Be one step ahead

With our dossiers for diluents you are one step ahead of your competition. You will receive our dossiers in CTD format and always together with comprehensive documentation including important stability data over a period of up to 60 months. Data that you have to submit for marketing authorisations are thus already available – and you save the time-consuming work of having to carry this out yourself.

Be flexible

Whether you want to have a diluent approved and manufactured as a stand alone variant, or whether you are looking for a diluent to supplement a primary pharmaceutical product – with our dossiers you will always have the right foundation. Our data allow you to enter the market quickly with a product and also to make amendments to technical data necessary for adaptation to your primary product.

Rely on our experience

There are a few hurdles along the way for you and your product before it reaches the market – dealing with authorities and technical production issues. In addition to our dossiers we therefore offer you both support over the period of the approval process and subsequent contract manufacture of your diluent.

The specialist knowledge that you have about your product we also have about ours. You can rely on us for all issues relating to marketing authorisation and production – together we will be a strong team!

Your direct contact to us

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Diluents – Quick motion into the market

hameln pharma

Responsive Flexible Reliable

Top products need top diluents

Companies which produce high quality pharmaceutical products do not want to make any compromises where water for injection is involved. And they don't have to either.

hameln pharma has been a specialist in supplying diluents for many years. Our dossiers which have been tried and tested form the basis for you to have exactly the diluent manufactured by us that matches your requirements.

Water for Injections EP/USP

Therapeutic class	diluents
Containers	ampoule, vial
Volumes	• 1 ml in 2 ml ampoule • 2 ml ampoule • 5 ml ampoule • 10 ml ampoule • 25 ml ampoule • 1 ml in 2 ml vial for injection • 2 ml vial for injection • 6 ml vial for injection • 10 ml vial for injection • 20 ml vial for injection • 50 ml vial for infusion • 100 ml vial for infusion
Dossiers status	CTD format module 3
Stability data	according to ICH Guidelines up to 48 months, details on demand
Packaging forms	bulk, packs of 5 or 10 ampoules, bundles of 10
Production	according to GMP standards Our facilities are approved by the relevant international authorities – FDA and more

Sodium Chloride solution BP

API	sodium chloride
Therapeutic class	diluents
Other ingredients	sodium chloride, hydrochloric acid, sodium hydroxide, water for injections
Containers	ampoule, vial
Concentrations	0.9 % – 1 ml ampoule 0.9 % – 1 ml in 2 ml ampoule 0.9 % – 2 ml ampoule 0.9 % – 5 ml ampoule 0.9 % – 10 ml ampoule 0.9 % – 20 ml ampoule 0.9 % – 250 ml vial
Dossier status	CTD format module 3
Stability data	according to ICH Guidelines 36 months
Packaging forms	bulk, packs of 5 or 10 ampoules, bundles of 10, single pack for vials
Production	according to GMP standards Our facilities are approved by the relevant international authorities – FDA and more