PRODUCT PORTFOLIO

GLASS TUBING, PRIMARY PACKAGING, AND MEDICAL DEVICES

NIPRO
PHARMAPACKAGING

Strategic Business Partner

FOR PRIMARY PACKAGING AND MEDICAL DEVICES

Nipro PharmaPackaging is an established market leader in the development and manufacture of primary packaging and medical devices in the pharmaceutical industry.

Vertically integrated

As a vertically integrated company, we draw our own premium glass tubing in multiple state-of-the-art plants worldwide. The integration of this step in-house ensures a stable supply of raw materials with a consistent high quality to our glass converting plants.

Extensive Experience

For over 60 years, we've been developing and manufacturing an innovative portfolio of Japanese quality products.

Our high-quality pre-fillable glass syringes, vials, cartridges, and ampoules are chosen by leading pharmaceutical companies to safely store a wide range of demanding drug products.

In addition, we produce a selected range of sophisticated medical devices for easier and safer drug reconstitution and administration.

Global Manufacturing Network

Your products are manufactured within our broad manufacturing network. We operate numerous state-of-the-art plants in North America, Europe, and Asia enabling local supply and the possibility to source the same high-quality products from multiple sites.

Comprehensive Customer Support

Products and technologies constantly increase in complexity. Our comprehensive and competent support organization comprising regulatory assistance, technical support, and laboratory services will address all your inquiries quickly and efficiently.

