

**LACHMAN CONSULTANT SERVICES, INC.**  
Westbury, NY 11590

## **ATTACHMENT 2**

**Comparative Formulation Information**

**Gemzar® for Injection, 200 mg/vial and 1 gm/vial vs. Proposed Product**

Ingredient	Gemzar® 200 mg/vial	Gemzar® 1 gm/vial	Gemcitabine for Injection USP, 2 gm/vial
Gemcitabine Hydrochloride (as free base)	200 mg	1 gm	2 gm
Mannitol	200 mg	1 gm	2 gm
Sodium Acetate	12.5 mg	62.5 mg	125 mg
Hydrochloric Acid	*	*	*
Sodium Hydroxide	*	*	*
0.9% Sodium Chloride Injection	5 mL	25 mL	50 mL
Final volume upon reconstitution	5.26 mL**	26.3**	52.6 mL**
Final concentration	38 mg/mL	38 mg/mL	38 mg/mL

\* As needed for pH adjustment during processing

\*\* Increase in total volume is due to displacement by the powder

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