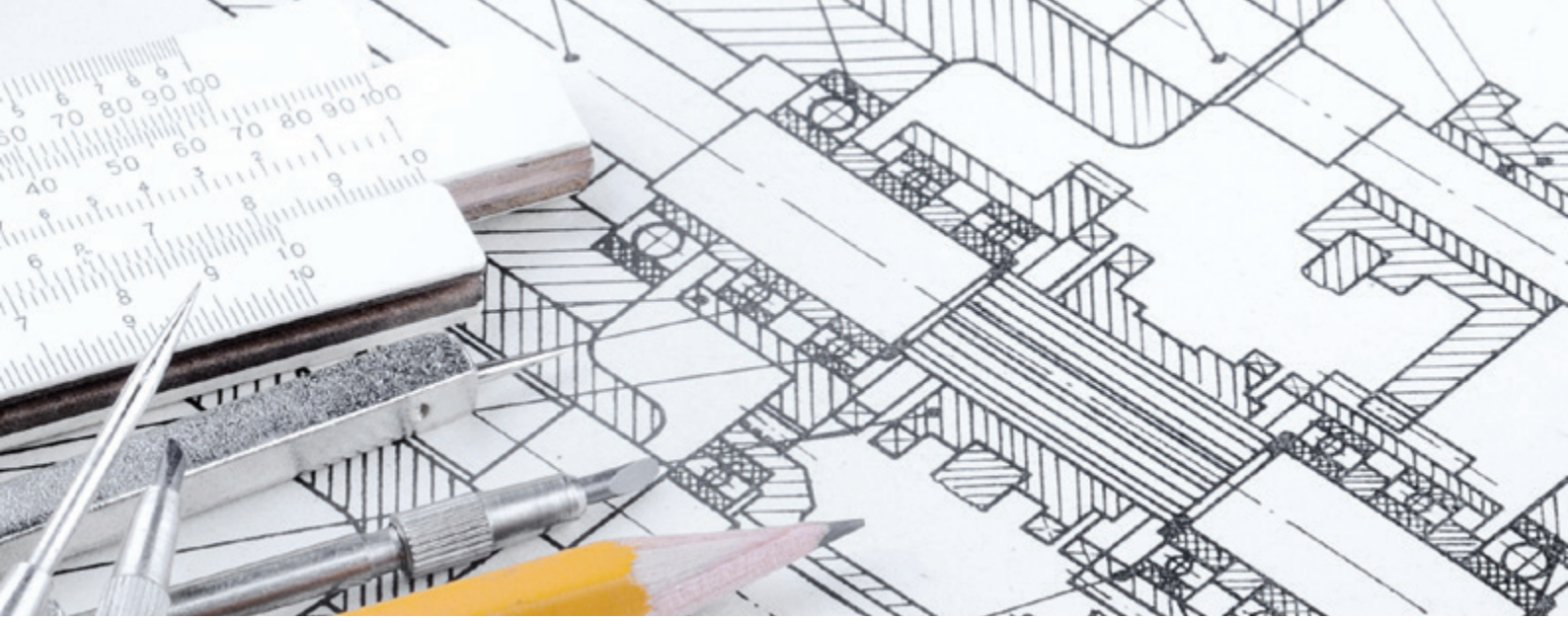
Staked needle	Luer lock	Plunger rod
Rigid needle shield	LInC™	Transparent
	V-OVS	Color

Components

Plunger stopper	Safety system
Standard	Safe'n'Sound
Coated	

Suppliers: Aptar Stelmi, Datwyler, West, Nipro, Nemera, Vetter


24
23
9
10
A&D

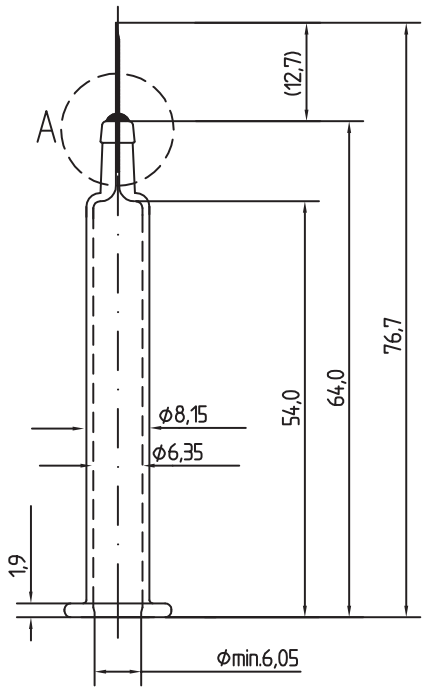


eNgage...

