



# PRODUCT PORTFOLIO

GLASS TUBING | PHARMACEUTICAL PRIMARY PACKAGING | MEDICAL DEVICES | SERVICES



# DELIVERING TRUST

WITH EACH PRIMARY PACKAGING SOLUTION

PRODUCT LIFE-CYCLE MANAGEMENT



## High-quality Glass Tubing and Primary Packaging Solutions

### Glass Tubing

Borosilicate | Soda Lime

(in-house production, quality & supply assurance, multi-site sourcing possible)

### Primary Packaging Solutions

Ampoules | Cartridges | RTU Syringes | RTU Vials | Components & Accessories

(stoppers, closures, plunger rods, backstops, safety systems, etc.)

### Medical Devices

Reconstitution devices | Hypodermic needles



## Extensive Experience

Active since 1954 | Vertically integrated with in-house knowhow from sand to container | Long standing supplier to pharmaceutical leaders | Serving the global pharmaceutical industry



## Global Manufacturing Network

Glass Tubing | Primary packaging | Medical devices | Components

13+ state-of-the-art factories | In Asia, Europe, America | Local supply | Shorter supply chains | Multi-site sourcing | 100% in-line advanced inspection systems – visual, laser, X-ray | Statistical process control (SPC) | Multiple in-process controls (IPC)



## Worldwide Quality Approach

ISO 15378 | ISO 14001 | ISO 50001 | ISO 45001 | ISO 13485

Strict quality systems | High-quality products | Compliance with legal and industry standards | Global standardization | Technology integration | Continuous improvement | Employee engagement | Customer focused



## Ambitious Sustainability Targets

ESG goals | SBTi | Compliance to environmental standards | Continuous modernization of production | Affiliate of relevant organizations | KPIs and reporting



## Comprehensive Service and Support

Customer service | Technical customer support | Regulatory & Quality support | Laboratory services  
Proactive assistance | Customer centric | Right first time

# Your Preferred and Trusted Partner

**TO SAFELY DELIVER PARENTERAL MEDICINES TO PATIENTS**

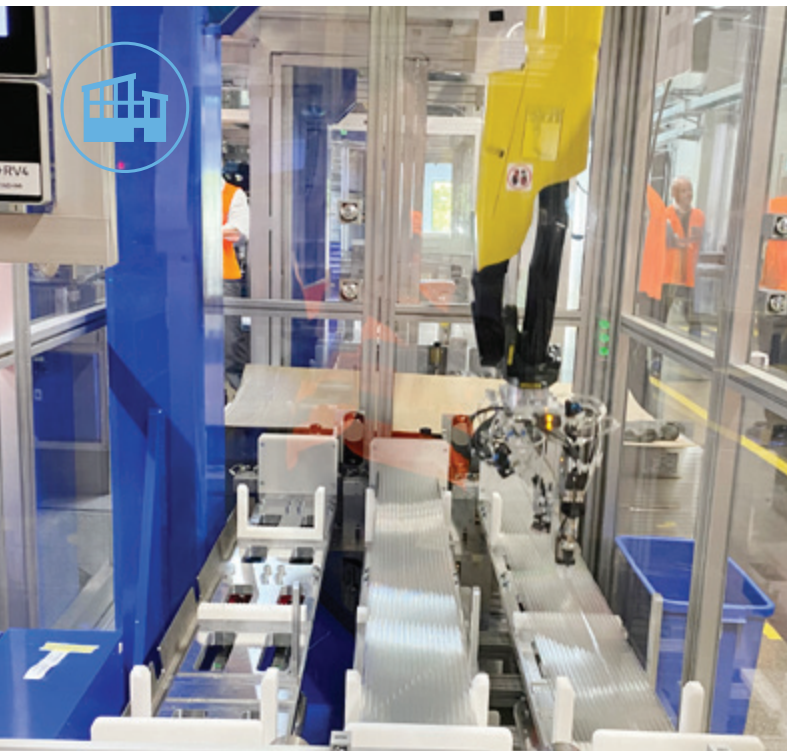
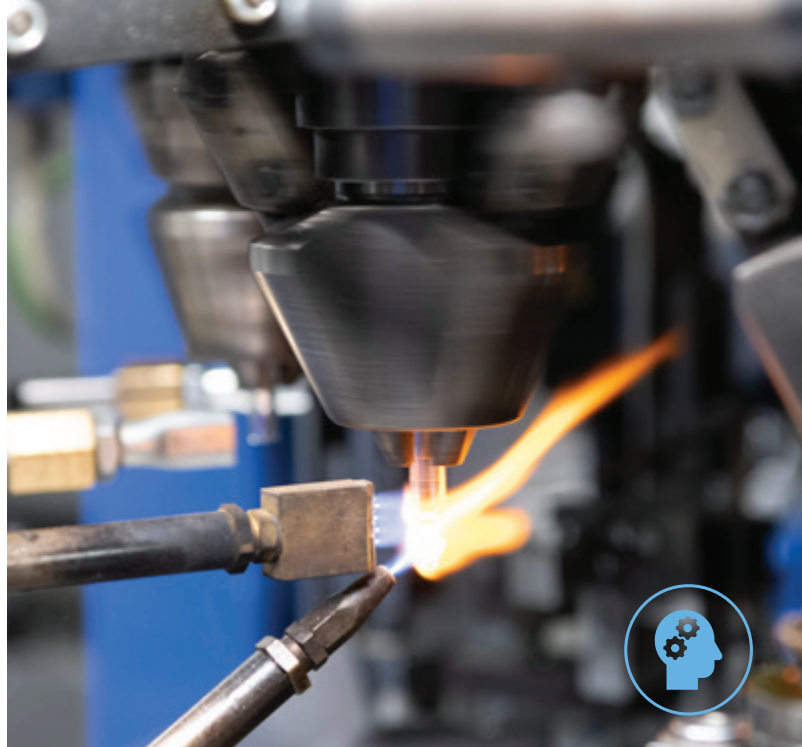


## Extensive Experience

NIPRO PharmaPackaging has been a trusted partner in primary packaging and medical devices for the global pharmaceutical industry since 1954. As a vertically integrated company, we manage the entire process, from raw materials to final delivery.

