



Diluents – important “excipients” for modern drugs



Modern drug technology, with a shift from small molecules to big molecules such as peptides and proteins, has created new challenges for the application methods. To keep these molecules chemically and physically stable we need quite different measures than the ones that work for small molecules.

Conventional drug formulations in premixed solutions are in most cases not feasible. The required shelf life can often only be achieved by storing the drug in a solid (powdery) state, sometimes even at low temperatures. Powder filling or lyophilization are common techniques used for such molecules. This makes filling and finishing of these drugs quite different.



All powdery products for IV application have to dissolve before use. The liquid used for reconstitution – the diluent – is a second drug product, one without API. Like the active drug, it has to be registered and approved by health authorities in each country. The most common dissolution solutions are WFI, isotonic sodium chloride and glucose solutions. What kind of product is finally used depends on the formulation and compatibility of the product to be dissolved.



The preferred strategy for providing such a diluent is co-packing. This ensures that the recommended diluent is used and also, it means that the manufacturer of the drug product can assure the optimal container form and volume for the dissolution process.

Fresenius Kabi Product Partnering can offer high quality diluents in a variety of different containers and volumes. Fresenius Kabi is supplying standard salt and glucose solutions in hundreds of million units to customers – mainly hospitals – around the world. At Fresenius Kabi Product Partnering we can offer you tailor-made solutions for diluents according to the needs of your product. We can fill your diluent of choice into glass or plastic containers – ampoules, vials, bottles, bags and pre-filled syringes. The products can be labeled with the artwork you choose, in order to provide an appealing and uniform presentation of drug product and diluent. We can also provide transfer sets for our containers that connect the diluent container with the drug container to enable a smooth transfer and dissolution process. We have several plants around the world that have their focus on the manufacturing of such solutions.

Therefore, we are able to offer the diluents for registration in all major markets with already-available dossiers.