

# GLASS TUBING 

# GLASS TUBING <br> OF NIPRO PHARMAPACKAGING 

## An excellent raw material

that contributes to smooth converting operations and enables the forming of high-quality primary packaging!

## Expertise in glass tubing

Nipro pharmapackaging, with a global capacity of more than 90,000 metric tons, is one of the largest glass tubing manufacturers in the world.
For decades, our high-quality glass tubing has been used by leading primary packaging converters to produce premium quality pre-fillable syringes, cartridges, vials, and ampoules for the pharmaceutical industry.
Our state-of-the-art glass tubing plants comply to the quality standards of the industry (ISO 15378, ISO 14001, ISO 45001). The glass tubing is manufactured according to the European Pharmacopoeia, Japanese Pharmacopeia, and United States Pharmacopoeia requirements.

## Our commitment to premium pharmaceutical quality glass is reflected by using the latest manufacturing equipment, combined with an extensive array of

 dimensional and cosmetic inspections.Within the pharmaceutical arena, our glass tubing is especially valued for its narrow dimensional tolerances, pristine cosmetic appearance, and chemical inertness.

## QuFW

is the cornerstone of all processes involved in the manufacture of Nipro premium glass tubing


## Continuous Improvement of the Product Quality

The manufacture of glass tubing is a highly automated process. Quality control is carried out by a sophisticated inspection system.

The inspection system not only allows us to deliver products with consistent high quality to our customers but also provides a means to capture our internal capabilities. The continuous monitoring enables us to discover process points where further optimization is possible.
Subsequently, our customers can rely on a consistent and continuously improving product quality.

## Quality Support at Your Side

At Nipro, a multi-disciplinary team of experts will be at your side. We will advise you during product selection up to the final commercial production; ready to answer any questions that might arise. We are committed to providing you with fast and competent service that is fully aligned with our high quality glass tubing

## Careful Selection of the Required Raw Material Quality

Many quality aspects of the final glass tubing are directly derived from their starting material. Constant monitoring of starting material from approved suppliers is paramount prior to the introduction to the process

Starting material are analyzed for compliance to purchasing specifications:

- Incoming inspection and testing
- CoA approval process by Nipro in-house laboratories prior to unloading
- Supplier audits per set schedule

The results of the incoming inspection of raw materials are proactively monitored for trends. In cases where raw materials are out-of-specification (OoS), the shipments concerned are immediately rejected and a complaint is initiated towards the supplier.

## Quality in Production

Manufacturing lines are equipped with in-line automated vision inspection systems that inspect every glass tube - for both dimensional and cosmetic parameters.
Statistical Process Control (SPC) provides control of our process at the point of manufacturing. The SPC system allows shop floor employees to make real-time, data driven decisions to the process, thereby maintaining consistent product quality and production yield. Moreover, regular manual inspection comes as a complementary check, in order to ensure that all quality parameters are met.

Strict control plans combining $100 \%$ vision systems, in-process controls, and final quality controls allow Nipro to guarantee high quality levels without compromising on the customized solutions that we provide.


## Nipro Quality Levels for Glass Tubing

Primary packaging is the first and last barrier that safeguards the final drug product for its intended purpose(s). Ultimately, the packaging must ensure that a patient receives a drug product in its intended quality so it can be safely administered. When deciding on packaging made from tubular glass, it is important to choose the right glass tubing quality.

## Various specifications of the final primary packaging will steer the choice of glass tubing, such as:

- Chemical inertness of the glass composition
- Optimal physical attributes for easy, consistent converting operations
- Multiple dimensional attributes
- Various cosmetic aspects (including particle levels)


## The Right Quality for Specific Needs

We offer our glass tubing in three distinct quality levels that address varying drug product requirements They form the perfect base to capture and fine-tune your quality and service requirements.


## Fast and reliable converting-line performance

- Control of critical cosmetic parameters minimizes the risk of rejections due to cosmetic defects
- Inspection of key dimensional quality attributes supports smooth loading and forming process
- Strong mechanical durability reduces risk of breakage
- $100 \%$ in-line camera inspection
- Statistical process control


## Compliant with regulatory and quality standards

- Cosmetic and dimensional AQLs according to main quality standards
- Compliant with Pharmacopoeias (EP, USP, JP)
- Fulfills ASTM 438-92 - Specifications for laboratory glass
- Meets requirements related to hydrolytic resistance and arsenic extraction


## Very strict cosmetic parameters

- Inspection of a wide range of cosmetic parameters
- Minimized particle levels lin-line air flushing system)
- High cosmetic quality reduces the risk of rejections
- $100 \%$ in-line camera inspection
- Statistical process control


## Highly precise dimensional parameters

- $100 \%$ in-line camera inspection of an extensive range of dimensional attributes with very tight tolerances
- Highly consistent wall thickness enhances the mechanical durability of the glass tubing and final containers
- Forming of containers with high dimensional barrel accuracy


## Meeting highest regulatory and quality

## requirements

- Very tight dimensional and cosmetic AQLs reflect exceptional glass tubing quality
- Compliant with Pharmacopoeias (EP, USP, JP)
- Fulfills ASTM 438-92 - Specifications for laboratory glass
- Meets requirements related to hydrolytic resistance and arsenic extraction
- Regulatory support


## Fully customizable parameters

- Customize your glass tubing 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



## Glass Tubing Range



NSV51 and WG6: optional with cerium

## Standard Sizes*

For Syringes

| Outside Diameter (mm) | Inner Diameter (mm) |
| :---: | :---: |
| 6.85 | 4.65 |
| 8.15 | 6.35 |
| 10.85 | 8.65 |
| 14.45 | 11.85 |
| 17.05 | 14.25 |
| 22.05 | 19.05 |

*other sizes upon request


For Vials

| Outside Diameter (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 |
|  | $1.40-1.60$ |
| 18.0-19.9 | 1.00-1.09 |
|  | 1.10-1.35 |
| 20.0-20.9 | 1.00-1.09 |
|  | 1.10-1.35 |


| Outside Diameter (mm) | Wall Thickness(mm) |
| :---: | :---: |
| $21.0-22.9$ | $1.00-1.09$ |
|  | $1.10-1.30$ |
| $23.0-24.9$ | $1.35-1.60$ |
|  | $1.00-1.09$ |
| $25.0-29.9$ | $1.10-1.30$ |
|  | $1.00-1.09$ |
|  | $1.10-1.29$ |
| $30.0-35.0$ | $1.30-1.59$ |
|  | $1.10-1.29$ |

*other sizes upon request


For Cartridges

| Outside Diameter (mm) | Inner Diameter (mm) |
| :---: | :---: |
| 8.65 | 6.85 |
| 10.85 | 8.65 |
| 10.95 | 9.25 |
| 11.60 | 9.70 |
| 14.00 | 12.0 |
| 14.45 | 11.85 |
| 18.25 | 16.05 |

*other sizes upon request


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 17 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 33.000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharma Packaging industries.