Choosing the right glass tubing is critical, as it determines key dimensional, cosmetic, and chemical properties. NIPRO produces high-quality glass tubing in-house for consistent quality and reliable supply. With billions of glass containers manufactured annually, we have the expertise to help you select the ideal container for your drug product and fill-finish operations.

We also offer a range of medical devices that simplify and enhance reconstitution and administration. Our partners benefit from complete packaging solutions that improve both usability and patient appeal.



## Global Manufacturing Network

NIPRO operates one of the largest manufacturing networks in the glass primary packaging industry with 13 state-of-the-art production sites across Asia, Europe, and America. Our global presence allows business partners to source packaging solutions worldwide with local production. This results in faster supply times, risk mitigation through multi-sourcing, and enhanced sustainability due to shorter supply chains.

To produce our medical device range, we collaborate with the medical division of NIPRO, a global market leader in healthcare products renowned for meticulous production processes and premium quality products.

All our plants are highly automated, equipped with advanced machinery, and utilize sophisticated dimensional and cosmetic in-line inspection systems to ensure your products are manufactured precisely and to agreed specifications.

## Sustainability Minded

NIPRO is deeply committed to sustainability, aiming to significantly reduce its environmental impact while continuing to deliver high-quality products and services.

NIPRO has a clear vision and global sustainability roadmap to achieve ambitious ESG goals such as meeting all SBTi objectives, maintaining an EcoVadis rating of silver or higher, ISO 50001 certification on all sites and a company-wide carbon neutrality by 2045.



## High-Quality Primary Packaging Solutions

NIPRO offers an extensive range of high-quality glass primary packaging solutions, including ampoules, dental and pen cartridges, D2F™ syringes, and D2F™ vials<sup>1</sup>. As a provider of complete injection systems, we also supply all essential components (closures, stoppers, plunger rods, caps, etc.) and accessories (finger flange extensions, safety systems, etc.).

Recognizing the widespread use of combination products in the industry, we collaborate with device manufacturers to ensure seamless integration of cartridges and pre-fillable syringes into injection devices, providing all necessary compatibility statements.

Additionally, NIPRO offers a selective range of medical devices, such as Curacase™ needles and D2Mix™ devices designed to facilitate safer and more efficient reconstitution and administration processes.



## Comprehensive Service and Support

Developing a new packaging solution that meets the specific requirements of a drug product, and then integrating it into the fill-finish process is a complex journey.

NIPRO's highly trained, customer-focused service organization is here to support you every step of the way.

Our dedicated team includes experts in sales and customer service, regulatory and quality affairs, and technical support. In addition, our in-house laboratory services provide analytical testing and studies to help optimize the performance of packaging solutions.

From development to commercialization, you'll be supported throughout the entire product life cycle by a competent, cross-functional team. We ensure your inquiries are addressed quickly and efficiently, with full commitment to your success.

## Worldwide Quality Approach

When it comes to medication and patient well-being, quality is paramount. Our processes are governed by stringent quality systems, including ISO 15378, ISO 13485, ISO 45001, ISO 14001, and ISO 50001.

Our glass tubing, primary container, and medical devices comply with the applicable ISO standards, Pharmacopeias, industry standards, and MDR.

To ensure consistently high product quality across all our plants, we continuously improve our global equipment, processes, and technologies.



# The Right Product Quality and Supporting Data

The process of defining the right product quality and essential supporting data to meet your specific requirements is a complex process. Multiple parameters need to be considered to ensure the correct match.

To simplify this process, NIPRO offers you three distinct quality levels. Within each level, relevant product attributes and supporting data are set to meet pre-defined quality targets. The comprehensive scope of attributes means the product and data quality can be fine-tuned to your requirements.

You will be supported by an experienced, cross-functional team to find what you need swiftly and efficiently.

○ = Available level of customization    ★ = Product, data & service quality

## ENABLE | STANDARD QUALITY |

- Standard product quality
- Pre-set, standardized product specifications
- Standard tolerance (AQLs | %)
- Comprehensive service and support
- Standard data package



## ENHANCE | HIGH QUALITY |

- High product quality
- Pre-set, standardized product specifications
- Strict tolerance (AQLs | %)
- Comprehensive service and support
- Extended data package



## ENGAGE | CUSTOM QUALITY |

- Product attributes and service level are fully customizable to fulfill the most challenging, non-standard quality requirements.



# Recommended Primary Packaging Solutions

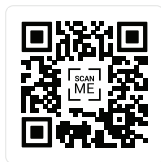
CONTAINER TYPE | SPECIFICATIONS | AQLS | QUALITY LEVEL | TOLERANCES | COMPONENTS | ACCESSORIES | PACKAGING TYPE | DATA SUPPORT



## The Right Solution for a Specific Therapy Area

Discover our recommended selection of high-quality primary packaging solutions for medicines used in specific areas. Designed with precision and care, our recommended solutions target the product and service requirements that are standard in each therapeutic area.

