



Custom Solutions Requirements Collection Form

Thank you for choosing Microbix for the manufacture of your reagents. We recognize they are critical to your development and manufacturing programs. Please take a few moments to complete this form and add any additional information that might be important to ensure that we can provide you with exactly the solutions you want and need. If you need any assistance, your Sales Representative can help you. Please complete one form for each solution.

Customer Information	Name:		Email:	
Company Name				
Solution Name				
Solution Use (check appropriate)	Research	Engineering	Clinical Trial	Other:

Solution Recipe:				
Component Name	Component Formula (please include hydration)	Conc. (eg. Molarity, g/L, mL/L)	Desired Grade (eg. USP, EP, ACS, not specified)	Comments (eg. Single source provider)
pH adjustment				Note addition limit:
pH adjustment				Note addition limit:

Please indicate if you have an assigned a solution number and written SOPs or specifications. If possible please list those documents in this space and attach those documents to this form:

Raw Material Requirements: select the most appropriate to your needs	
Accept material on C of A	Yes or No
Identity test required	Yes or No
Identity and other characterization required	<p>Yes or No*</p> <p>*If Yes please indicate tests and limits required to meet your project needs.</p>

Batch Preparation:							
Solution Volumes (Liters)	Minimum Batch Volume preferred:		Single Shipment Volume:		Annual Volume:		
List in process test requirements: (eg pH pre-filtration, osmolarity)							
Filtration Requirements	None	0.45µm	0.22µm	0.1 µm	Sterilizing*	Filter train (describe)	
Packaging size	Standard		Custom Sizes				
	20L	200L	1L	5L	10L	1000L	Other
Storage conditions	Please provide range in °C.:						
Microbix ships Custom Solutions labeled with dates of manufacture rather than expiry dates.							

*Filtration to generate a solution with a sterility release claim requires process and release test validation.

Package Detail: (check appropriate boxes and provide additional detail if required)					
Standard Sterile Bag Configuration	200L:		Diagram of 200 L Packaging		
	20L:		Diagram of 20L Packaging		
Custom Sterile Bag*		ID inches	OD inches	Length	Connector
	Port 1				
	Port 2				
	Port 3				
	Port 4				
	Other requirements:				
Rigid Container (e.g. HDPE barrel, carboy, 1L plastic bottle,)					
	Other Requirements:				

*Custom bags require an additional 6-8 weeks for drawings, approvals and manufacture.
Microbix uses C-flex tubing.

Release Tests:		
	Specification	Test method (eg. USP, EP, other)
Microbial limits		
Sterility* Sterility testing requires test method qualification		
Endotoxin		
pH		
Osmolarity		
Others:		