

Tubular Glass

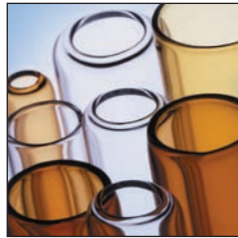


GERRESHEIMER

Our service spectrum for pharmaceutical tubular glass packaging

Tailor-made solutions based on glass

www.gerresheimer.com



Vertically integrated manufacturer



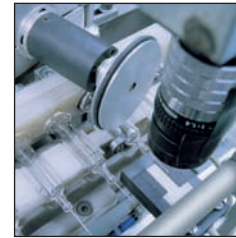
...with tubular glass products in many standard variants



...or individually and innovatively developed



...mainly produced in completely closed clean-room processes



...with assured quality from A to Z



...and full and efficient system partnership

Gerresheimer Tubular Glass comprises our operations across the field of tubular glass for the pharma & life science industry. We have at our disposal the expertise of ten production plants around the world, manufacturing high-quality packaging and system solutions and also the tubing itself. Our converted product range extends from ampoules, vials and cartridges to systems such as prefillable syringes. All our products are specifically designed and produced in accordance with cGMP requirements to fulfill the high quality expectations of our customer base. Our specialities include sterile all-glass syringe systems under the trade mark RTF® (Ready-to-Fill).





Our commitment to high-class service and customer support – Tailor-made solutions based on tubular glass

Gerresheimer Tubular Glass enjoys a reputation as a technology leader in the world market. We concentrate on problem solutions relating to all aspects of pharmaceutical tubular glass packaging and syringe systems. With vials, ampoules, prefillable syringes, cartridges and the preliminary tubing products we offer a comprehensive product and service range to meet all your requirements.

Customised developments and extensive system partnerships

Gerresheimer makes its customer priorities its own, and we like individual challenges. The know-how, professionalism and creativity of our product developers are available to you to optimise existing system approaches or develop completely new ones. Here we offer ourselves as a partner who can contribute options for customised glass primary packaging solutions as well as integrated drug-delivery concepts during drug development. This means you profit from our specific knowledge about the special properties of glass as a primary packaging material and about suitable surface-treatment processes. We accompany your project with life-cycle management and extensive technical documentation, and hold drug master files so that we can also support you with your product registrations.







Production and quality

Our facilities work at the highest technical level and to comprehensive quality standards. In parallel with innovative adjustments to our product range we also develop and refine the procedures and processes themselves. Our objectives are high glass quality combined with minimum risk of contamination. This can only be achieved by constant monitoring of the entire production process and by safe packaging procedures. For production of sterile syringes, for example, we today have a unique technology centre in which state-of-the-art WFI water processing plants and clean-room systems set the basic standards. In our technology centre for vials ongoing optimisation of our highly regarded visual inspection systems insure that constantly rising quality standards can be guaranteed. The high-value input material is also manufactured in-house since of course as a vertically integrated manufacturer we also produce glass tubes ourselves. Our plants rigorously follow the rules of good manufacturing practice (cGMP) and are certified in accordance with DIN EN ISO 9001, 13485 and/or 15378. Our products comply with the European and US pharmacopoeia requirements.



The descriptions West®, Helvoet® and Stelmi® of the needle shield caps, tip caps, needle seals and rubber stoppers as well as the description ADD-Vantage® of vials used by us are trademarks or business descriptions of the companies which manufacture these products, West Pharmaceutical Services, Helvoet Pharma, Stelmi and Abbott.

Tubular Glass

	Tubing
	Drug delivery systems Syringe systems: bulk, Readyject®, RTF®, syringe accessories
	Cartridges
	Vials
	Ampoules
	Finishing processes Baked-on siliconisation, treatment with ammonium sulphate

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Gerresheimer high-quality glass tubing as an intermediary product

As one of the leading manufacturers in the world with tubing plants in Europe and the US, Gerresheimer produces borosilicate glass tubing of top hydrolytic quality in flint and amber.