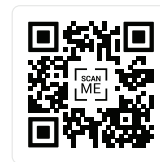
### Cardiovascular



### Oncology



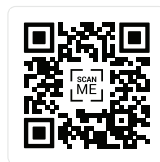
### Hematology



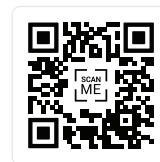
### Dental



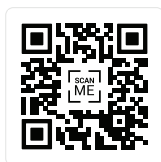
### Animal Health



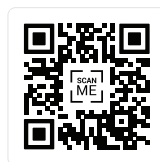
### Infectious Disease



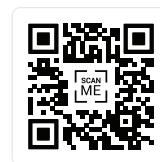
### Chronic Disease Self-administration



### Chronic Disease Advanced



### Chronic Disease Diabetes





# Glass Tubing

## FOR PHARMACEUTICAL PRIMARY PACKAGING

Our high-quality glass tubing has been a foundation for leading primary packaging converters, enabling the production of premium RTU syringes, RTU vials, pen cartridges, and ampoules for the pharmaceutical industry. We supply our customers from two state-of-the-art plants in France and the USA.

They enable multi-site sourcing, inherent risk mitigation, and a local supply. Additionally, the two plants offer supply assurance with an annual capacity of more than 50,000 tons. We employ advanced inspection technologies 100% inline for a wide range of dimensional and cosmetic parameters. Quality is further monitored through statistical process control (SPC) and multiple in-process controls (IPCs).

### Outstanding Cosmetic Quality

We carry out highly accurate inspections using a wide range of cosmetic quality parameters. The lines are equipped with in-line air flushing systems to minimize particle levels. Additionally, a coating can be applied to protect the glass tubing against contact-related defects during handling and storage.

### Extremely Precise Dimensional Accuracy

Visual and laser-based inspections are carried out to an extensive range of dimensional attributes with very narrow tolerances. Highly consistent wall thickness enhances the mechanical durability of the glass tubing and final containers.

### Meeting the Highest Regulatory and Quality Requirements

Our state-of-the-art facilities adhere to stringent industry standards, including ISO 15378, ISO 14001, and ISO 45001. We manufacture our glass tubing in compliance with European Pharmacopoeia, Japanese Pharmacopoeia, and United States Pharmacopoeia requirements, ensuring the highest quality and safety in all markets.

NSV 51	W33	WG06
Clear	Clear	Clear
Borosilicate	Borosilicate	Soda Lime
Type I	Type I	Type III
Exp: 51	Exp: 33	Exp: 93

NSV51 and WG06 optional with Cerium

### Quality Levels

ENABLE	ENHANCE	ENGAGE
✓	✓	✓

### Standard Sizes for Vials

OD (mm)	Wall thickness (mm)
6.8 - 8.9	0.80 - 0.95
	1.00 - 1.10
	1.10 - 1.20
	1.30 - 1.50
9.0 - 9.9	0.70 - 0.99
	1.00 - 1.19
	1.20 - 1.29
	1.30 - 1.50
10.0 - 14.9	0.70 - 0.99
	1.00 - 1.19
	1.20 - 1.29
	1.30 - 1.50
15.0 - 17.9	0.80 - 0.99
	1.00 - 1.09
	1.10 - 1.29
	1.30 - 1.39
18.0 - 19.9	1.40 - 1.60
	1.00 - 1.09
20.0 - 20.9	1.10 - 1.35
	1.00 - 1.09
	1.10 - 1.35

### Standard Sizes for Ampoules

OD (mm)	Wall thickness (mm)
10.0 - 14.9	0.45 - 0.59
	0.60 - 0.69
15.0 - 17.9	0.45 - 0.60
	0.65 - 0.80
18.0 - 19.9	0.55 - 0.60
	0.65 - 0.99
20.0 - 20.9	0.55 - 0.60
	0.65 - 0.99
21.0 - 22.9	0.65 - 0.99
23.0 - 24.9	0.80 - 0.99
25.0 - 29.9	0.89 - 0.99

### Standard Sizes for Syringes

OD (mm)	ID (mm)
8.65	6.85
10.85	8.65
10.95	9.25
11.60	9.70
14.00	12.00
14.45	11.85
18.25	16.25

### Standard sizes for Cartridges

OD (mm)	ID (mm)
8.65	6.85
10.85	8.65
10.95	9.25
11.60	9.70
14.00	12.00
14.45	11.85
18.25	16.25



# D2F™ Pre-Fillable Glass Syringes

READY-TO-USE PRIMARY PACKAGING SOLUTIONS FOR PHARMACEUTICAL APPLICATIONS

As a leading manufacturer of high-quality pre-fillable glass syringes for the pharmaceutical industry, NIPRO offers packaging solutions precisely engineered to three different quality levels (ENABLE, ENHANCE, ENGAGE) to meet the stringent demands of both standard and complex drug formulations.

## Excellent Compatibility Between Drug and Container

Tungsten residues and silicone oil can interact with sensitive drug products such as monoclonal antibodies and enzymes, potentially affecting their stability. To mitigate this, our D2F™ syringes are available in tungsten-free (Luer) or low-tungsten (staked-needle) formats, with minimal or no silicone oil, controlled within narrow tolerances. We ensure 100% in-line monitoring of silicone quantity and distribution and apply advanced washing and strict inspections to reduce particulate contamination. Each batch undergoes precise particle measurement using light obscuration to meet the highest quality standards.

## Designed for Integration into Auto-Injection Devices (AIDs) & for Compatibility with Needle Free Connectors (NFCs)

The growing use of combination products (staked needle syringe + AID) is driven by their ability to enhance convenience and adherence, supporting the delivery of large-volume or high-viscosity drugs, and ultimately improving patient outcomes. In parallel, needle-free connectors (NFCs) are widely adopted in healthcare settings to prevent sharps injuries and enable safer, easier intravenous administration.

D2F™ syringes are engineered for seamless integration into AIDs and compatibility with NFCs, offering high mechanical durability and precise dimensions within tight tolerances achieved through advanced forming and annealing processes. Every critical specification is inspected 100% in-line, while x-ray inspection provides an enhanced control of container closure integrity for safer, more reliable use.