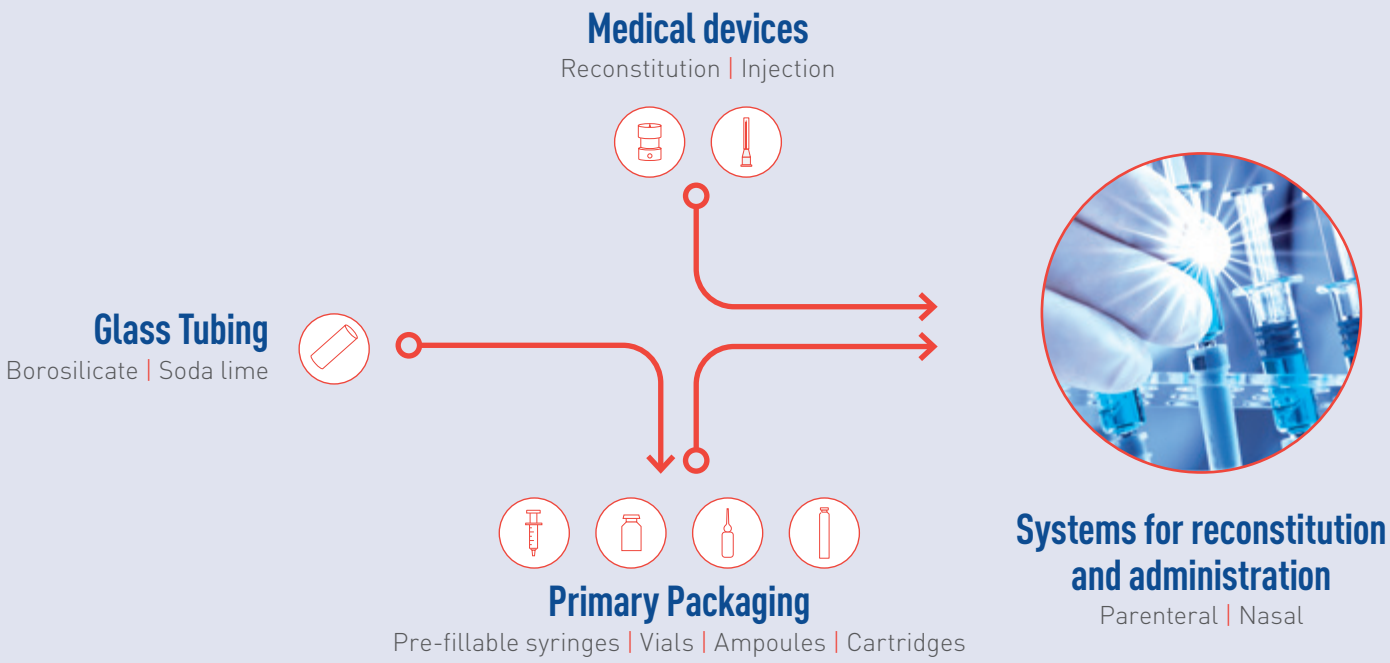
Commitment to Quality

When medication and ultimately the well-being of patients are concerned, quality is fundamental. Strict quality systems govern all our processes (ISO 15378, ISO 9001, ISO 45001, ISO 14001, and ISO 50001).

An extensive array of dimensional and cosmetic inspections safeguards that your product is made exactly according to agreed specifications.

You will source primary packaging and medical devices made precisely to your drug product requirements, from a single business partner constantly striving to meet and exceed your quality and service expectations.

Worldwide Quality Approach



Comprehensive Customer Support

Regulatory assistance | Technical support | Laboratory services

Quality Levels

PRODUCTS FINE-TUNED TO YOUR REQUIREMENTS

The process of defining the right quality of your primary packaging to meet your drug product requirements is a complex process. Multiple parameters need to be considered to ensure the right match.

Parameters influencing the required primary container quality

Drug Complex biotech drugs require highly sophisticated packaging solutions when it comes to drug-container compatibility. (silicone amount, tungsten levels, particles, ...)	**Device** Attributes that are essential when the container is combined with a device. (mechanical glass durability, dimensional aspects, ...)
Data Any data required to confirm compliance to agreed specifications and market standards. (certificate of analysis,...)	**End-user** Parameters that are important to end-users in terms of safety, comfort, and ease-of-use. (gliding force, safety system, needle size, ...)

To simplify this process, Nipro offers you three distinct quality levels. Within each Quality Level, the primary packaging and service specifications are defined to meet specific drug product requirements. The comprehensive scope of attributes facilitates the fine-tuning of the packaging to your requirements.

Primary packaging made precisely to meet your quality requirements!

Glass Tubing

FOR PHARMACEUTICAL PRIMARY PACKAGING

With decades of experience in manufacturing high-quality glass tubing for the pharmaceutical industry, Nipro has acquired the expertise to advice you on the glass tubing that is best suited for your primary container.

ENABLE

Fast and reliable converting-line performance

Compliant with regulatory and quality standards

ENHANCE

Very strict cosmetic parameters

Highly precise dimensional attributes

Meeting highest regulatory and quality requirements

ENGAGE

Customize your glass tubing parameters to meet specific primary packaging quality and service requirements that differ from the current quality levels

Customization is fully supported by an experienced and dedicated team

NSV51	W33	WG06	G38
Clear	Clear	Clear	Amber
Borosilicate	Borosilicate	Soda Lime	Borosilicate
Type I	Type I	Type III	Type III
Exp.: 51	Exp.: 33	Exp.: 93	Exp.: 76

Glass tubing best suited for your primary container

Pre-fillable Glass Syringes

FOR PHARMACEUTICAL APPLICATIONS

The careful selection of raw materials and precisely-controlled manufacturing processes yield D2F™ pre-fillable glass syringes that are made exactly for their intended applications, offering the right quality for prevailing drug products as well as challenging Biotech drugs.