To meet our customers' growing demand for top technological performance we use state-of-the-art furnace technologies guaranteeing a homogeneous melting process which is checked by modern control systems and regular chemical analysis.

Our product range includes glass types with different expansion coefficients (33 and 51). The following sizes are available:

- Diameter 4 – 150 mm
- Wall thickness 0.18 – 8 mm
- Length 1.0 – 3.5 m

For further information please contact our technical support team
for Europe/Asia via info-tubing-eu@gerresheimer.com or
for the Americas via info-tubing-us@gerresheimer.com

Tubular Glass Tubing

GX-51 Flint GX-51 Amber GX-51 Cerium GX-33

Tubular glass compositions

Chemical composition
(main components/approximate wt%)

SiO ₂	73	70	73	80
B ₂ O ₃	12	10	11	13
Al ₂ O ₃	7	6	6	3
Na ₂ O + K ₂ O	9	8	9	4
CaO + MgO	1	1	1	<0.1
BaO	–	2	–	–
Fe ₂ O ₃	–	1	–	–
TiO ₂	–	3	–	–
CeO ₂	–	–	1	–

▶ Continued on page 1.3

Tubular Glass Tubing

GX-51 Flint GX-51 Amber GX-51 Cerium GX-33

Tubular glass compositions

► Continued from page 1.2

Physical properties (typical values)

Thermal expansion 0-300°C (x10 ⁻⁷)	52	53	61	32
Softening point (°C)	780	765	740	825
Annealing point (°C)	560	545	565	565
Strain point (°C)	525	515	530	515
Density (g/cm ³)	2.34	2.38	2.41	2.23
USP extractable arsenic (ppm)	<0.01	<0.01	<0.01	<0.01

Hydrolytic properties

USP	Type I	Type I	Type I	Type I
EP	Type I	Type I	Type I	Type I
JP	Type I	Type I	Type I	Type I
ISO 720	Class HGA1	Class HGA1	Class HGA1	Class HGA1



A high-tech range of prefillable syringe systems

We offer prefillable syringes in well proven quality, perfectly tailored to your requirements, extremely variable in terms of design features yet with optimum coordination of all individual components and also technically compatible with the commonly found standards in the pharmaceutical industry.

Our range comprises:

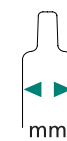
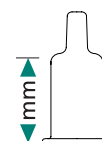
- Sizes from 0.5 to 5 ml,
- pre-mounted needles of widely varying formats,
- Luercone and Luerlock systems,
- pharmaceutical rubber formulations in many variants,
- all relevant interior tempering options (see pages 6.1 and 6.2),
- syringe accessories and
- ceramic printing on the glass.

We are able to deliver prefillable syringes not only as bulk products but also completely ready to fill in all regards: washed, silicised, pre-assembled and sterilised in compliance with all the pharmaceutical regulations. With these sterile glass syringe systems under the trade mark RTF® (Ready-to-Fill) we are regarded as the international technology leader.

Through our innovative system components we have achieved important developments in application safety: for example rigid needle shields with thermoplastic elastomer (TERNS) to protect the needle point from deformation before the injection, ensure the essential sharpness of the needle and reduce the risk of needle-prick injuries. An intelligent solution for Luer systems is offered by the TELC, a tamper-evident Luerlock closure with a guided twist-off action.