Additionally, multiple parameters are controlled to guarantee a consistently smooth needle performance and needle shield removal force, optimizing AID functionality and user experience.

For NFCs featuring an internal blunt cannula, NIPRO offers specific Luer lock syringe variants with a widened syringe tip channel, enabling safer and more secure connections.

## Optimized Processability for Minimal Rejection

We manufacture our syringes to support seamless integration with the sophisticated workflow of our pharmaceutical customers. High dimensional accuracy and cosmetic quality, strong mechanical durability, and reliability processing D2F™ nest and tub formats contribute to an efficient fill-finish process and stable storage.

## Standard Range

Volume mL	OD mm	ID mm	Tip		Flange		Packaging	
			Luer (lock)	Staked needle	Round	Cut	Per nest (pcs)	Tub height (mm)
0.5	6.85	4.65	✓	✓	✓	✓	100   160	96
1.0 long	8.15	6.35	✓ <sup>1</sup>	✓	✓	✓		96   120 <sup>1</sup>
1.0 std.	10.85	8.65	✓	✓	✓	✓	100	96
1.25	10.85	8.65	✓	✓	✓	✓		
1.5	10.85	8.65	✓	✓	✓	✓		
2.25	10.85	8.65	✓	✓	✓	✓		
3.0	10.85	8.65	✓	—	✓	✓		
								120

<sup>1</sup> in combination with a 1-inch cannula

## Staked Needle Syringes - Needle Range

G	OD		Free Length		ID	Wall thickness	Bevel
	mm	inch	mm	mm	mm	type	type
23	0.641 ± 0.007		1	25.4	0.33 ± 0.02	RW	3
25	0.500 ± 0.01		1	25.4	0.30 ± 0.01	RW	3
	0.514 ± 0.007				0.26 ± 0.02	RW	3
27	0.400 ± 0.01		1/2	12.7	0.20 ± 0.01	RW	5
					0.27 ± 0.01	TW	
					0.30 ± 0.01	ETW	
29	0.330 ± 0.01		1/2	12.7	0.16 ± 0.03	RW	5
					0.20 ± 0.01	TW	
					0.25 ± 0.01	ETW	



RW = Regular Wall, TW = Thin Wall, ETW = Extra Thin Wall | Material: Steel ASTM S30400 (US-Standard) / AISI 304 - X5CrNi18-10

## Staked Needle Syringes - Needle Shield Range

Syringe Range		Quality Level	Soft Needle Shield			Nest & Tub	
mL	OD (mm)	ENABLE	Datwyler • V6542 • FM27 • ½"	Datwyler • V6544 • FM27 • ½"	Aptar • C0038 4800GS • ⅝"	Per nest (pcs)	Tub Height (mm)
0.5	6.85	✓	✓	✓	—	100   160	96
1.0 long	8.15	✓	✓	✓	✓		
1.0 std.	10.85	✓	—	—	✓	100	



Syringe Range		Quality Level		Rigid Needle Shield					Nest & Tub	
mL	OD (mm)	ENABLE	ENHANCE	Aptar • P0038 • 4800GS • ⅝"	Aptar • P0037 • 4800GS • ½"	Aptar • P0046 • 4800GS • 1"	Datwyler • V9812 • FM30 • ½"	West • 4144 • 7025 • ½"	Per nest (pcs)	Tub Height (mm)
0.5	6.85	✓	✓	—	✓	—	✓	—	100   160	96   120
1.0 long	8.15	✓	✓	✓	✓	✓	✓	✓		
1.0 std.	10.85	✓	✓	✓	—	✓	✓	—	100	
1.25	10.85	✓	✓	—	—	—	✓	—		
1.5	10.85	✓	✓	✓	—	—	—	—		
2.25	10.85	✓	✓	✓	✓	—	✓	—		



4800GS = Polyisoprene | FM30 = Styrene Butadiene | 7025/65 = Polyisoprene-Bromobutyl blend | Product group available in silicone oil free syringe system with 0.5, 1 long and 1-3 mL Gore Plunger, ENHANCE quality only | <sup>1</sup> only for 1 mL long + 1" RNS

## Luer Lock Syringes – Closure Range

Syringe Range		Quality Level		Easy Turn Tip Cap	Nest & Tub	
mL	OD (mm)	ENABLE	ENHANCE	West • 3131 • 7025/65	Per nest (pcs)	Tub Height (mm)
0.5	6.85	✓	✓ <sup>1</sup>	✓	100	96
1.0 long	8.15	✓	—	✓		
1.0 std.	10.85	✓	—	✓		
1.5	10.85	✓	—	✓		
2.25	10.85	✓	—	✓		
3.0	10.85	✓	—	✓		120



<sup>1</sup> available in silicone oil free syringe system in 0.5 mL | 7025/65 = Polyisoprene-Bromobutyl blend

Syringe Range		Quality Level		LInC™				Nest & Tub	
mL	OD (mm)	ENABLE	ENHANCE	Datwyler • V9507 • FM27 <sup>1</sup>	Datwyler • V9507 • FM30	West • 3155 • 7025	West • 3155 • 7028 <sup>1</sup>	Per nest (pcs)	Tub Height (mm)
1.0 long	8.15	✓	✓	✓	✓	✓	✓	100	96
1.0 std.	10.85	✓	✓	✓	✓	✓	✓		
1.25	10.85	✓	✓	✓	✓	✓	✓		
1.5	10.85	✓	✓	✓	✓	✓	✓		
2.25	10.85	✓	✓	✓	✓	✓	✓		
3.0	10.85	✓	✓	✓	✓	✓	✓		120



