PRODUCT PORTFOLIO
GLASS TUBING, PRIMARY PACKAGING, LABORATORY SERVICES
PHARMAPACKAGING

FUELED BY INNOVATION, QUALITY, AND PARTNERSHIP

In recent years, pharmaceutical companies have been facing substantial challenges in an increasingly competitive market. The dawn of new and complex drug products drives quality requirements to new heights, while the rising number of generics calls for optimized Fill-Finish operations.

Safeguarding patients, as the principal objective, results in even stricter regulatory standards amid increasing end-user expectations that raise the bar when it comes to providing safe, easy to use combination products. As a result, primary packaging, an essential part of the drug product, has to fulfill the novel and cutting edge needs of pharmaceutical companies and end-users alike.

Nipro PharmaPackaging, with more than 60 years of experience in the fields of drawing premium glass tubing, developing and manufacturing innovative primary packaging, and performing distinct pharma packaging analysis, provides you with prudently devised pharma packaging, thereby enabling you to master today’s competitive market environment.

GLASS TUBING:
SELECTING GLASS TUBING THAT SUITS YOU BEST

The first crucial step in realizing the target quality of your primary packaging is choosing the most appropriate glass tubing for your product. Nipro PharmaPackaging, with a global capacity of more than 90,000 metric tons, is one of the largest glass tubing manufactures in the world. Our glass tube drawing sites are certified according to ISO 9001, ISO 15378, ISO 14001, and OHSAS 18001.

With decades of experience in supplying a broad range of premium quality clear and amber glass tubing, Nipro offers you professional advice on dimensional and cosmetic tolerances, AQL levels, and special surface treatments that are best suited to your specific drug needs.
LABORATORY SERVICES: OPTIMIZING YOUR PACKAGING CHARACTERISTICS

Nipro PharmaPackaging is a vertically integrated company that draws upon decades of experience to create an exceptional knowledge base. In addition to producing high-quality primary packaging, Nipro translates this expertise into Nipro Laboratory Services: analytical laboratory services that guide pharmaceutical companies in finding suitable packaging solutions for new drugs and improvements in the packaging quality of existing drugs.

You will work closely with a service partner who has a comprehensive understanding and exceptional know-how of analytical processes, state of the art analytical equipment, and wide-ranging solutions to industry problems.

PRIMARY PACKAGING: MATCHING YOUR DRUG PRODUCT REQUIREMENTS

8 billion units of high-quality primary packaging leave our manufacturing sites each year, safeguarding pharmaceutical drug products around the globe.

In order to meet the quality requirements of our customers, our plants feature state of the art converting machines that produce both bulk and Direct To Fill pharmaceutical packaging. Our high-end inspection systems control an extensive array of cosmetic and dimensional specifications suited for standard or high-end Biotech drugs.

Whether you choose bulk or Direct To Fill, your packaging will be produced precisely to your specifications to ensure optimal compatibility with your drug product, smooth Fill-Finish operations, and easy integration into injection devices.
NIPRO QUALITY LEVELS
MEETING DRUG PRODUCT REQUIREMENTS

The process of defining the right quality level for primary packaging is a complex, involved process. In order to ensure the optimal match, there must be understanding and collaboration: specific data must be exchanged, requirements discussed, and numerous parameters defined.

Our Nipro Quality Levels form the perfect base to fine-tune your quality and service requirements, thereby providing you with the optimal packaging solution.

eNgage with Nipro to develop a tailored packaging quality, whereby we apply our profound analytical competencies and align our cutting-edge production and inspection technologies to satisfy your unmet drug product requirements.

eNable a packaging quality that answers to prevailing drug product requirements.

eNhance the packaging quality to fulfil the requirements of highly-sensitive drug products.

SIMPLY SELECT THE QUALITY LEVEL FINE-TUNED TO YOUR SPECIFIC DRUG REQUIREMENTS!
The majority of pharmaceutical companies rely on primary packaging made of glass tubing to protect their drug products. The quality of glass tubing is one of the key elements that will define the quality of the final primary packaging. Nipro PharmaPackaging combines the exceptional knowledge of a manufacturer experienced in drawing premium glass tubing and converting first-class pharmaceutical packaging.

**ADVISING YOU ON THE OPTIMAL GLASS TUBING**

Understanding the full process from “Sand to Packaging” enables us to advise you on the proper glass tubing type. Be it cosmetic and dimensional parameters, defining narrower AQLs, or offering a special surface treatment, we will provide you with the glass tubing quality best suited to your specific drug product needs.