ENABLE

Optimized processability for reduced TCO

Designed for reliable and safer manual administration

Standard data support confirming compliance to agreed specifications

ENHANCE

Excellent drug-container compatibility

Smooth integration into auto-injection devices

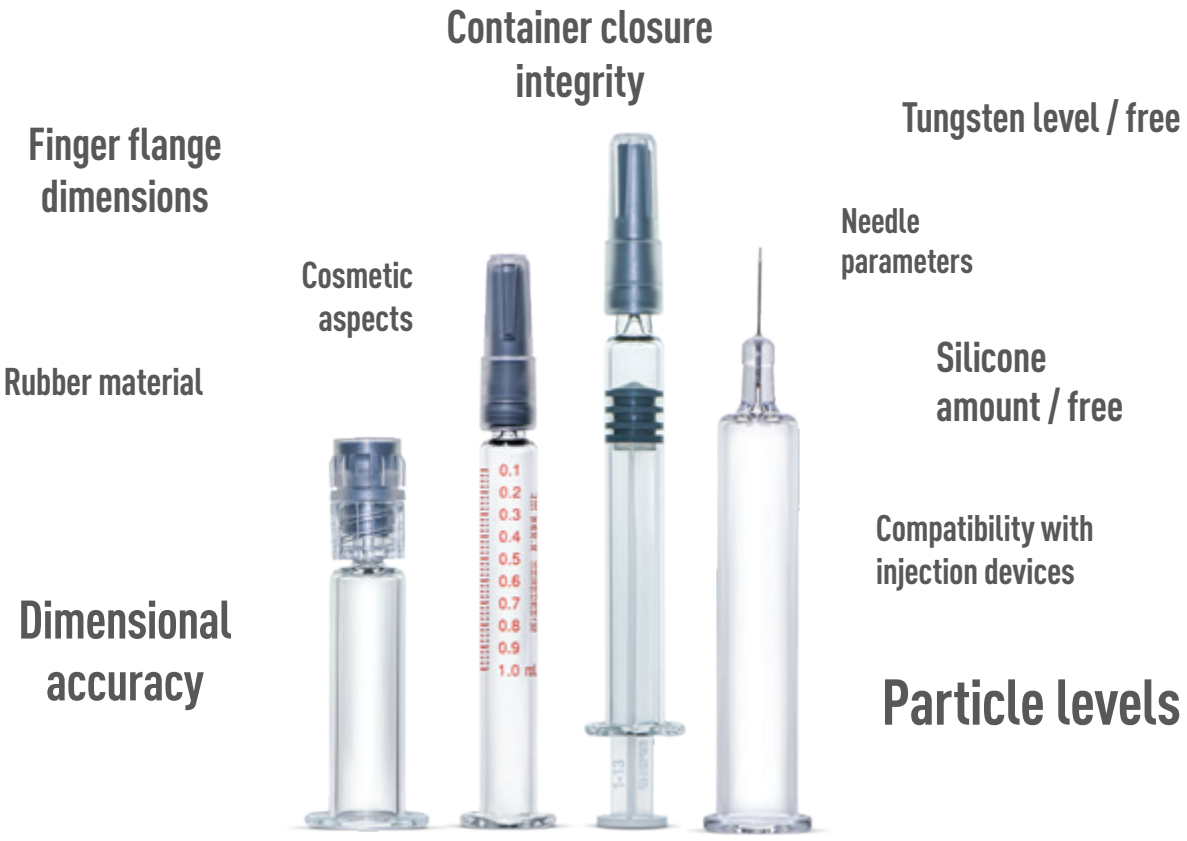
Optimized processability for minimal drug loss

Extended data support confirming compliance to agreed specifications

ENGAGE

Customize your syringe specifications to meet specific primary packaging quality and service requirements that differ from the current quality levels

Customization is fully supported by an experienced and dedicated team



Syringe Size & Type

Volume (ml)	Outer Ø (mm)	Inner Ø (mm)	Staked needle	Luer	Luer lock
0.5	6.85	4.65	✓	✓	✓
1.0 std.	8.15	6.35	✓	✓	✓
1.0 long	10.85	8.65	✓	✓	✓
2.25	10.85	8.65	✓	✓	✓
3.0	10.85	8.65		✓	✓

Staked Needles

Outer Ø (G | mm)	Inner Ø (mm)	Free length (inch | mm)	Bevel	Wall type
25 | 0.50	0.30	⅝ | 16.0	V-bevel	Regular
27 | 0.40	0.20	½ | 12.7	V-bevel	Regular
27 | 0.40	0.26	½ | 12.7	V-bevel	Thin
29 | 0.33	0.13	½ | 12.7	V-bevel	Regular
29 | 0.33	0.19	½ | 12.7	V-bevel	Thin
30 | 0.30	0.12	½ | 12.7	V-bevel	Ultra-thin