<sup>1</sup> on request

<sup>2</sup> FM27 = Styrene Butadiene containing natural rubber latex | FM30 = Styrene Butadiene; 7025/65 = Polyisoprene-Bromobutyl blend; 7028/55 = Polyisoprene | Product group available in Silicone oil free syringe system with Gore Plunger | Product group available with Luer lock syringe variant allowing safer connection to NFC having internal blunt cannula

## Luer Syringes – Closure Range

Syringe Range		Quality Level	Ribbed Tip Cap	Nest & Tub	
mL	OD (mm)	ENABLE	Datwyler • V9406 • FM30	Per nest (pcs)	Tub Height (mm)
1.0 std.	10.85	✓	✓	100	96
2.25	10.85	✓	✓	100	96



FM30 = Styrene Butadiene

Syringe Range		Quality Level	Easy Turn Tip Cap	Nest & Tub	
mL	OD (mm)	ENABLE	West • 3131 • 7025	Per nest (pcs)	Tub Height (mm)
0.5	6.85	✓	✓	100   160	96
1.0 long	8.15	✓	✓	100   160	
1.0 std.	10.85	✓	✓	100	
1.5	10.85	✓	✓	100	96
2.25	10.85	✓	✓		120
3.0	10.85	✓	✓		



7025/65= Polyisoprene-Bromobutyl blend

## Plunger Stopper, Plunger Rod, Backstop

Plunger rod	Plunger stopper <sup>1,3</sup>	Backstop <sup>2</sup>
0.5 to 3 mL	0.5 to 3 mL	0.5 to 3 mL
Transparent	Non-coated	Transparent
Color	Coated	—
—	Silicone oil free	—

## Compatible Safety Systems and Auto-injectors

Compatible safety system	Compatible auto-injector
Needle Trap™ Schreiner MediPharm	Piccoject 100 Haselmeier
Safe'n'Sound® Nemera	Molly® SHL Medical
—	Ypsomate Ypsomed

Compatibility statement on request available



# D2F™ Glass Vials

READY-TO-USE PRIMARY PACKAGING SOLUTIONS FOR PHARMACEUTICAL APPLICATIONS

NIPRO, a trusted manufacturer of high-quality RTU glass vials, delivers tailored solutions for both conventional and advanced pharmaceutical formulations. Whether for vaccines, biologics, or other sensitive medications, NIPRO D2F™ glass vials<sup>1</sup> provide a reliable option for pharmaceutical companies.

## D2F Vials Shorten Time to Market

For pharmaceutical companies transitioning to RTU vials, D2F vials<sup>1</sup> eliminate the need for in-house washing and depyrogenation. Ready to use in aseptic environments, they support scalable production, from test batches to commercial volumes. Developed in collaboration with leading machine manufacturers, D2F nest and tub formats are compatible with a wide range of fill-finish lines, ensuring smooth and rapid integration.

## No Glass-to-Glass Contact Improves Filling Line Container Performance

D2F™ nest and tub formats prevent glass-to-glass contact, reducing the risk of breakage, cosmetic defects, and particle generation during transport and handling. This protection helps maintain the vials' mechanical strength and visual quality, resulting in fewer breakages, less downtime on fill-finish lines, and lower rejection rates during final inspection.

## Outsourcing of Non-Core Activities Improves Total Cost of Ownership

By outsourcing non-core activities for sterile vials to NIPRO, our business partner will save the time and cost involved in preparing RTU containers. Our customers will receive D2F™ vials<sup>1</sup> washed, depyrogenated, and sterilized, ready to be used directly in aseptic fill-finish operations.

# Standard Range

## Crimp Neck<sup>2</sup> Vials - Sizes and Types

Volume	d1	d2	h	s	VIALEX™	D2F™
mL	mm	mm	mm	mm	available	available
2R	16	13	35	1	✓	✓
4R			45		✓	✓
6R	22	20	40		✓	✓
8R			45		✓	✓
10R	24	20	40	1.2	✓	✓
15R			60		✓	✓
20R	30	20	55	1.5	✓	✓
25R			64		—	✓
30R	40	20	75	1.7	—	✓
50R			73		—	—
75	47	28	75	1.5	—	—
75		20		1.95	—	—
75		32		—	—	
75	40	20	100	1.5	—	—
100R					—	—
100	47	28	95	1.95	—	—
100		32			—	—

1 powered by Stevanato Group EZ-fill® technology | ISO 8362-1:2018-compliant | d1 = OD body | d2 = OD neck | h = Height | s = wall thickness | Custom developments on request

Blowback	Printing	Options
None	Ceramic	Ammonium sulfate treatment
European		
US		



## Screw Neck Vials<sup>1</sup>

Volume	d1	d2	h	s	
mL	mm	mm	mm	mm	
5	18	14	45	1.2	
7.5	22	18	40		
10	24	18	45		
15			60		
20	30	22	55	1.5	
25			65		
30			75		
50	40	22	73		1.7
60			80		
70			90		
75			28	80	
75	47	32	85	1.7	
80			90		
90			95		
100	28	32	110		
125					

1 ISO 11478-7:2016-compliant available | d1=OD body | d2=OD neck | h = Height | s = wall thickness



Printing	Options
Ceramic	VIALEX™
	Ammonium sulfate treatment
	Siliconization inside

VIALEX™ = proprietary thermal treatment of inner vial surface

## Quality Levels

ENABLE	ENHANCE	ENGAGE
✓	✓	✓

# Specialty Vial Range

## Unit-dose™ Micro Vials

Volume	d1	d2	h	s
mL	mm	mm	mm	mm
0.35	6.6	8.75	19.5	0.8
0.5			28	

d1=OD body | d2=OD neck | h = Height | s = wall thickness

## High-Recovery Vials

Max. Volume	d1	d2	h	s
mL	mm	mm	mm	mm
0.66	16	13	40	1
1.1		12.3	52	1
2.06	22	16	40	1.2
2.77	24	20	45	1

d1=OD body | d2=OD neck | h = Height | s = wall thickness | Custom developemnt on request



# ENHANCE Quality Vials

## Treated with VIALEX™

### FOR VIALS WITH EXCEPTIONAL INNER SURFACE DURABILITY

Most drug products for injection in the current drug pipeline are large molecules, including biologics, oligonucleotides, and gene therapy drug products.

