



# PRE-FILLABLE GLASS SYRINGES

COMPLETE PACKAGING SOLUTIONS



# PRE-FILLABLE SYRINGES MEETING TOMORROW'S MARKET NEEDS

Increasing competition on the pharmaceutical market, stricter regulatory scrutiny and growing end-user expectations push the demand of pharma companies for innovative and cost-effective primary packaging solutions.

We offer a wide range of standard pre-fillable syringes and customized products, that answer to the various needs of customers marketing drugs in various therapeutic areas.



## PREMIUM GLASS TUBING FOR PHARMACEUTICAL PACKAGING

Nipro PharmaPackaging, with a global capacity of 97000 metric tons is the second largest tubing glass manufacturer in the world.

Among a wide range of high quality clear and amber glass tubing, we manufacture our premium type I, borosilicate tubing glass "NSV51".

Valued in the pharmaceutical market for its exceptional hydrolytic resistance and narrow dimensional tolerances, it is an excellent material for forming high quality pre-fillable syringes.



### OPTIMIZED PERFORMANCE ON FILLING LINES

- Advanced forming process leads to strong mechanical syringe stability
- Multiple inspection systems to ensure correct closure positioning
- Tight visual tolerances minimize cosmetic rejects

### HIGH COMPATIBILITY BETWEEN DRUG AND PACKAGING

- Customized siliconization 100% controlled in-line
- Reduced risk of drug-glue interaction as a result of precise UV curing
- Agreed tungsten levels or tungsten free allow best setup for drugs

### RELIABLE INCORPORATION IN INJECTION DEVICES

- Narrow dimensional tolerances support optimal fitting in device
- Adjustable siliconization results in smooth and consistent plunger gliding properties
- State-of-the-art forming process leads to strong mechanical flange stability

### SAFE AND COMFORTABLE HANDLING BY END-USER

- 100% X-ray in-line inspection for correctly assembled syringe closure
- Needle bonding is tested 100% in-line ensuring high pull-out forces
- Precise bevel design of Nipro needles provides a nearly painless injection

Nipro pre-fillable syringes support you in mastering the challenges of the competitive primary packaging environment - today and tomorrow!



Nipro PharmaPackaging is specialized in developing and manufacturing advanced pharma packaging products and complete packaging solutions for early development drugs or enhancement of packaging solutions of 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 its 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. With over 20000 employees worldwide, as a leading global healthcare company, Nipro serves the "Pharmaceuticals", "Medical devices" and "PharmaPackaging" industries.

# Pre-fillable syringes



## SYRINGE WITH LUER SLIP CONE GLASS BARREL

Volume (in mL)	Outside Ø (in mm)	Inside Ø (in mm)	Flanges (type)	Shoulders (type)	Printing
0.5	6.85	4.65	Round Round small Cut	Round Flat	Graduation Dose mark
1.0 long	8.15	6.35			
1.0	10.85	8.65			
2.25	10.85	8.65			
3.0	10.85	8.65			

### COMPONENTS

Luer slip closure	Plunger stopper	Plunger rod
Tip cap	Standard	Transparent
Ribbed tip cap		
	Coated	Color

Components from Aptar Stelmi, Datwyler, West, Nipro

### PACKAGING

Bulk	Packed in rondo trays
Direct-to-Fill	Washed, siliconized, assembled, packed (nest & tub), sterilized



## SYRINGE WITH STAKED NEEDLE GLASS BARREL

Volume (in mL)	Outside Ø (in mm)	Inside Ø (in mm)	Flanges (type)	Shoulders (type)	Printing
0.5	6.85	4.65	Round Round small Cut	Round Flat	Graduation Dose mark
1.0 long	8.15	6.35			
1.0	10.85	8.65			
2.25	10.85	8.65			

### STAKED NEEDLE

Bevel (type)	Outside Ø (in G & mm)	Inside Ø (in mm)	Free length (in Inch & mm)
3-bevel	23 G (0.60 mm)	0.40 mm	1" (25.4 mm)
V-bevel	25 G (0.50 mm)	0.30 mm	5/8" (16.0 mm)
Spoon point	27 G (0.40 mm)*	0.20 mm	1/2" (12.7 mm)
	27 G (0.40 mm)	0.26 mm	1/2" (12.7 mm)
	29 G (0.33 mm)	0.13 mm	1/2" (12.7 mm)
	29 G (0.33 mm)*	0.19 mm	1/2" (12.7 mm)

\*Wall type = "Thin walled" (TW). Other sizes upon request.