Components

Needle shield	Closures	Plunger stoppers	Safety devices
Soft needle shield	LInC™	Standard	Safe'N'Sound®
Hard needle shield	V-OVS®	Coated	Novaguard®
	Easy-turn tip cap		Ypsomed®
	Ribbed tip cap		

Rubber components are supplied by the prevailing manufacturers of the pharmaceutical industry

D2F™ Direct To Fill Sterile Packaging

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

Key Technologies

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

Nest & tub are cleaned with ionized air

Washed 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 correctly filled & 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 indicator on the label

Glass Vials

FOR PHARMACEUTICAL APPLICATIONS

Nipro vials are characterized by precise dimensional and pristine cosmetic parameters. The carefully-controlled specifications enable a smooth integration on fill-finish lines. Our glass vials are made from high-quality glass tubing offering secure storage of drug products. Nipro's proprietary **VIALEX**™ technology offers exceptional glass surface durability for highly sensitive drugs.

ENABLE

Fast and reliable filling-line performance

Compliant with prevailing quality standards

ENHANCE

Outstanding drug-container compatibility

Optimized filling-line performance

Meeting the highest regulatory and quality requirements

ENGAGE

Customize your vial specifications to meet unique drug product quality and service requirements that differ from the current quality levels

Customization is fully supported by an experienced and dedicated team

Crimp neck

Volume (ml)	d1 (mm)	d2 (mm)	h (mm)	s (mm)
2R	16	13	35	1
4R		13	45	
6R	22	20	40	
8R			45	
10R	24		40	
15R			60	
20R	30		55	1.2
25R			64	
30R	40		75	
50R			73	1.5
75	47	28	75	1.7
75		20		1.5
75		32		1.95
75	40	20	100	1.5
100R	47		95	
100		28		
100		32		1.95

Blowback

EU | US | None

Surface

Ammonium sulfate treatment
VIALEX™

Printing

Ceramic

Screw neck

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

Surface

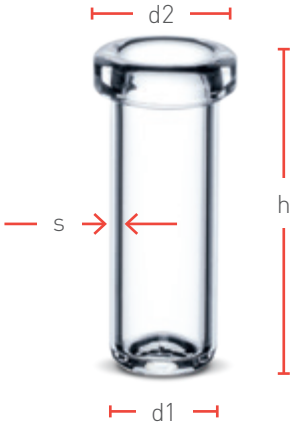
Ammonium sulfate treatment
VIALEX™

Printing

Ceramic

Unit / Bi-dose

Volume (ml)	d1 (mm)	d2 (mm)	h (mm)	s (mm)
0.35	6.6	8.75	19.5	0.8
0.5	6.6	8.75	28	0.8



Specialty vials

We offer a broad range of special and customized vials such as high recovery vials, V-bottom vials, and double chamber vials.

Glass Ampoules

FOR PHARMACEUTICAL APPLICATIONS

Economical and well-proven, glass ampoules are a frequently selected primary packaging type by the pharmaceutical industry. Nipro offers a wide range of high-quality ampoules.

Benefits

Precisely Formed for Fill-Finish Operations

Nipro ampoules are carefully monitored during the manufacturing process. The 100% in-line visual camera inspection ensures precise dimensional forming of the ampoules according to agreed quality 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 an easy opening by end-users.

Low levels of extractables and leachables

Nipro's eNhance glass tubing NSV51 is an excellent raw material for ampoules. Our borosilicate, Type I glass complies to prevailing Pharmacopoeias (USP, JP, EP) and offers excellent results for extractables and leachables. It contributes to drug stability during the entire shelf life.