Given their high value and sensitivity to drug-container interactions, selecting the right primary container for these products is critical. The VIALEX™ process has been developed to improve the inner surface of vials to contribute to stable and safe storage of sensitive drug products.



## Benefits of VIALEX™ Process

### VIALEX™ process

The inner glass surface of the vial is treated with NIPRO's proprietary VIALEX™ thermal process after the standard vial converting process. This involves no extra materials and no change to the glass chemistry, with 100% in-line inspection that the treatment was applied successfully. The treatment mitigates unwanted effects from the converting process twofold.

### Improved inner vial surface

- Sodium concentration reduced
- Inner glass surface improved

### Benefits

- Less interaction between drug molecules and formulations with the inner glass surface
- Reduced level of extractables and leachables
- Lower pH shift
- Reduced risk of glass delamination
- Optimized lyophilization process (less fogging)

### Industry standard vial converting process

Up to 1200°C temperature during parting & forming. Consequently, glass components start to sublime and re-sublimate in the heating zone, typically 3-5 mm from the heel up.

### Inner vials surface Altered

- Highly soluble sodium borate deposits
- Inner surface more silica-rich and alkali-depleted

### Potential Risks for Drug Products

- Increased levels of leachables and extractables
- Higher pH shift
- Delamination incidents

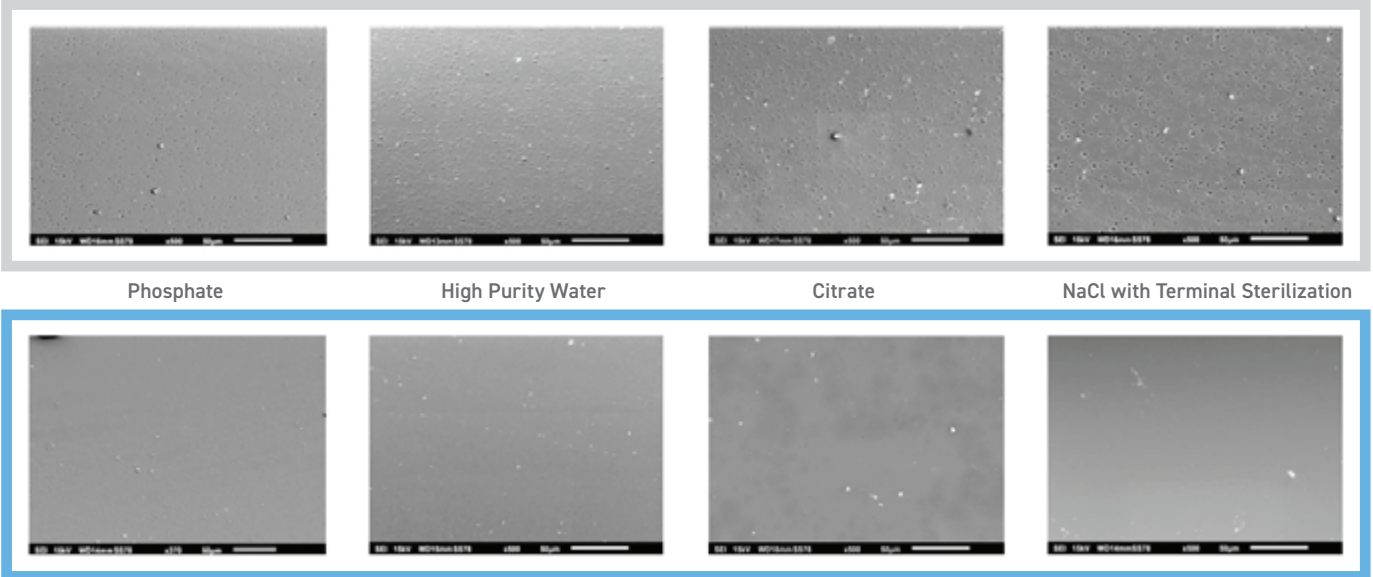
VIALEX™ processed vials are tested according to industry standards, under challenging conditions and with aggressive buffer solutions such as phosphate, high purity water, citrate, and NaCl with terminal sterilization. The results underline the exceptional inner surface durability compared to industry standard vial.

# Test Results Long-Term Study

(24 WEEKS AT 40°C - 51EXP)

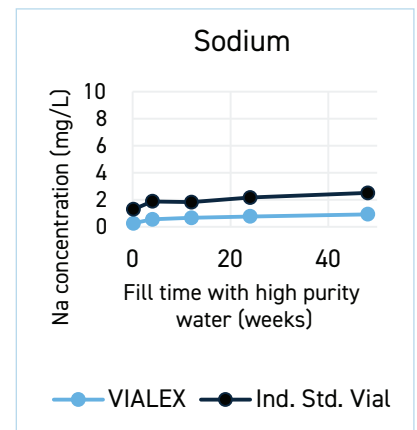
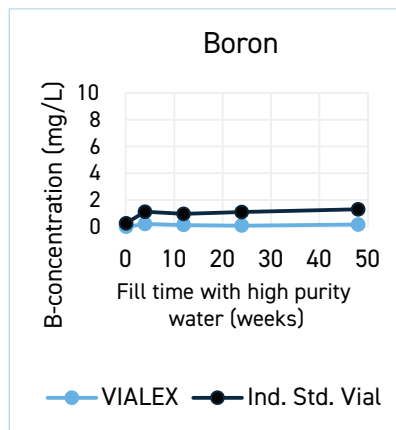
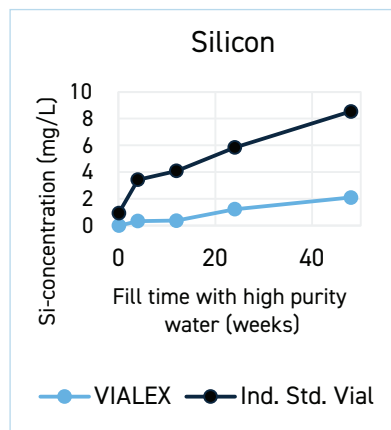
## SEM - Surface images

