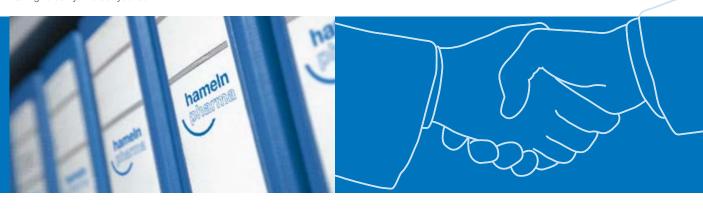
Be one step ahead

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









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 ampoule5 ml ampoule

10 ml ampoule25 ml ampoule

• 1 ml in 2 ml vial for injection

2 ml vial for injection6 ml vial for injection

• 10 ml vial for injection

• 20 ml vial for injection

• 50 ml vial for infusion

• 100 ml vial for infusion

siers status CTD format module 3

Dossiers status Stability data

according to ICH Guidelines

up to 48 months, details on demand

Packaging forms bu

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