Tubular Glass Syringe systems



Bulk syringes with staked-in needle

0.5 ml	47.6	6.85	4.65	1/2 or 5/8
1.0 ml long	54.0	8.15	6.35	1/2 or 5/8
1.0 ml standard	35.7	10.85	8.65	5/8 or 1
1.5 ml	43.2	10.85	8.65	1/2 or 5/8

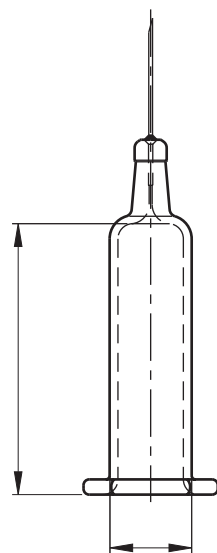
Material:

Type I glass (EP/USP/JP compliant), plunger rod PP, PS

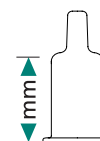
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

Needle shields and stoppers in various rubber formulations and designs are available on request.
Rigid needle shields (Stelmi® 4800, Gerresheimer TERNs – thermoplastic elastomer) are also available.

Our technical support team would be happy to provide you with further information.
Please contact info-buende@gerresheimer.com.

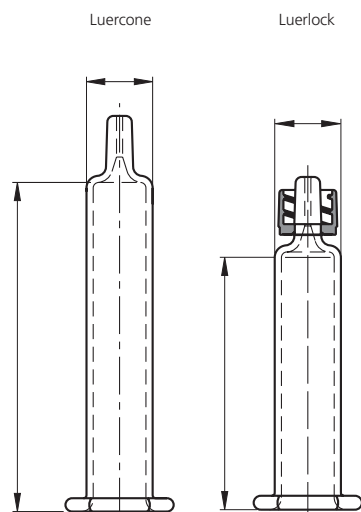


Tubular Glass Syringe systems



Bulk syringes Luercone/Luerlock

0.5 ml	47.6	6.85	4.65
1.0 ml long	54.0	8.15	6.35
1.0 ml standard	35.7	10.85	8.65
1.5 ml	43.2	10.85	8.65
2.25 ml	54.4	10.85	8.65
3.0 ml	72.2	10.85	8.65
5.0 ml	66.7	14.45	11.85



Material:

Type I glass (EP/USP/JP compliant), plunger rod PP, PS, Luerlock adapter PC

- Baked-on siliconisation as option (see page 6.1)
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

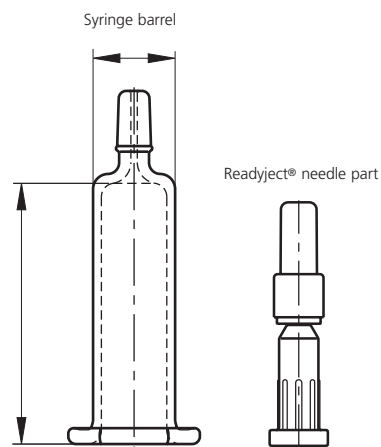
Tip caps and rubber stoppers in various rubber formulations and designs available on request including the Gerresheimer TELC (Tamper-Evident Luerlock Closure).

Our technical support team would be happy to provide you with further information. Please contact info-buende@gerresheimer.com.

Tubular Glass Syringe systems



Gerresheimer Readyject® syringe systems



0.5 ml	47.6	6.85	4.65	5/8 inch 25 G 1 inch 25 G	West® 4023/50 grey Helvoet® FM 257/2
1.0 ml long	54.0	8.15	6.35		
1.0 ml standard	35.7	10.85	8.65		
2.25 ml	54.4	10.85	8.65		
3.0 ml	72.2	10.85	8.65		
5.0 ml	66.7	14.45	11.85		

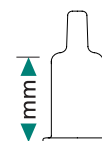
Material:

Type I glass (EP/USP/JP compliant), plunger rod PP, PS

- Readyject® as bulk version: glass barrel non-sterile; needle part gamma irradiated
- Readyject® as RTE®-version: glass barrel pre-sterilised; needle part gamma irradiated
- Tamper-evident rigid needle shield
- Baked-on siliconisation as option (see page 6.1)
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

Our technical support team would be happy to provide you with further information.
Please contact info-buende@gerresheimer.com.

Tubular Glass Syringe systems



Gerresheimer RTF® syringe systems Luercone

0.5 ml	47.6	6.85	4.65
1.0 ml long	54.0	8.15	6.35
1.0 ml standard	35.7	10.85	8.65
1.5 ml	43.2	10.85	8.65
2.25 ml	54.4	10.85	8.65
3.0 ml	72.2	10.85	8.65

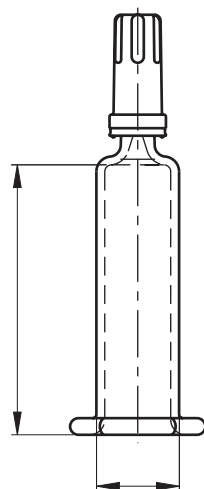
Material:

Type I glass (EP/USP/JP compliant)

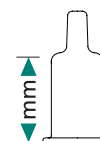
- RTF® – Ready-to-Fill
- System is completed by bulk or nested stoppers (see page 2.8)
- RTF® process steps: washing, silicisation, assembly, nesting
- ETO sterilisation
- Baked-on silicisation as option (see page 6.1)
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

Tip caps in various rubber formulations and designs available on request.

Our technical support team would be happy to provide you with further information.
Please contact info-buende@gerresheimer.com.



Tubular Glass Syringe systems



Gerresheimer RTF® syringe systems Luerlock

0.5 ml	47.6	6.85	4.65
1.0 ml long	54.0	8.15	6.35
1.0 ml standard	35.7	10.85	8.65
1.5 ml	43.2	10.85	8.65
2.25 ml	54.4	10.85	8.65
3.0 ml	72.2	10.85	8.65

Material:

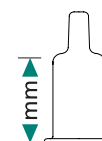
Type I glass (EP/USP/JP compliant)

- RTF® – Ready-to-Fill
- System is completed by bulk or nested stoppers (see page 2.8)
- RTF® process steps: washing, siliconisation, assembly, nesting
- ETO sterilisation
- Baked-on siliconisation as option (see page 6.1)
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

Tip caps in various rubber formulations and designs available on request as well as Gerresheimer TELC (Tamper-Evident Luerlock Closure)

Our technical support team would be happy to provide you with further information. Please contact info-buende@gerresheimer.com.

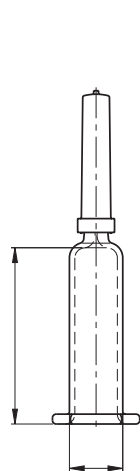
Tubular Glass Syringe systems



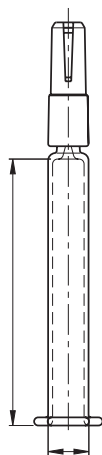
Gerresheimer RTF® syringe systems staked-in needle

0.5 ml	47.6	6.85	4.65	1/2
1.0 ml long	54.0	8.15	6.35	1/2
1.0 ml standard	35.7	10.85	8.65	5/8
1.5 ml	43.2	10.8	8.65	5/8

Flexible needle shield



Rigid needle shield



Material:

Type I glass (EP/USP/JP compliant)

- RTF® – Ready-to-Fill
- System is completed by bulk or nested stoppers (see page 2.8)
- RTF® process steps: washing, silicisation, assembly, nesting
- ETO sterilisation
- Drug Master File Type III
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance (see page 6.2)

Needle shields in various rubber formulations and designs available on request including rigid needle shields (Stelmi® 4800, Gerresheimer TERNs – thermoplastic elastomer).

Our technical support team would be happy to provide you with further information. Please contact info-buende@gerrsheimer.com.

Gerresheimer RTF® syringe accessories

We offer you a wide range of sterilised rubber stoppers suitable for all our RTF® syringe types. All rubber formulations are available as nested stoppers or in bags. Packaging in port bags for use with isolators or RABS is an additional option. For our 1 ml long syringes and 1 – 3 ml syringes, backstops are available on request.

Our range also includes plunger rods made from PP or PS for all syringe sizes from 0.5 ml – 5 ml. Customised versions are available on request.