Industry Standard Vial = Pitting & Surface Interactions



VIALEX™ = Improved Surface Durability & Significantly Fewer Surface Interactions

## High Purity Water - Extractables



## Vials Treated with VIALEX are Superior to Current Alternatives

	VIALEX™	Process Control	Washing or Etching	Change in Glass Chemistry	Inner Surface Coating
Sodium deposits removed	✓	X <sup>1</sup>	✓	✓   n/a <sup>2</sup>	✓
Inner glass surface improved	✓	X	X	X	X
No additional material (risk factor)	✓	✓	✓	X <sup>3</sup>	X <sup>4</sup>
No extensive regulatory work	✓	✓	✓	X	X
100% in-line inspection of VIALEX™ process finished properly	✓	X <sup>5</sup>	X <sup>5</sup>	X <sup>5</sup>	X <sup>5</sup>
Optimized lyophilization process (less fogging)	✓	X	X	X	✓

1 reduction, no elimination | 2 depending on glass | 3 new glass material | 4 coating = new material | 5 samples = statistical



# Glass Cartridges

FOR DENTAL AND PEN APPLICATIONS

NIPRO offers high-quality dental and pen cartridges that ensure reliable fill-finish operations and are designed for precise integration into injection pens and injection devices.

## Support reliable and fast filling line operations

Tight dimensional tolerances contribute to reliable filling nozzle insertion into the container and subsequent stopper placement. High cosmetic quality reduces the risk of rejects due to glass defects. Strong mechanical durability minimizes the risk of breakage while being processed on the fill-finish line.

## Designed for precise integration into injection devices and pens

Extremely accurate dimensional tolerances enable precise integration and functionality with injection pens. Very accurate inner dimensional tolerances support accurate filling and dose delivery. Strong mechanical durability minimizes the risk of breakage while being used within devices.

## Exceptional cosmetic quality

Pristine appearance helps acceptance by end-users.

### Dental Cartridges

Volume	d1	d2	h	s
mL	mm	mm	mm	mm
1.8	8.65	7.15	63	0.9
2.2	8.65	7.15	75	0.9

d1=OD body | d2=OD neck | h = Height | s = wall thickness

### Pen Cartridges

Volume	d1	d2	h	s
mL	mm	mm	mm	mm
1.5	8.65	7.15	56.95	0.9
3.0	11.6	7.15	62.3	0.95

d1=OD body | d2=OD neck | h = Height | s = wall thickness





# Glass Ampoules

FOR PHARMACEUTICAL APPLICATIONS

NIPRO offers a wide range of high-quality ampoules that contribute to reliable fill-finish operations and provide a stable break force for consistent and easy opening.

## Contribute to reliable and fast filling line operations

NIPRO ampoules are carefully monitored during the manufacturing process. The 100% in-line visual inspections ensure high cosmetic and dimensional quality according to agreed specifications. The ampoules support quick and easy fill-finish operations.

## Stable break force facilitates easy opening

The force necessary to open an ampoule is an essential factor. NIPRO carefully controls the break force required to open an ampoule during the production process. As a result, NIPRO ampoules offer a stable break force, thereby facilitating easy opening by end-users.

Type	Volume mL	d1 mm	h mm	s mm	Code rings	Printing	Breaking systems
Form B	1 to 25	10.75 to 22.50	60 to 128	0.5 to 0.7	Up to 3 max. 3 colors	Ceramic max. 2 colors	Color break ring Scoring ring One point cut
Form C			67 to 135				
Form D			70 to 126				
Fine tip	45 to 100						
Double tip	1 to 20	8.25 to 19.12	60 to 135		Up to 2 max. 2 colors		Color break ring Scoring ring

d1 = OD body | h = total height | s = wall thickness

### Options

- Brushing/coating on the outside<sup>1</sup>
- Anti-counterfeit technology<sup>2</sup>

### Quality Levels

ENABLE	ENHANCE	ENGAGE
✓	✓	✓

<sup>1</sup> Additional protection for higher cosmetic quality  
<sup>2</sup> Special feature





# D2Mix™ Reconstitution Devices

FOR PHARMACEUTICAL APPLICATIONS

Many drugs in primary containers are stored in lyophilized form to keep them stable throughout their entire shelf-life. To facilitate the reconstitution of those drugs, NIPRO offers a distinct portfolio of reconstitution devices that supports faster, safer, and more efficient mixing procedures.

- Simpler and safer reconstitution procedure thanks to easy-to-use devices
- Reduced risk of contamination with fewer preparation steps
- Lower risk of exposure because of device design
- Increased user safety with needle-free devices

## Standard Range

Application	Compatible Vial neck OD (mm)	Sterilization method	Unit pack
D2Mix™ Vial-to-Syringe	13   20	EtO	Single blister pack
D2Mix™ Vial-to-Vial-to-Syringe	20		

D2Mix™ Vial-to-Syringe



D2Mix™ Vial-to-Vial-to-Syringe



# CURACASE™ Hypodermic Needles

IN HARD PLASTIC UNIT PACK

Hypodermic needles are often processed on packaging lines. The CURACASE™ needles unit pack is specifically designed to support compatibility with feeders and pick-and-place-systems.