**MEETING YOUR MOST STRINGENT QUALITY REQUIREMENTS**

Our strict quality system regulates all processes: from the batch house, where raw materials are received and mixed, to the melting and forming processes, to tube finishing, packing, and warehouse storing. Our tube drawing sites are certified according to ISO 9001, ISO 15378, ISO 14001, and OHSAS 18001.
PARAMETERS ACCORDING TO YOUR NEEDS
A wide range of premium quality clear and amber glass tubing is manufactured by applying Vello and Danner drawing processes. Sophisticated inspection systems ensure adherence to dimensional and cosmetic parameters. The inspections are automated and carried out 100% in-line. Additional manual in-process controls (IPC) ensure that functional parameters are met.

PRODUCTION SITES IN CLOSE PROXIMITY TO YOUR PLANT
Our plant network, with an annual capacity exceeding 90,000 metric tons, is comprised of five drawing sites strategically situated on three continents, offering you a global approach with local solutions.

PRODUCT RANGE

<table>
<thead>
<tr>
<th>NSY51*</th>
<th>W33</th>
<th>WG06*</th>
<th>G38</th>
<th>BSA60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear</td>
<td>Clear</td>
<td>Clear</td>
<td>Amber</td>
<td>Amber</td>
</tr>
<tr>
<td>Boroslicate</td>
<td>Boroslicate</td>
<td>Soda Lime</td>
<td>Boroslicate</td>
<td>Boroslicate</td>
</tr>
<tr>
<td>Type I</td>
<td>Type I</td>
<td>Type III</td>
<td>Type III</td>
<td>Type I</td>
</tr>
<tr>
<td>Exp.: 51</td>
<td>Exp.: 33</td>
<td>Exp.: 93</td>
<td>Exp.: .76</td>
<td>Exp.: .60</td>
</tr>
</tbody>
</table>

*Optional with cerium
The pre-fillable syringe market has grown significantly in the past years. Pharmaceutical companies are developing an increasing number of drug products in injectable formats, since this packaging type offers exceptional benefits: optimized total cost of ownership, improved drug-container compatibility, and increased patient safety.

At Nipro, we offer our pre-fillable glass syringes in three distinct quality levels to meet the various quality requirements of the pharmaceutical industry.

**OPTIMIZED PERFORMANCE ON FILLING LINES**

Our converting lines feature an advanced forming process that leads to strong mechanical syringe stability. Visual inspection systems ensure tight cosmetic tolerances. X-ray capabilities lead to correct closure positioning and inherent CCI. Our syringes minimize the risk of breakage during your Fill-Finish operations and rejects during final inspection.

**HIGH COMPATIBILITY BETWEEN DRUG AND PACKAGING**

Agreed tungsten levels or tungsten-free, a needle bonding process applying precise UV curing, and customized siliconization that is 100% controlled in-line, provide you with a syringe optimally matched to your drug product, thus reducing the chance of unwanted interactions.

**RELIABLE INCORPORATION INTO INJECTION DEVICES**

An accurate forming process leads to strong mechanical flange stability while high-end inspection systems ensure adherence to tight dimensional tolerances. Siliconization is also adjustable, resulting in smooth and consistent plunger gliding properties. You will receive syringes precisely shaped to fit your device dimensions, thereby enabling safe and reliable administrations.

<table>
<thead>
<tr>
<th>VOLUME (ml)</th>
<th>TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5, 1.0 long, 1.0, 2.25, 3.0</td>
<td>Staked needle, Luer slip cone, Luer lock</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NEEDLE (G)</th>
<th>BEVEL</th>
<th>FLANGES</th>
<th>SHOULDERS</th>
<th>PRINTING</th>
<th>SPECIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>25, 27, 29</td>
<td>3-bevel, V-bevel, Spoon point</td>
<td>Round, Round small, Cut</td>
<td>Round, Round small, Cut</td>
<td>Graduation, Dose marks</td>
<td>Double chamber</td>
</tr>
</tbody>
</table>
CLOSURES | PLUNGER STOPPER | PLUNGER ROD | Luer Lock Adapter | Special
---|---|---|---|---
Soft needle shield, Rigid needle shield, Tip cap, Ribbed tip cap, LLA + Tip cap, LLA + Tamper evident cap | Standard, Coated | Transparent, Color | Standard | Safety device, Nasal spray

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

- Cleaned with ionized air
- 100% camera inspection
- No glass-to-glass contact
- Intelligent label

Nipro’s D2F packaging design is a smart, efficient choice. It prevents glass-to-glass contact while enabling immediate and direct use on the filling line.

In essence, Direct To Fill.
Glass vials have been the Gold Standard in the Pharmaceutical industry for decades. Their characteristics make them suitable for the safe and reliable storage of drug products. To this day, the market requires drug products to be packaged in glass vials, especially in lyophilized form. Nipro, with more than 60 years of experience in converting standard and customized vials, offers a wide range of high-quality vials that meet the diverse requirements of drug products.