PRE-FILLABLE GLASS SYRINGES

For drug products with extraordinary packaging requirements

Customize your syringe specifications to meet your particular drug product requirements that surpass the eNhance quality level.



- Flange type
- Needle type
- Particle load
- Silicone level
- Cosmetic aspects
- Dimensional aspects

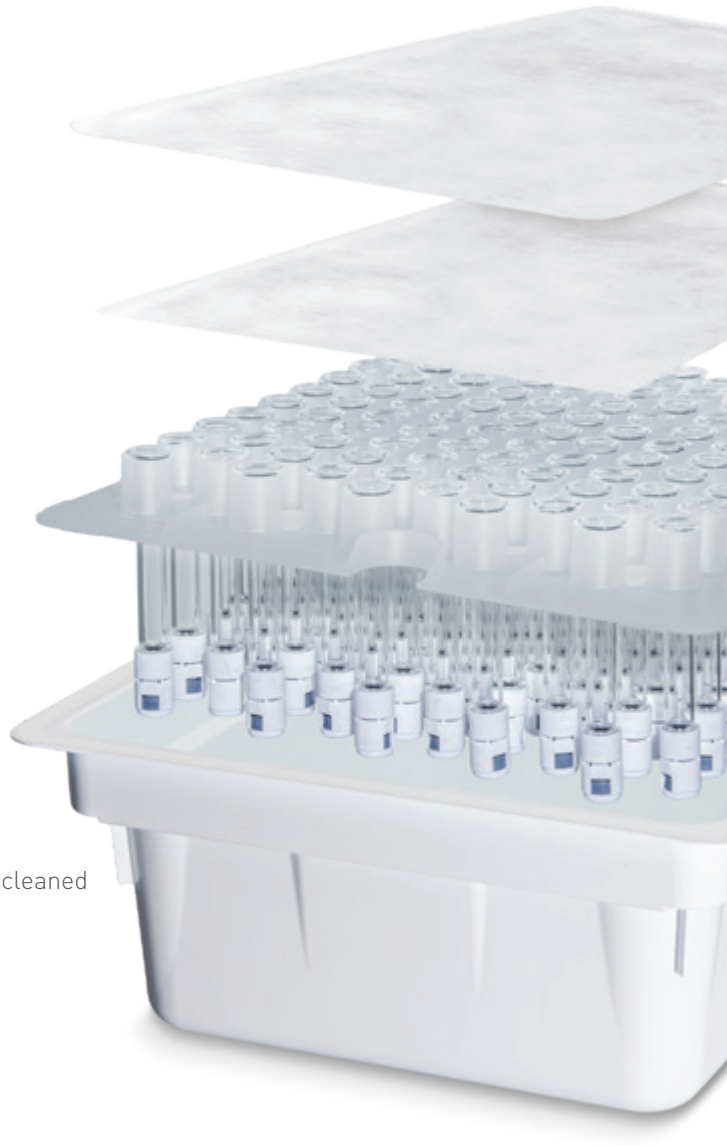
D2F™
Direct To Fill

Direct-To-Fill

STERILE PACKAGING SOLUTIONS

Nipro PharmaPackaging manufactures D2F™ syringes in technologically advanced production sites that are certified according to ISO 9001, ISO 15378, ISO 14001, and ISO 50001.

Our fully automated cleaning and packaging process takes place in an ISO 7 / ISO 8 cleanroom with 100% monitoring under laminar air flow.



Nest & tub are cleaned with ionized air

Washed & siliconized syringes are loaded into nest & tub

Covered with insert(s) and sealed with lid (Tyvek®)

Sealed tub is entered into breather bag(s) and welded closed

100% camera inspection confirms each tub is filled & correctly sealed

Tubs are transferred into outer boxes

Outer boxes are placed on pallets and secured for safe transportation

External sterilization is performed & EtO exposure is confirmed by the label

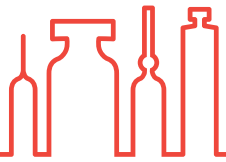
Key Technologies

- Cleaned with ionized air
- 100% in-line camera inspection
- No glass-to-glass contact
- EtO sensitive label

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.



MM-1613 - Bro-Prefillable Syringes-21.Jan2022

NIPRO PHARMAPACKAGING

NIPRO PHARMAPACKAGING INTERNATIONAL HEADQUARTERS
Blokhuisstraat 42, 2800 Mechelen, Belgium | pharmapackaging@nipro-group.com | www.nipro-group.com