Grifols Partnership

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PARENTERALS CDMO

Manufacturing of Complex Parenterals

SUPPORTING SMALL VOLUME AND SMALL MOLECULE PARENTERAL PROJECTS

Empty IV bags

Reliable empty IV bag solutions for pharmaceutical filling

GRIFOLS

Why choose Grifols?

A trusted pharmaceutical partner

With in-house capabilities to design, manufacture, and supply empty IV bags, Grifols brings together CDMO expertise, advanced medical plastics know how, and full global quality standards compliance—ensuring reliability at every stage of the product lifecycle.

A global healthcare leader

Decades of experience in IV bag manufacturing, supported by flexible industrial capabilities and a reliable, compliant supply chain, enable Grifols to deliver tailored solutions to partners worldwide.

From materials of construction to plastic components and containers for pharmaceutical use

Grifols applies a fully validated injection, assembling and thermos-sealing processes designed to ensure consistent quality, performance, and regulatory compliance at every stage. Each step is optimized and continuously monitored to deliver reliable, high quality empty IV bags and closures, ready for downstream pharmaceutical filling.

Empty IV bags

Grifols offers a broad portfolio of **empty IV bags** designed for customers requiring **high quality, reliable pharmaceutical containers**. Manufactured using proven materials and validated processes, our solutions support safe handling, flexibility, and consistent performance across multiple healthcare applications.

Material options

Grifols works with different types of materials to address diverse application requirements and customer needs:

Polypropylene (PP)

Standard and barrier versions

Grifols manufactures high clarity polypropylene (PP) bags with excellent mechanical strength and thermal resistance. Available in both standard and gas barrier multilayer structures, they can be adapted to different needs: standard PP for general applications, and barrier PP to reduce oxygen (O_2) and carbon dioxide (CO_2) transmission in more sensitive products.

PVC- and DEHP-free, these bags ensure high drug compatibility, support validated sterilization processes and maintain product quality and stability. Compliant with European and U.S. pharmaceutical standards, they are offered in both standard and fully customizable configurations to meet specific requirements.

In addition to empty IV bag manufacturing, Grifols operates advanced form-fill-seal (FFS) technology for the production of finished sterile parenteral products in polypropylene containers.

Polyethylene (PE)

Gas-barrier

A flexible, robust and inert material that incorporates advanced multilayer structures that significantly reduce oxygen transmission, providing enhanced protection for oxygen sensitive drug products and helping to preserve product quality, stability and shelf life.

Supplied as pre-sterilized bags (gamma irradiated), these solutions are designed for aseptic filling of heat sensitive molecules and can be delivered in standard or fully customized configurations, with adaptable volumes, ports and components to meet specific pharmaceutical requirements. This option requires the use of compatible ultrasonic equipment (supplied by Grifols) to complete port sealing.

UNDER DEVELOPMENT

Polypropylene (PP) and polyethylene (PE) sterile IV bags

Aseptic filling

Grifols manufactures polypropylene (PP) bags and polyethylene (PE) bags supplied as pre-sterilized bags (gamma irradiated or e-beam), these solutions are designed for aseptic filling of heat sensitive molecules and can be delivered in standard or fully customized configurations, with adaptable volumes, ports and components to meet specific pharmaceutical requirements. Integration into the filling line requires suitable equipment to ensure proper sealing of the dosing tube, supporting a reliable and efficient final container closure.

Key general features

Designed for safe and easy handling

Integrated eyelet support for easy and safe handling of the container during utilization.

Robust seal integrity

Manufactured using validated thermo-contact sealing to ensure leak-free performance, durability, consistent quality and reliable performance. Comply with the UNE ISO 15747 standard 'Plastic containers for intravenous injections', which establishes a pressure resistance specification of 50 kPa for 15 minutes.

High transparency

Enables easy visual inspection of the bag content throughout handling and use.

Latex and natural rubber free

Reduces risk of allergenic reactions and supports broad clinical compatibility.

Quality standards and safety compliant materials

Materials are selected in accordance with recognized quality and safety standards for pharmaceutical applications, including relevant requirements of the European Pharmacopoeia (Eur Ph), United States Pharmacopeia (USP), and biocompatibility. Transmissible spongiform encephalopathy (TSE)-.and bovine spongiform encephalopathy (BSE)-free. Also free from carcinogenic mutagenic reprotoxic (CMR) substances. This ensures suitability for parenteral use and supports patient safety throughout the product lifecycle.