**EXCEPTIONAL SURFACE DURABILITY**

We begin by selecting high-quality glass tubing that complies to USP, EP, and JP as starting material. Production takes place in controlled environments monitored by quality systems that comply to ISO 15378, ISO 9001, ISO 14001, and OHSAS 18001. For exceptionally sensitive drugs, Nipro’s premium technology for surface durability, known as VIALEX™, will be applied to ensure the best vial-drug compatibility.

**OPTIMIZED PERFORMANCE OF FILLING LINES**

Our high-end converting lines follow a precise forming process that results in vials with strong mechanical stability. Visual inspection systems ensure tight cosmetic tolerances. Combined, these control systems minimize the risk of breakage during your Fill-Finish operations and the number of rejects during final inspection.

**BROAD RANGE OF SPECIALITY PRODUCTS**

We routinely develop specialty vials for our customers, designed to meet specific requirements, e.g. handling extremely low drug volumes, withstanding high pressure, offering optimal integration into injection devices. With decades of experience, Nipro is an ideal partner for providing you with tailor-made vials.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>VOLUME (ml)</th>
<th>OUTSIDE Ø (mm)</th>
<th>NECK Ø (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crimp neck – Injection vials</td>
<td>2 to 30</td>
<td>16, 22, 24, 30</td>
<td>13, 20</td>
</tr>
<tr>
<td>Crimp neck – Infusion vials</td>
<td>20 to 100</td>
<td>40, 47</td>
<td>20, 28, 32</td>
</tr>
<tr>
<td>Screw neck – Injection vials</td>
<td>5 to 30</td>
<td>18, 22, 24, 30</td>
<td>14, 18, 22</td>
</tr>
<tr>
<td>Screw neck – Infusion vials</td>
<td>50 to 125</td>
<td>40, 47</td>
<td>22, 28, 32</td>
</tr>
</tbody>
</table>
Upon request, a specific blowback (Type I or II), surface treatment, and VIALEX™ will be considered in the product design and manufacturing process.

We offer a broad range of special and customized vials:

- Unit dose
- High recovery
- V-bottom
- Double chamber

**STERILIZED PACKAGING**

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

- Cleaned with ionized air
- 100% camera inspection
- No glass-to-glass contact
- Intelligent label

Nipro’s D2F packaging design is a smart, efficient choice. It prevents glass-to-glass contact while enabling immediate and direct use on the filling line.

In essence, Direct To Fill.
Glass cartridges are frequently incorporated into diabetes pens and dental injection systems. Nipro PharmaPackaging cartridges meet the high quality requirements of the pharmaceutical industry. Our cartridges are an ideal choice of packaging to be combined with injection devices.

**RELIABLE INCORPORATION INTO INJECTION DEVICES**

An accurate forming process leads to strong mechanical stability, while our high-end inspection systems ensure adherence to tight dimensional tolerances. Your cartridges will have an optimal fit with your device, thereby supporting safe and reliable administrations.

**HIGH COMPATIBILITY BETWEEN DRUG AND PACKAGING**

Premium glass tubing that complies to USP, EP, and JP is selected as starting material. Production takes place in controlled environments monitored by quality systems that comply to ISO 15378, ISO 9001, ISO 14001, and OHSAS 18001.

**TIGHT COSMETIC TOLERANCES**

Our advanced inspection systems ensure adherence to tight cosmetic parameters. We provide cartridges that offer a pristine surface in order to meet the quality expectations of both pharmaceutical customers and end-users alike.

<table>
<thead>
<tr>
<th>VOLUME (ml)</th>
<th>OUTSIDE Ø (mm)</th>
<th>PRINTING</th>
<th>SPECIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8</td>
<td>8.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>8.80</td>
<td>Ceramic</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>11.40</td>
<td></td>
<td>Double chamber</td>
</tr>
<tr>
<td>3.0</td>
<td>11.60</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ampoules are an economical and well-proven primary packaging for drug products. In large parts of the pharmaceutical market, ampoules are chosen as the preferred primary container. As a long standing player with an annual sales quantity of several billion high-quality ampoules, Nipro has acquired the experience to offer unparalleled service in ampoule development and conversion.

**BROAD PRODUCT PORTFOLIO**

Nipro offers a large portfolio of glass ampoules. Our customers can choose from multiple forms, breaking systems, and volumes. Various printing options and surface treatments complete the offer.

**PREMIUM QUALITY AND COMPLIANCE**


**TIGHT DIMENSIONAL TOLERANCES**

Dimensional inspections are automated and 100% in-line. Manual IPCs are also performed frequently.

