

CONTRACT MANUFACTURING

Our partner company is an industrial and commercial company that is “revolutionary” in its markets of reference. It is innovative regarding products, careful about using quality materials and unique technological production process. The company is provided with sophisticated equipment and instrumentation. Their key feature process is an integrated combined production-filling cycle: the production of infusion bags and the filling of themselves with solution, then the final sterilization in autoclave. This innovation sure offers protection against a wide range of contamination and environmental risk. Besides, all company processes take place by ISO standards 9001-2000 and 14001-2004.

Manufacturing

Due to a long manufacture experience and availability of technical data, such as stability studies, manufacturing process and batch validation, the company is involved in offering assistance to the clients in preparing of registration files in CTD format for submission to the authorities.

The Quality Control laboratories are the core of production. Qualified and performed staffs (in conformity to the EU-GMP) check throughout the manufacturing process the product meets the quality specification by regulation, through physical chemical and microbiological test.





For packaging material our partner chooses the Polypropylene “Cryovac” that has a good reputation for its quality and the primary packaging characteristics are successful in preparing sterile fluid. The Food and Drug Administration (FDA) approved this material suited perfectly for sterile pharmaceutical solutions. But the use of PVC for the infusion bags and of the glass bottles is also possible. Besides it is possible to manufacturing different size of the infusion bags, until 5000 ml. After production and filling of bags, it could be put an over-bag that should be under-vacuum or not under-vacuum.

Pharmaceutical Contract Manufacturing Services for IV bags and IV bottles.

As a cGMP API manufacturer, our pharmaceutical contract manufacturing can support the development process of your IV business regarding the procurement of empty IV bags. All Projects are supported by our chemistry expertise, GMP compliance and extensive quality control. Our partner currently manufactures sterile medical devices and sterile commercial products under GMP. They have manufactured many products for clinical trials (Phase I, II and III).

Validation

In a regulated industry, special care must be taken to ensure all equipment and processes are performing to specifications. Deviations from the norm could have unpredictable and sometimes devastating results. Therefore, special attention is paid to equipment qualification and process validation to provide full regulatory compliance to the clients. Strictest guidelines are followed to perform the most rigorous testing and





execute studies in a timely fashion to ensure your product is of the highest quality when it reaches its destination. has capabilities to develop, create and execute validation protocols and studies required for your products and equipment that are required for your projects in accordance with current Guidelines (HPFBI, FDA, EP, ICH, WHO) and acceptable formats (prospective, retrospective and concurrent). These include process, cleaning, aseptic and terminal sterilization processes, environmental control, IQ/OQ/PQ/PV and utility qualifications. Statistical and decision making analysis is also part of the service.

We stand by our products which are manufactured to the highest quality standards. Please review our following product list.

Product overview

For Human Use (PP/PVC)	For Human Use (Glass)	Medical Devices
Water for Injection	Water for Injection	Destillate Water
Glucose 10%	Glucose and Sodium Chloride	Sodium Chloride Solution
Sodium Chloride 0,9%	Electrolytic Enteric Equilibrate	Sodium Bicarbonate Solution
Mannitol 5%, 10%, 18%, 20%	Electrolytic Gastric Equilibrate	
Glucose	Hydratant Solution	
Electrolytic Enteric Equilibrate	Maintenance Equilibrate Solution with Glucose 5%	
Dextrose 5%, 10%, 25%, 33%	Glucose	
Electrolytic Integration with Sodium Gluconate	Glycerol and Sodium Chloride 10% + 0,9%	



Anticoagulant	Mannitol Solutions	
Dextrose 5% Sodium Chloride 0,225%, 0,45%, 0,9%, 0,18%	Electrolytic Integration Solution with Sodium Gluconate	
Ringer	Ringer Lactate	
Ringer Lactate	Ringer Acetate	
Ringer Acetate	Sodium Chloride	
Sodium Bicarbonate 1,4%, 8,4%	Concentrate Solution with/w/o Acetate	
Glycerol 10% and Sodium Chloride 0,9%	Concentrate Acid Solution with/w/o Glucose	
Maintenance Equilibrate Solution with Glucose 5%	Acid and Basic Solution with- out Glucose	
Hydratant Solution I, III	Concentrate Basic Solution	
Electrolytic Gastric Equilibrate	Sodium Bicarbonate	

**We also contract manufacture every
 kind
 of SPECIAL IV solutions
 on demand and order**