Form B

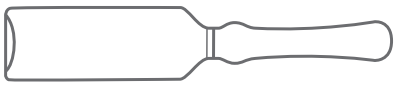
Volume (ml)	Outer Ø – Body (mm)	Total Height (mm)	Wall Thickness (mm)
1 – 25	10.75 - 22.50	60 – 128	0.5 - 0.7

Form C

Volume (ml)	Outer Ø – Body (mm)	Total Height (mm)	Wall Thickness (mm)
1 – 25	10.75 - 22.50	67 – 135	0.5 - 0.7

Form D

Volume (ml)	Outer Ø – Body (mm)	Total Height (mm)	Wall Thickness (mm)
1 – 20	10.75 - 22.50	70 – 126	0.5 - 0.7



Fine Tip

Volume (ml)	Outer Ø – Body (mm)	Total Height (mm)	Wall Thickness (mm)
1 – 20	10.75 - 22.50	45 – 100	0.5 - 0.7

Double Tip

Volume (ml)	Outer Ø – Body (mm)	Total Height (mm)	Wall Thickness (mm)
1 – 20	8.25 – 19.12	60 – 135	0.5 - 0.7

Options	Form B | Form C | Form D | Fine Tip	Double Tip
Code rings	Up to 3 (max. 3 colors)	Up to 2 (max. 2 colors)
Printing	Ceramic (max. 2 colors)	
Surface treatment	With or w/o Teflon (natural fiber brush)	—
Breaking system	Color Break Ring, Open Point Cut, Scoring Ring	Color Break Ring, Scoring Ring

Glass Cartridges

FOR PHARMACEUTICAL APPLICATIONS

Glass cartridges are frequently incorporated into diabetes pens and dental injection systems. Nipro PharmaPackaging cartridges meet the high-quality requirements of the pharmaceutical industry. Depending on your drug product requirements, eNable, eNhance, or eNgage cartridges will be the optimal choice.

ENABLE

Tight dimensional tolerance

High mechanical durability

Designed for integration into dental devices

ENHANCE

Excellent drug-container compatibility

Reliable integration into insulin pens

High-quality cosmetic attributes

ENGAGE

Customize your cartridge specifications to meet unique drug product quality and service requirements that differ from the current quality levels

Customization is fully supported by an experienced and dedicated team

Volume (ml)	Outer diameter (mm)	Printing	Special
1.8 to 3	8.15 to 11.6	Ceramic	Double chamber

Reconstitution Devices

FOR PHARMACEUTICAL APPLICATIONS

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

Benefits

- Fast and easy preparation thanks to easy-to-use devices
- Reduced risk of contamination as there are fewer preparation steps
- Less risk of exposure as a result of device design
- Increased user-safety through needle-free devices
- Avoids misinjection of unmixed solution (SAFETECT™ only)
- Connection point of the device to syringe complies to ISO 80369-7

Range

Application	Compatible vial neck O.D. (mm)	Sterilization method	Unit pack
Vial-to-Vial	20 | 32	EtO	Single blister pack
Vial-to-Vial-to-Syringe (vented with filter)	20		
Vial-to-Vial-to-Syringe (non-vented)	20		
Vial-to-syringe	20 | 13		
SAFETECT™ Pre-filled plastic syringe with pre-connected transfer needle unit	20	Autoclave	

CURACASE™

HYPODERMIC NEEDLES IN HARD PLASTIC UNIT PACK

Established as one of the world's largest needle manufacturers, Nipro has the resources to manufacture and supply large volumes on demand and to ensure a continuous supply. Nipro's focus on quality is acknowledged in the industry.

Benefits

- Minimized damage to the vessel as a result of a precise bevel design
- Easy and fast administration of viscous fluids thanks to thin needle walls
- Smooth puncture and placement by virtue of optimized siliconization
- Easy integration into automated packaging processes thanks to hard case packaging

Product Range

Needle	21 G (0.8 mm)		22 G (0.7 mm)		23 G (0.6 mm)		25 G (0.5 mm)		26 G (0.45 mm)		27 G (0.4 mm)	
Length	RW	TW	RW	TW	RW	TW	RW	TW	RW	TW	RW	TW
½" (13 mm)	–	–	–	–	–	–	–	–	–	–	Grey	Grey
⅝" (16 mm)	–	–	–	Black	–	Blue	–	Salmon	Brown	–	Grey	Grey
1" (25 mm)	–	–	–	Black	–	Blue	–	Orange	Brown	–	Grey	Grey
1 ¼" (32 mm)	–	–	–	Black	–	Blue	–	Orange	Brown	–	Grey	Grey
1 ½" (38 mm)	–	Green	–	Black	–	Blue	–	Orange	Brown	–	Grey	Grey

