

STERILITY / ENDOTOXIN SAMPLE SUBMISSION FORM

Client Information	
Company Name:	Purchase Order (if available):
Mailing Address:	Quotation No (Compulsory for proper registration of samples):
	Submitted by:
Tel: Mobile:	Email Address:
Fax:	Date:

Sample Information										
No. of vials	Volume / vial	Batch No.	Sample Description	Please tick (✓) to select the test(s) required						
				Sub-Visible Particles	LAL	LAL Validation	Sterility	Sterility Validation	Stasis Test	

Please help us to help you by providing the details below for **validation** testing purposes:

Check list	Yes	No	Details
What is the batch size of the product? (i.e how many units are produced per batch?)			
Is the product filterable through a 0.45µm membrane?			
Does the product contain any preservative or antibiotic substance? If so, its name, % or concentration?			
Does the product contain	1. protein or serum component?		
	2. polysaccharide eg dextran?		
Is the product (if powder) soluble in water?			
If not, is it soluble in any solvent? Please specify.			
If liquid, is it miscible with water?			

Does the product have an endotoxin specification limit? If so, please specify				
Check list		Yes	No	Details
Please specify the potency of the product.				
Please specify the Dose/Kg of body weight that would be administered in a single one hour period.				
Please specify whether the product is a parenteral or an intrathecal drug.				
Is the pH of the product between 6.0 to 8.0? If not, please specify.				
Has the product come into contact with the following during processing;	1. cellulosic material			
	2. yeast hydrolysate			
Is the product of biological origin?				
Is the product from a GMO (genetically modified organism)?				
Is it hazardous to operators? Is the MSDS available? (Please supply us with one).				

**Please specify the test in the special requirements below*

Any other special requirements (please specify):