SYRINGE WITH STAKED NEEDLE

SYRINGE WITH LUER SLIP CONE

SYRINGE WITH LUER LOCK CONE

## SYRINGE WITH LUER LOCK CONE

### GLASS BARREL

Volume (in mL)	Outside Ø (in mm)	Inside Ø (in mm)	Flanges (type)	Shoulders (type)	Printing
0.5	6.85	4.65	Round	Round	Graduation
1.0 long	8.15	6.35	Round small	Flat	Dose mark
1.0	10.85	8.65	Cut		
2.25	10.85	8.65			
3.0	10.85	8.65			

### COMPONENTS

Luer lock closure	Plunger stopper	Plunger rod
LLA + Tip cap	Standard	Transparent
LLA + Tamper evident system	Coated	Color

Components from Aptar Stelmi, Datwyler, West, Nipro, Vetter-OVS®

### PACKAGING

Bulk	Packed in rondo trays
Direct-to-Fill	Washed, siliconized, assembled, packed (nest & tub), sterilized

### COMPONENTS

Needle shield	Plunger stopper	Plunger rod
Flexible/soft	Standard	Transparent
Rigid	Coated	Color

### PACKAGING

Bulk	Packed in rondo trays
Direct-to-Fill	Washed, siliconized, assembled, packed (nest & tub), sterilized

# State-of-the-art Manufacturing Process - The Key to Premium Quality!

Nipro's ongoing commitment to quality leads to manufacturing lines equipped with the latest technologies.

Fully automated camera inspection (360°) at various stages ensures narrow dimensional and cosmetic tolerances, fulfilling and exceeding prevailing customer expectations. The different stations of bulk production, needle bonding and sterile production are highly optimized, resulting in a stable and efficient production process.

Gentle transportation of the syringe barrels prevents glass-to-glass (-to-metal) contact. All processes are performed in controlled environments or ISO class clean rooms that are regulated by ISO and GMP standards.

Step	Key-Processes	Important controls <sup>1</sup> (automated, in-line 100%)
<b>LOADING</b>	Automated glass tube loaders transfer tubing glass onto the forming line, avoiding glass-to-glass contact and preventing micro cracks, scratches and impact related defects.	
<b>FORMING</b>	Precise laser based thermal cutting of the glass tubing and an automated adjustment and control of burner & flames lead to an accurate and reproducible forming of glass syringes with high mechanical stability.	Cosmetic defect tolerances, Dimensional defect tolerances (barrel, tip, flanges).
<b>BONDING</b>	Optimized UV curing process ensures proper needle bonding. Additional inspection steps control multiple needle specifications.	Hook detection, Total length, Free needle length, Upright & axial deviation, Pull out force.
<b>WASHING</b> (ISO 7 clean room <sup>2</sup> )	Washing is performed with WFI and servo driven dive-in technology.	
<b>SILICONIZATION</b> (ISO 7 clean room <sup>2</sup> )	An optimized silicone layer and tighter tolerances on silicone level, are created by servo-controlled siliconization nozzles (dive in technology) and the auto dosing systems for needle siliconization.	Presence + Homogeneity, Overlapping, Amount.
<b>ASSEMBLY</b> (ISO 7 clean room <sup>2</sup> )	Fully automated sorting and assembly of the closures (tip cap, needle shield, luer lock adapter) combined with an advanced visual inspection system (camera & X-ray technology), provide precisely positioned closures (needle shield, tip caps).	Total length, Finger flanges damaged LLA (damage, correct assembled, inclination, orientation), NS/TC (correct assembly inclination), NS not pierced (double stage).
<b>PACKAGING</b> (ISO 7 clean room <sup>2</sup> )	Nests and tubs are cleaned with ionized air prior to packaging. Final assembled pre-fillable syringes are loaded into nests & tubs. The tubs are covered with a Tyvek insert and sealed with a Tyvek lid. Sealed tubs are packed into a breather bag (double insert & bag possible) and transferred to final packaging station. Special packaging design prevents glass-to-glass contact.	PFS closures presence, Tub full, Sealing properly done.

<sup>1</sup> Non-exhaustive list

<sup>2</sup> Cleanroom with GMP 100% monitoring system, under LAF

Nipro's production process unlocks premium quality that fulfills the demands for Biotech drugs.



# Customized to meet your needs!

In order to comply with your quality requirements, Nipro is customizing the specifications to your needs.



GAUGE | LENGTH | BEVEL

Select needle type



Narrow cosmetic tolerances



Increase tubing glass quality



Tighten dimensional tolerances



Optimize silicone layer



Reduce tungsten level



Strengthen stability



## Committed to compliance & quality

Nipro quality management system is ISO 9001 and ISO 15378 certified, safeguarding that all processes and products are complying to prevailing standards.

Furthermore Nipro is investing time and resources to increase the energy efficiency of our plants and reducing our environmental footprint. This initiative has resulted in the certification according to ISO 50001 and ISO 14001.

Final products are only distributed to our customers after having passed severe quality checks.

## Your long-term partner for pre-fillable syringes

Strong investments in R&D, production capabilities and human capital enable Nipro also to be in the future your reliable provider of cutting edge product solutions.



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NIPRO PHARMAPACKAGING INTERNATIONAL HEADQUARTERS  
Weihoek 3H, 1930 Zaventem, Belgium  
[www.nipro-pharmapackaging.com](http://www.nipro-pharmapackaging.com) | [info@nipro-pharmapackaging.com](mailto:info@nipro-pharmapackaging.com)