Our technical support team will be happy to assist you in selecting the most appropriate combination. Please contact info-buende@gerresheimer.com.



Glass cartridges for diverse drug delivery systems



As an approved supplier of cartridges for various pharmaceutical applications we produce cartridges for contents ranging from 1 to 10 ml.

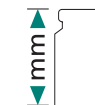
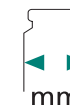
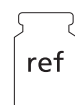
Our product range includes clear and amber cartridges (glass type I) for the following applications:

- Cartridges for pen systems, auto-injectors and needle-free injectors
- Insulin cartridges
- Dental cartridges

To fulfil high and constantly increasing quality demands by our customers, all our cartridge lines are equipped with visual inspection systems for 100% dimensional control. In addition, our high quality lines use visual inspection systems to check for cosmetic defects and line-scan cameras to control the glazed end. Final packaging is performed under controlled environmental conditions.

Individual options round off the range. These include, for example, ammonium sulphate treatment to improve the glass quality and processability (see page 6.2).

Tubular Glass Cartridges



Cartridges

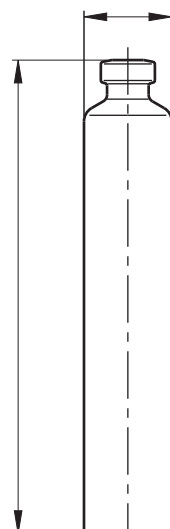
61007	3.0	11.60	9.65	62.30
61001	3.0	11.60	9.70	62.30
62075	1.8	8.65	6.85	62.00
61006	1.5	8.65	6.85	56.95

Material:

Type I glass (EP/USP/JP compliant)

- Sizes from 1 to 10 ml, other sizes on request
- Packaging options: PP-box, tray, shrink wrap
- Suited to standard filling and packaging equipment
- Customised ceramic printing with heavy-metal-free inks
- Optional: special treatment with ammonium sulphate for greater surface resistance
- Cartridges (ISO or customised) to be used for pen systems, auto- or needle free injectors

Our technical support team would be happy to provide you with further information.
Please contact info-buende@gerresheimer.com.



Glass vials for pharmaceutical applications

We offer a wide variety of vials from 1 to 50 ml in different designs, with or without blowback (European and American version) which covers any need our customers may have. Production is carried out according to industry standards or your individual specifications. Packaging is performed under controlled environmental conditions.

Our product range includes clear and amber vials in glass types I, II, III.
A brief overview is given below:

- **Pharmaceutical vials**

- Injection vials
- Lyophilisation vials
- Tablet vials
- Large OD vials

- **Diagnostic vials**

- Screw thread vials
- Screw thread tubes
- Chromatography vials

- **Special vials**

- ADD-Vantage® vials
- Two-compartment vials
- Sampler vials
- Onion skin vials

We offer the following options enhancing glass quality and processability:

- Ammonium sulphate treatment to reduce alkali ion emission
- Optimised design for lyophilisation
- High quality pharmaceutical serum vials using proprietary visual inspection systems
- Siliconised vials for optimum emptying characteristics
- Our Pharma Plus™ service to meet the most stringent cosmetic and dimensional control requirements



Glass ampoules as primary packaging for numerous drugs

With special expertise in the field of pharmaceutical ampoules we are available to you around the world as a highly competitive supplier and partner. Even our standard range offers you a wide variety of top-calibre products in high-quality type I pharma glass (EP/USP/JP compliant). You can choose between:

- Flint and amber glass ampoules
- Filling capacities from 1 to 30 ml
- Straight-stem, funnel-type and closed ampoules (ISO types B, C and D as well as customised special shapes)
- Various break systems such as OPC (One Point Cut), CBR (Colour Break Ring) and Score Ring.

