



Section 1: Basic Information

Client name: _____ Product name: _____

Type of finished product: (check one) LYO LIQUID

Target batch size: _____ Target fill date: _____
(Number of containers)

Length of cycle: _____
(Please attach lyo cycle parameters if known)

Fill volume: _____ mL Regulatory requirements (US, EU, etc.): _____

Fill type: (check one) containment non-containment

Section 2: Component, Container, and Closure Information

	Size	Manufacturer	Part Number	In Stock or To Be Ordered
Vials				
Stoppers				
Seals				

Or check here for LTI to recommend.

Please list the API and all Components required for the batch. If specific manufacturer/part numbers are known, please provide:

1. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	

2. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	
3. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	
4. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	
5. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	
6. Name:	
Storage Condition:	
Compendia Requirement: (USP, EP, both, etc.)	
Type of Testing Required: (ID, Endotoxin, etc.)	
Quantity Required to perform each test:	

Section 3: Formulation Requirements (If compounding procedures are available, please provide them to your Study Director):

Quantity of bulk solution: _____

Vessel(s) size required: _____

Bulk solution sensitivities? Light Oxygen Plastic None Other: _____

NOTE: If bulk solution cannot be compounded in a HDPE vessel, please notify the Study Director or alternate LTI contact promptly so they may source an appropriate dedicated vessel.

Bulk solution temperature requirements? Warm Cool Ambient
List temperature range: _____

Mixing requirements? _____

pH range requirements? _____

Time limitation? _____

In-process samples: pH Bioburden Assay Density Other: _____
Describe sample requirements:

Filter type required: LTI uses Millipak filters with Durapore membrane from Millipore. If this is not acceptable please notate filter information below. P/Ns are not necessary unless a specific filter is to be utilized.

Filter Size (0.22µ, 0.45µ, etc.)	Filter Manufacturer	Filter Part Number

Special filtration requirements? _____

Other unique formulation requirements? _____

Section 4: Filling Requirements:

Temperature requirements during filling? Heat Cool Room temperature
List temperature range: _____

Time limitation? _____

Weight check frequency: LTI SOP Client specified: _____

Environmental Monitoring requirements: LTI SOPs Client specified (requires planned DIR)

Pre fill samples: _____

Post fill samples: _____

Other unique filling requirements? _____

Section 5: Finished Product Requirements:

Inspection requirements:

Storage condition: _____

Shipping condition: _____

Address to ship finished product:

Sampling requirements:

Storage condition of samples: _____

Shipping condition of samples: _____

Address to ship samples:

