

GERRESHEIMER



Gx[®] RTF vials

Prefillable vials based on the Ompi EZ-fill[®] packaging formats



Gx® RTF Vials:

combined know-how in glass forming, processing of prefillable primary packaging materials and packaging technology – two manufacturers – one packaging

For more than 15 years now, Gerresheimer has been producing Gx RTF® glass syringes (ready-to-fill glass syringes) that are harmonized with the current requirements of the pharmaceuticals industry, the specific medication, and the requirements of modern filling systems.



Gerresheimer also produces the most varied forms of vials made of tubular glass for the packaging of parenteral medication in accordance with international standards or individual specifications. These two areas of competence of Gerresheimer, the glass forming of vials and the ready-to-fill processing of prefillable glass primary packaging materials, are now even combined with the recognized Ompi EZ-Fill® packaging technology. The result is the new Gx® RTF Vials, which are washed, packed in trays

or in a nest and tub, sterilized and delivered to pharmaceuticals customers. They can then immediately begin filling without further process steps.

The special feature here: the customer can acquire identically packaged, sterile vials from two different manufacturers! By establishing this standardized platform for prefillable, sterile vials, we simplify the process for the customer in a fundamental way and reduce potential risks.



Gx[®] RTF Vials:

flexibility through different packaging configurations from the development phase of new medications through the small series to large series production

Gx[®] RTF Vials are available in a variety of packaging variants that are optimally coordinated to the filling technology at the customer. We offer the packaging in nests & tubs or in trays.



Gx[®] RTF Vials
in nest & tub

Format	Volume (ml)	Diameter (mm)	Height (mm)	Crimp finish (mm)	Pcs.
2R	4	16	35	13	120
6R	10	22	40	20	48
10R	13,5	24	45	20	48

Further formats on request



Gx[®] RTF Vials
in tray

Format	Volume (ml)	Diameter (mm)	Height (mm)	Crimp finish (mm)	Pcs.
2R	4	16	35	13	228
6R	10	22	40	20	96

Further formats on request

Gx[®] RTF Vials:

the highest quality requirements

All Gx[®] RTF vials are manufactured of borosilicate glass of type I. The tubular glass originates from approved and qualified suppliers. The vials fulfill all of the standard requirements of the applicable ISO standards and pharmacopoeias (USP and Ph. Eur.).

Gerresheimer offers a broad portfolio of vials, with or without blowback, in accordance with applicable standards or individual specifications, and manufactured with the most modern production and inspection processes.

Gx[®] RTF Vials:

the highest standards with regard to glass breakage, cosmetic defects, and particle contamination



The new Gx[®] RTF vials are transferred into a class C clean room in accordance with GMP after the forming of the glass and are washed with WFI (Water for Injection) in order to ensure the required germ count and endotoxin reduction. The vials are then dried with sterile-

filtered air. Depending upon their size, the vials are inserted into a perforated tray or nest as 48 or 120 units. The filled nest is then transferred to a tub. Alternatively, packaging can take place in trays with 96 or 228 units respectively.

Both packaging forms are provided with a protective Tyvek[®] layer in the next step in order to prevent possible particle contamination, and are then sealed with an additional Tyvek[®] sealing layer. Depending upon customer requirements, the sealed tubs or trays are packaged in single or double pouches. These then leave the clean room area for final packaging in specific boxes for Ethylene Oxide (EtO) sterilization.

Gx[®] RTF vials are packed in nests, tubs, or trays using the established Ompi EZ-fill[®] packaging formats. Glass-to-glass contact is thus minimized.

Gx® Vials: delivered sterile

Treatment with EtO-gas is a standard procedure for the sterilization of prefillable glass containers. The completely validated EtO-sterilization process of the Gx® RTF vials is carried out by a contract company certified by us.

Sterilization is based on validated processes in accordance with applicable standards. Sterility proofs are carried out as part of the final product approval for each batch. A COC (certificate of conformity) is created and issued for each batch.

Gx® RTF Vials: flexibility for a variety of filling and sealing technologies

During the filling process at pharmaceutical customers, Gx® RTF vials are unpacked step-by-step and further processed using the most modern filling and sealing technology. As with the familiar Gx RTF® syringes, the filling and sealing procedure takes place

directly in the nested container without glass-to-glass contact. Or the vials are removed from the nested containers and further processed conventionally in the filling line.

Gx® RTF Vials: improvement of the total manufacturing costs over the product life cycle

Long and expensive product development times and strong competition make a streamlined production process and concentration on the core competence of active ingredient development unavoidable for pharmaceutical companies. Thanks to the ready-to-fill format of the vials, our customers benefit from a reduction of the necessary process steps:

no washing and sterilization required. That means less investment in operating equipment and personnel for customers. Thanks to the many years of expertise of Gerresheimer in the field of sterile, prefillable primary packaging, we minimize the most varied risks that can arise for our customers when dealing with sterile primary packaging.



You too can profit from the unique quality of our Gx® RTF portfolio, standardized packaging, our many years of experience, as well as technical support during the entire product life cycle!

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