A wide variety of options are available to complement this range. These enable us to match the type and properties of our ampoules to your special requirements and wishes in many regards – and well in excess of the ISO norms:

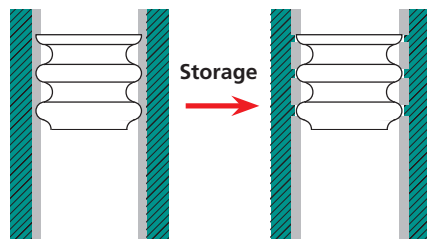
- Optimised machine-running properties for high-performance filling operations
- Targeted minimisation and consistency of opening force
- Special treatment with ammonium sulphate for greater surface resistance (see page 6.2)
- Inner surface siliconisation to provide a slide coating for optimum emptying of the ampoules
- Optimised designs for lyophilisation
- Customised ceramic printing with heavy-metal-free inks
- Identification with up to three coloured code rings.

In this field, as in all its production operations, Gerresheimer attaches particular importance to innovative technologies. Often in partnership with our customers we continuously develop and refine these across the entire process chain. The quality of our ampoules is monitored at every stage of the ongoing production process by state-of-the-art in-line camera systems – right through to complete inspection of the printing.

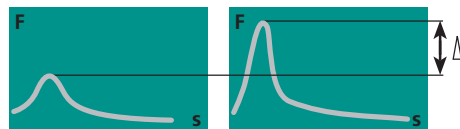


Gerresheimer Baked On RTF™ – Baked-on siliconisation for prefillable syringes*

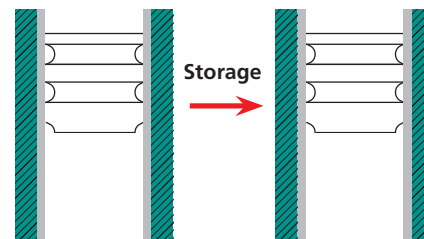
Oily siliconised syringes



Direct contact rubber to glass surface can lead over time to higher break-out forces.

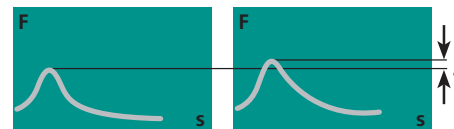


Baked-on siliconisation



Baked-on silicone provides consistent coating of the glass barrel walls.

→ Break-out force stays low during storage



Today, many of the new drugs developed by the pharmaceutical industry demand increasingly individual packaging approaches to meet specific requirements. Special finishing processes to ensure compatibility of the packaging material with the active substance in the drug product hold it stable in solution and prevent it becoming inactive.

In the production of syringe systems at Gerresheimer Bünde, certain processes such as baking of silicone oil on the inside of the syringe barrel help to stabilize sensitive biotech drugs in solution. A particular problem is that silicone oil droplets generated by conventional liquid siliconisation can under specific circumstances interact with the drug. An example of this is silicone-oil-induced protein aggregation in biotech-derived drug products, which in the worst case can lead to rejection of the drug. Our patented baked-on siliconisation provides the syringe barrel with a lasting, stable and even glide coating so that problem-free application is guaranteed over the whole shelf life of the drug.

Treatment with ammonium sulphate



Nearly insoluble
in water



Very soluble
in water

In general, the impact which the drug delivery system can have on product stability should not be underestimated. With the glass material used (type I), the main factor influencing stability is the resistance property of its surface, measured by its alkalinity. Despite the use of glass type I, some drugs frequently cannot be kept stable in solution long enough under the conditions typical for glass application systems. They can therefore be marketed only as a freeze-dried substance in a glass vial.

A specific surface treatment process used by Gerresheimer Bünde helps to overcome this serious problem and offers an optimised drug-delivery system approach for non-buffered/low-buffered drug solutions or WFI delivery systems. Together with the use of a special glass composition with lower alkali content (KG33 glass), treatment with ammonium sulphate offers a significant improvement in the pH stability of solution-based or WFI delivery systems.

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GERRESHEIMER

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