## Optimized processability

Curacase™ needles are individually packed in hard plastic packaging. Their compact unit packs take up less space when placed into secondary packaging.

The unit pack's design supports compatibility with feeders and automated pick-and-place systems. Additionally, each unit pack label is color-coded and includes a 2D Data Matrix UDI barcode, enabling in-line product identification by vision systems.

## Easier and smoother administration

Color-coded hubs enable healthcare workers to select the required needle size quickly and accurately. Prior to use, the tamper-proof labels provide visual confirmation of the unused state of the needles.

Ergonomic packaging allows for firm grip for easy opening and removal of the cap. NIPRO's proprietary grinding process results in a sharp lancet point that supports smooth tissue penetration. The siliconized cannula offers consistent gliding performance. These attributes contribute to easier administration.

For high-viscosity medications, we offer thin-walled needles. With the same-sized outer diameter, a thin-walled needle's inner diameter is larger. Increased flow rates enable the use of smaller gauge sizes for more viscous medicines, resulting in less discomfort for patients.



Established as a global leader in needle manufacturing, NIPRO ensures reliable supplies of high-quality products.

## Standard Range : Needle - outer diameter (gauge | mm)

Needle length		Needle - outer diameter (G   mm) and wall type													
inch	mm	21   RW	0.8   TW	22   RW	0.7   TW	23   RW	0.6   TW	25   RW	0.5   TW	26   RW	0.45   TW	27   RW	0.4   TW		
1/2	13											●	●		
5/8	16				●		●		●	●		●	●		
1	25				●		●		●	●		●	●		
1 1/4	32				●		●		●	●		●	●		
1 1/2	38		●		●		●		●	●		●	●		

RW = regular wall | TW = thin wall | ● = hub color



# Comprehensive Support



## Technical Customer Support

Management of customer projects and development



## Regulatory Support

Assistance with product and drug registration



## Laboratory Services

Quality and performance optimization of glass containers

## Technical Customer Support

### CUSTOMER-CENTRIC SOLUTIONS

#### Management of Projects and Development

NIPRO provides end-to-end support for your primary packaging projects:

- Capturing expectations and translating them into strategic product solutions
- Resolving technical challenges with expert guidance
- Issuing detailed drawings and specifications for full clarity
- Accompanying customers throughout their journey, from ideation to product industrialization

#### Day-to-day Support

Our experienced team is always ready to help with your operational inquiries:

- Fast response to technical and process-related queries
- Timely delivery of documents and information
- Proactive and reactive on-site support when needed
- Comprehensive customer training programs
- Global presence for optimal and consistent support

## Regulatory Support

### FACILITATING REGISTRATION

We understand that regulatory compliance is critical for the success of your pharmaceutical products. To support you in the regulatory process, we offer an easy Letter of Authorization (LoA) procedure, ensuring quick and efficient access to the required regulatory information.

#### Drug Master Files (DMFs) with centralized LoA management

- FDA - Food and Drug Administration (USA)
- Health Canada
- NMPA - National Medical Products Administration (China)

Support for other countries is available.



## Laboratory Services

### OPTIMIZING YOUR GLASS CONTAINER PERFORMANCE

NIPRO PharmaPackaging is a vertically integrated company with decades of experience, which gives us a deep and comprehensive knowledge base. Beyond manufacturing high-quality glass tubing and glass primary packaging, NIPRO leverages this expertise through NIPRO Laboratory Services — a group of advanced analytical services designed to support pharmaceutical companies. These services help identify optimal glass packaging solutions for new drug formulations and enhance the packaging quality for existing products.

#### Advanced equipment

We operate a specialized range of advanced analytical equipment dedicated to the testing and characterization of glass pharmaceutical packaging. This cutting-edge technology enables us to deliver highly accurate, reliable data on glass container performance.

#### Extensive experience

With decades of technical and scientific expertise in glass pharmaceutical packaging, we offer exceptional insight into the chemical, mechanical, physical, and thermal properties of packaging material, as well as their corresponding analytics.

#### Committed to compliance and quality

To provide reliable and meaningful results, all systems and procedures are based on applicable cGMPs.

#### Service-minded partner

Through flexible solutions, results-driven analysis, and a strong focus on customer-oriented service, NIPRO Laboratory Services is committed to becoming—and remaining—your trusted partner in pharmaceutical packaging.

#### Laboratory locations

- Germany
- USA<sup>2</sup>

### Standard Range of Analytical Services<sup>1</sup>

- Aggressive/accelerated study
- Chemical and physical analysis of glass properties
- Extractables and leachables study
- Infrared & SEM/EDS contamination analysis
- Particle analysis and characterization
- Glass fracture analysis
- Glass defect microscopy
- Glass durability study
- Pharmacopoeia test

<sup>1</sup> non-exclusive list  
<sup>2</sup> ISO 17025-compliant

# Extensive Support from Conceptual Phase to Commercialization

NIPRO provides comprehensive support for primary packaging solutions, guiding customers from initial concept to full commercialization. Our expertise spans every stage of the process, including design, material selection, regulatory compliance, and manufacturing, ensuring that the final packaging solution meets the targeted drug product and performance requirements.

With NIPRO as your partner, you benefit from a seamless journey from idea to market-ready solution, backed by innovation and reliability.



NIPRO Corporation Japan, is a leading global healthcare company established in 1954. With more than 39,000 employees worldwide, NIPRO serves the Medical Device, Pharmaceutical, and Pharma Packaging industries.

As a total solution provider of medical devices and pharma packaging, NIPRO continues to build long-term, meaningful partnerships. Together with its people, products, and processes, NIPRO demonstrates a continuous commitment to improving patient outcomes and quality of life, offering safe and superior quality products that optimize time, effort, and cost.

