

# Diluent Prefilled Syringes

Easy for you, easier for your customers

**1****Select the diluent required for reconstitution**

- Sterile Water for Injection (SWFI)
- Sodium Chloride (NaCl)

**2****Select a BD Hypak syringe size**

- 1.00 mL
- 1.25 mL
- 2.25 mL
- 3.00 mL

**3****Select the desired fill volume**

- From 0.25 to 3.00 mL

**4****Select inspection and packaging requirements**

- Option to design custom label
- Option for manual or fully automated Eisai inspection
- Choose from a variety of secondary packaging options and product enhancements including plunger rod, finger flange, product insert, carton, and blister pack

**5****Reference BioPharma Solutions' Master File (DMF)\***

- Reduce cost and time to market

\*DMFs reviewed by FDA in conjunction with biologic/drug applications only

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## Established DMFs save time and money

- No development work required
- Reduced time to market
- No capital equipment required (nor associated time/cost)
- Diluent DMF updates become our responsibility, and are continually evaluated to help ensure compliance

## Five (5) years of expiry dating (SWFI and NaCl)

- Longer than the typical 2-3 years seen in current diluent market
- Promotes supply chain flexibility
- Diluents meet USP and EP testing specifications

## Customizable fill volume

- From 0.25 to 3.00 mL

## Customizable label

- Offers further brand enhancement

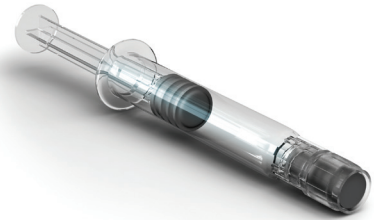
## Manufacturing flexibility and risk mitigation

- Flexibility to manufacture on multiple redundant syringe lines in separate buildings (independent water and HVAC systems)

## Regulatory experience

- Established DMFs have been successfully incorporated into client submissions for use with biologic/drug application
- Solid track record of GMP compliance; routinely audited by global regulatory agencies

Diluent Type	Date DMF Filed	Months of Stability Data
SWFI	2002	60
NaCl	2008	60



## Prefilled syringes enhance and improve patient safety vs. vials:

- Less steps for reconstitution
- Reduced contamination risk
- Reduced risk of errors

Contact us via *email* today:  
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