<table>
<thead>
<tr>
<th>TYPE</th>
<th>VOLUME (ml)</th>
<th>OUTSIDE Ø (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form B, C, D, Double tip, Fine tip</td>
<td>1 to 25</td>
<td>10.75, 12.75, 14.75, 17.75, 20.75, 22.75</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BREAKING SYSTEM</th>
<th>PRINTING</th>
<th>CODE RINGS</th>
<th>SPECIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color Break Ring (CBR), Open Point Cut (OPC), Scoring Ring (SCR)</td>
<td>Text (max 2 colors)</td>
<td>1 to 3 rings (max 3 colors)</td>
<td>Surface treatment</td>
</tr>
</tbody>
</table>
Nipro PharmaPackaging offers an extended portfolio of products related to our contract manufacturing organization (CMO) activities. This allows you to source complete pharma packaging solutions at a single point, enabling you to master today’s demanding pharma packaging environment.

**DUAL CHAMBER BAG**

Dual chamber bags combine the storage of a powdered/liquid drug and a diluent into one primary packaging. By simply exerting higher pressure on the diluent chamber, the seal between the two chambers is forced open, and the content of both chambers can be mixed with each other.

- Simplified preparation procedure of a powdered/liquid drug and diluent
- Closed system mixing procedure reduces risk of contamination
- Prevents dosage and volume errors
- Easy bedside preparation and administration
- Neither oxygen nor humidity are permeable through the packaging

**NASAL SPRAY**

We offer compact-sized, multidose intranasal sprays for more convenient and accurate administration.

- Easy preparation
- Ensured administration of exactly half a dose in each nasal cavity
- VORTEX™ technology creates a wider spray further inside the nose cavity
DUAL CHAMBER SYRINGE

Dual chamber syringes combine the storage of a powdered/liquid drug and a diluent into one primary packaging. By simply exerting pressure on the plunger, the liquid of the lower chamber is forced into the chamber that houses the drug product. Afterwards, the content of both chambers can be mixed and easily administered.

- Simplified preparation procedure of a powdered/liquid drug and diluent
- Closed system mixing procedure reduces risk of contamination
- Prevents dosage and volume errors
- Easy bedside preparation and administration
- Safety system increases user safety

HYPODERMIC NEEDLES

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 continuous supply. Nipro’s focus on quality is acknowledged in the industry.

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

TRANSFER DEVICES

Transfer devices enable simple, fast transfer and mixing for the reconstitution of drug products. Nipro offers transfer devices suitable for mixing drug products stored in vials and syringes.

- Fast and simple preparation due to ease of use of device
- Reduced risk of contamination due to fewer preparation steps
- Less risk of exposure as a result of device design
- Increased user safety due to needle-free devices
Nipro Pharma Packaging is a vertically integrated company that draws upon decades of experience to create an exceptional knowledge base. In addition to producing high-quality primary packaging, Nipro translates this expertise into Nipro Laboratory Services: analytical laboratory services that guide pharmaceutical companies in finding suitable packaging solutions for new drugs and improvements in the packaging quality of existing drugs.

When choosing for Nipro Laboratory Services, you will work closely with a service partner who has a comprehensive understanding and exceptional know-how of analytical processes, state of the art analytical equipment, and wide-ranging solutions to industry problems.

EXCEPTIONAL SKILL SET

ADVANCED EQUIPMENT
We operate a distinct assortment of advanced analytical equipment dedicated to the testing and characterization of pharma packaging.

EXCEPTIONAL EXPERTISE
Over 100 years of technical and scientific expertise in pharmaceutical packaging equips us with an exceptional know-how in chemical, mechanical, physical, and thermal properties of packaging material, as well as their corresponding analytics.

ENHANCED QUALITY
We support pharma companies in finding:
• suitable packaging solutions for new drugs
• improvements in the packaging quality of existing drugs
in order to increase the drug-packaging compatibility to enable safer administrations.
WIDE-RANGING SET OF ANALYTICAL AREAS

<table>
<thead>
<tr>
<th>GLASS FRACTURE ANALYSIS</th>
<th>GLASS DEFECT MICROSCOPY</th>
<th>EXTRACTABLES AND LEACHABLES STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLASS ANALYSIS FOR CHEMICAL &amp; PHYSICAL PROPERTIES</td>
<td>AGGRESSIVE/ACCELERATED STUDIES</td>
<td>INFRARED &amp; SEM/EDS CONTAMINATION ANALYSIS</td>
</tr>
<tr>
<td>PARTICLE ANALYSIS AND CHARACTERIZATION</td>
<td>PHARMACOPOEIA TESTS</td>
<td>GLASS DURABILITY STUDY</td>
</tr>
</tbody>
</table>

COMMITTED TO COMPLIANCE AND QUALITY

In order to provide reliable and meaningful results, all systems and procedures are based on applicable cGMP’s.

SERVICE-MINDED PARTNER

With flexible solutions, results-driven analysis, and customer-oriented service, Nipro Laboratory Services continuously strives to gain and maintain the position of your preferred business partner.
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 16 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 27,000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharmaceutical Packaging industries.