Non-sterile and sterile bags

Supplied non sterile, as empty containers intended for subsequent pharmaceutical filling and terminal sterilization according to customer defined processes.

Supplied sterilized by validated gamma irradiation or e-beam processes, as empty containers intended for aseptic filling.

Wide range of applications

Suitable for IV fluids, antibiotics, and specialty drug delivery - designed with reinforced seals and customization options to ensure safety.

Multiple volume configurations

Available formats from 50 mL to 1000 mL.

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Tube configurations

Available in one-tube and two-tube designs, Grifols empty IV bags offer flexibility to support different filling operations, administration needs, and specific requirements.

Single-tube

Optimized for straightforward filling processes and standard administration setups, providing simplicity, efficiency, and reliable performance.

Two-tube

Designed for applications requiring 2 independent ports. One dedicated to the infusion of the solution to the patient, and a second port intended for drug addition.

Port integration options (Closures)

A wide range of closure port types can be integrated, allowing Grifols empty IV bags to be configured as complete container systems. The combination of bag and ports supports diverse and complex applications, with flexibility to adapt configurations to specific customer and application needs.

Twist off port

Integrated PP twist off port designed to act as infusion port. This protects the fluid path prior to use and enable secure connection when required. The port remains closed and protected until activation, reducing the risk of contamination during handling and filling. Available in pre-irradiated and non-sterile in bulk versions.

Injection port

Designed for safe and reliable drug addition, the injection port is composed of a polypropylene (PP) body, a latex free rubber injection site and a PP cap available in various colors (e.g., blue, white, red) for easy identification. The port incorporates a dedicated internal membrane within the body, creating a physical barrier between the solution and the elastomer. This design enhances product compatibility while ensuring aseptic access and maintaining container integrity during use.

Needle-free luer port

Luer lock valve with automatic locking mechanism that enables easy, quick, and safe access to the interior of the bag through the connection of a needle-free syringe or a male vial adaptor. Designed to support secure injection and extraction operations while maintaining system integrity.

It is made from blue silicone and transparent polycarbonate, these materials are resistant to gamma radiation.

Correct connect port

(connector for citrate-based anticoagulant for apheresis application)

Integrated breakable inverted female connector made of polycarbonate and thready closed by a PP cap. Port designed to enable safe and secure connections while minimizing connection errors and in accordance with ISO 18250-8, supporting applications such as anticoagulant for apheresis- related uses. The port remains closed and protected until activation, supporting contamination control during handling and filling.

Grifols rigid port system

Designed to support safe and reliable drug preparation and administration. Medication and outlet ports feature rigid, extended tubes to help prevent perforation during needle insertion.

The internal membrane ensures secure attachment of the infusion set, while the outlet port design allows access without removing or breaking any protective components (no parts of the cover have to be removed/ broken in order to access the outlet port), supporting ease of use and container integrity.

The infusion port is polypropylene piece, designed to be punctured when administering the parenteral solution, sealed by a membrane of the same polypropylene and protected by a tab.

The injection port is a polypropylene piece with an internal membrane and latex-free rubber (not in contact with the solution). The stopper consists of the following components: stopper component made of PP, cover made of PP, and the injection point made of synthetic rubber.

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Pre-irradiated bags for aseptic filling

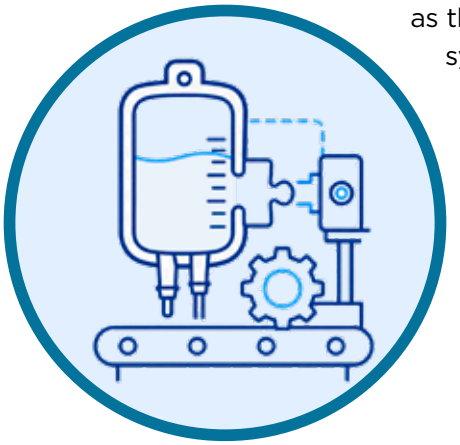
For bags supplied sterilized by gamma irradiation or e beam, the sterilization cycle is developed and validated in accordance with the ISO 11137 series of standards. This ensures a controlled, reproducible process that meets the required sterility assurance levels while maintaining the integrity and performance of the final product.