G = Gauge | RW = Regular Wall | TW = Thin Wall | ● = Label color

Exadose™

NASAL SPRAYS

Intranasal drug administration is one of the preferred routes of healthcare professionals as it is non-invasive. Drugs are easily administered without causing any discomfort to patients.

Nipro offers different types of nasal sprays that offer easy, controlled, and comfortable administrations.

Benefits

- Very uniform spraying performance
- Exact half-dose administration per nasal cavity
- Enables reconstitution
- As part of the D2F™ prefilled syringes portfolio, allows fast time to market

Range

Type	Spraying volume per shot	Compatible vial size	Options for customization	Compatible with D2F™ tub&nest
Exadose Nasal Spray pre-fillable glass syringe	100 - 250µL	—	Particle size Spray volume per shot	Yes
Exadose Nasal Spray plastic syringe with pre-attached vial adapter		Vials with neck outer diameter of 13 mm		—

Extensive Supporting Services

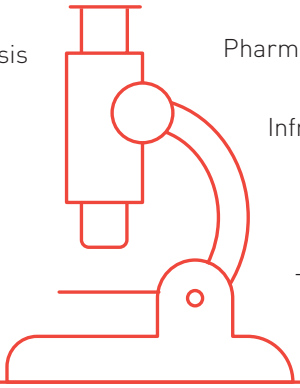
Laboratory Services

OPTIMIZE YOUR GLASS CONTAINER PERFORMANCE

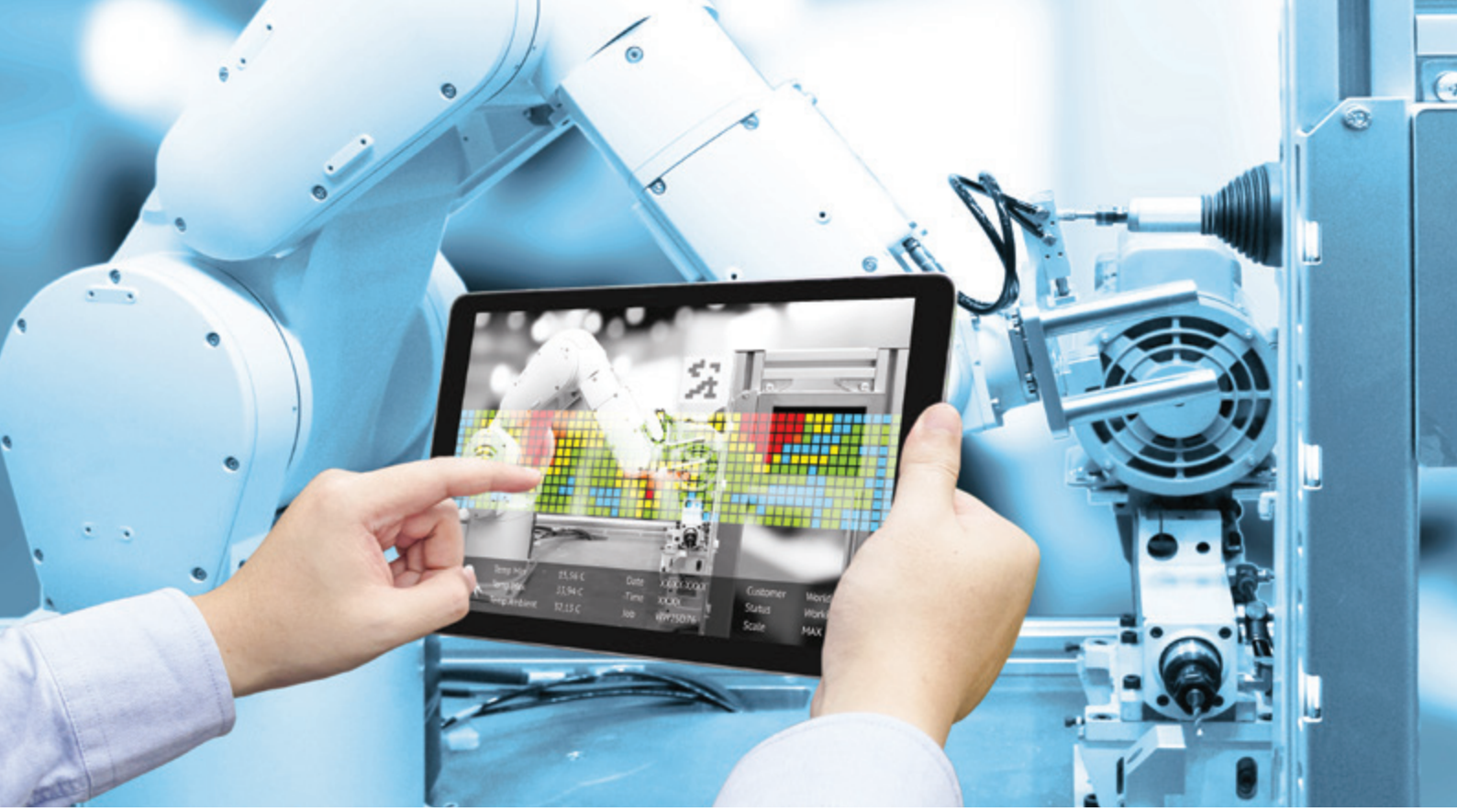
The development of new primary glass containers or the use of existing ones requires, in many cases, various analyses. They will confirm compliance to necessary standards or establish the route cause of specific challenges such as particles, breakage, or pH shift.

