GLASS AMPOULES

FOR PHARMACEUTICAL APPLICATIONS

NIPRO PHARMAPACKAGING

Glass ampoules are established primary containers for a diverse range of pharmaceutical products. As a leading manufacturer for the pharmaceutical industry, Nipro PharmaPackaging has acquired extensive experience to offer unparalleled service in ampoule development and production.

Large Manufacturing Network

Our large manufacturing network comprises eight state-of-the-art plants and supports your global supply strategy. You choose the manufacturing location closest to your fill-finish operations, thus resulting in shorter supply routes. Moreover, the option to verify multiple sites provides supply security.

Stringent quality systems (ISO 15378, ISO 14001, ISO 45001, ISO 50001, ISO 14644) govern all our processes. Hence, our ampoules are strictly compliant to pharmacopeia (USP, EP, JP) and prevailing industry standards. Our global quality approach ensures that you will receive the same product quality every time, independent of the selected plant.

Comprehensive Support

You will be advised by an experienced, cross-functional team throughout development and commercialization of your ampoules. Technical customer support, regulatory affairs, and laboratory services will provide you with all the necessary data and services you require.

AMPOULES FOR PHARMACEUTICAL APPLICATIONS

Precisely Formed

Each ampoule is carefully monitored throughout the entire manufacturing process. The 100% in-line visual camera inspection ensures precise dimensional forming of the ampoules according to agreed quality specifications. The ampoules yielded support fast and easy fill-finish operations.

- Highly accurate dimensional parameters contribute to fast and reliable fill-finish operations
- Reduced risk of incidences during fill-finish operations (breakage, rejects at final inspection)

Stable Break Force

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.

- Minimized risk of breakage while opening
- Improved end-user experience

Premium Glass Quality

Nipro's eNhance glass tubing NSV51 is an excellent raw material for ampoules. Our borosilicate glass (Type I) 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.

- Low levels of extractables and leachables
- Contributes to drug stability

AMPOULES WITH ANTI-COUNTERFEIT TECHNOLOGY

Counterfeit medicines are a worldwide problem. Around 50% of drugs sold on the internet are fake. In low- and middle-income countries, 10% of medical products are either substandard or falsified. Counterfeit medicines have potentially the wrong dose, no dose, or are even toxic and therefore pose a threat to the health of patients.

Nipro offers ampoules with anti-counterfeit technology. A special enamel ink is used to print the color rings, dots, and prints on the ampoule. It contains light emitting particles that light up only under UV light. In daylight, the ink is white and cannot be distinguished from standard ink by the naked eye.

The ink is **compatible** with existing ampoules and presents a low regulatory impact as it **does not come into contact** with the filled drug product.

The ink is **compliant** to prevailing standards and **does not contain** any restricted substances (SVHC, REACH, RoHS 3 Directive).

The ink is an additional feature to prove drug product authenticity.

Product Range

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, One Point Cut, Scoring Ring	Color Break Ring, Scoring Ring

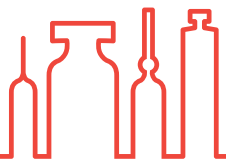
Nipro glass ampoules for drug products

Precise dimensions, easy opening, and exceptional glass quality

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

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