Printing options

Bags are available with high-quality printing in a wide range of pharmaceutical-grade colors, including black, red, blue, green and other options, allowing clear product identification and an attractive, professional appearance. Design layouts can be fully tailored to customer needs, with dedicated areas reserved for variable data such as batch number, expiry date and barcodes. We also provide expert guidance in the selection of printing films and technologies, ensuring sharp, reliable and consistent marking of variable information.

Overwrapping options

Support is provided in the selection of suitable secondary packaging materials for the primary bag, ensuring the required barrier against gases, moisture and light. Options include multilayer films and aluminum-based laminates, compatible with terminal steam sterilization. Recommendations are also aligned with the selected packaging equipment, such as thermoforming or flow-pack systems, to ensure efficient and reliable processing.



Extractables Assessment

Support is provided in the evaluation of extractables, leveraging available data from materials of Grifols standard IV bags and printing films used in bag manufacturing.

Engineering Integration Support

Collaboration with Grifols Engineering is available to support the seamless integration of bag solutions into customer production lines. This includes guidance during process development and equipment adaptation, ensuring compatibility with existing manufacturing setups and optimizing performance, efficiency and reliability throughout filling and packaging operation

Customized bags

Tailor-made bag designs available upon request, enabling customized configurations to meet specific customer, process, and application requirements.

Grifols offers comprehensive support throughout the entire IV bag development and manufacturing lifecycle, from initial concept definition to validated, compliant industrial supply

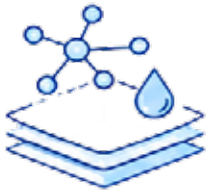
Our capabilities include:

1

Concept definition

Definition of product requirements and intended use, including shelf-life considerations

2



Material selection

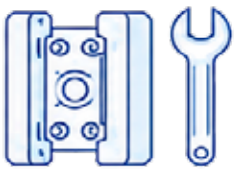
Selection of materials of construction for bags and ports based on composition, quality, biocompatibility transparency sterilization resistance and specific requirements

3

Design and engineering

Design of IV bags and components (films, ports, tubing) in compliance with functional, performance, and quality standards

4



Tooling and molds

Design and construction of molds and tooling, including injection molds for ports and connectors, welding molds, and assembly tooling

5

Process development and validation

Development and validation of robust, reproducible manufacturing processes

6

Design verification

Mechanical integrity, leak testing, stability, sterilization, and transportation studies to ensure consistent quality and performance.

Certifications and compliance

Our facilities include the following certifications

European GMP

Good manufacturing practice for medicinal products in compliance with European regulations.

FDA cGMP (21 CFR Parts 210 & 211)

Good manufacturing practice for medicinal products intended for the US market.

ISO 13485

All products are developed, manufactured, and marketed under an ISO 13485-certified Quality Management System.

CE Certification

Compliance with European Medical Device Regulation (EU) 2017/745 (MDR) for selected medical devices.

Medical Device Single Audit Program (MDSAP)

Laboratorios Grifols holds Medical Device Single Audit Program certification, enabling multi-market regulatory acceptance.

FDA Establishment Registration

Registered manufacturing facility for products supplied to the US market.

FDA Quality System Regulation (21 CFR Parts 820 & 821)

Compliance with US medical device quality and traceability requirements.

21 CFR Part 4

Compliance with FDA regulations for combination products.

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A Global Healthcare Company

GLOBAL EMPLOYER

Grifols, with more than 23.000 employees in over 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership in the industry.

GLOBAL MANUFACTURER

Grifols has the infrastructure to meet the needs of patients and customers worldwide including manufacturing facilities located in the US, Spain, Germany, Ireland, Switzerland, Brazil and Australia.

INNOVATIVE

We conduct our own R&D programs and make strategic investments in promising start-ups and novel technologies. We also modernize our manufacturing facilities and develop novel processes to help ensure product safety and efficacy.

> **Grifols** is a global healthcare company that since its founding in Barcelona in 1909 has **enhanced the health and well-being** of people around the world.

We produce essential plasma medicines for patients to treat chronic, rare and, at times, life-threatening conditions. The company provides a comprehensive portfolio of solutions in transfusion medicine and also offers hospitals, pharmacies and healthcare professionals information and services that deliver efficient, expert medical care.

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