Nipro operates modern laboratories in the USA and Germany that offer advanced equipment for a wide range of analyses. Whether standard or customized, an analysis will be handled by our highly skilled and experienced lab personnel.

- Extractables and leachables study
- Contact angle and surface roughness measurements
- Tungsten residuals measurement with ICP-MS
- Aggressive/accelerated studies
- Glass analysis for chemical & physical properties
- Glass fracture analysis
- Pharmacopoeia tests
- Particle analysis & characterization
- Infrared & SEM/EDS contamination analysis
- Silicone oil layer thickness measurement
- Glass durability study
- Glass defect microscopy
- Tungsten residuals measurement with ICP-MS



non-exhaustive list



Technical Customer Support

MANAGEMENT OF CUSTOMER PROJECTS AND DEVELOPMENTS

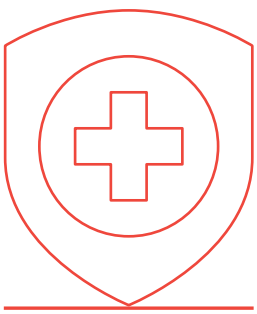
Primary packaging constantly increases in complexity which directly leads to an increased number of technical inquiries.

Our team of experienced engineers will provide you with a high level of technical, scientific, and product support. You will work with a dedicated and driven contact who stands ready to address your project and day-to-day inquiries.

Provide day-to-day technical customer support → Accompany customer as coordinating expert → Handle customer projects & developments → Provision of documentation → Contact point for quality related topics → **Excellent Customer Experience**

Regulatory Affairs Support

ASSISTANCE ON PRODUCT AND DRUG REGISTRATION ACTIVITIES



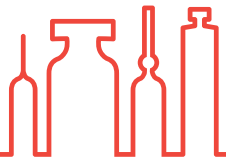
The registration of drug products is a precise and time-consuming process that requires a lot of specific data.

Our Global RA team will assist you in all aspects related to an easy access to our drug master files (DMFs for USA, Canada, China,...). Furthermore, the team handles all your regulatory queries and provides necessary statements, declarations, and documents.

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.



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NIPRO PHARMAPACKAGING

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