



C. Control Article Submitted by the Sponsor:    Yes        No        N/A

1. Description:					
2. Batch/Code/Lot Identification (Circle One):				Expiration Date:	
3. Storage Conditions:	Ambient	4°C	-20°C	-70°C	Other:
4. Handling and Safety Precautions:					
5. Stability (As outlined in 21 CFR subpart F, Section 58.105):					
N/A					
Stability testing is in progress by the Sponsor.					
Stability Testing is complete and on file with the sponsor.					
6. Control Article has been sterilized prior to submittal:				Yes	No
Method of Sterilization: _____					
7. Disposition of Excess Control Material:	Discard / Destroy		Return to Sponsor		
8. Disposition of Used Control Material:	Discard / Destroy		Return to Sponsor		

D. Extraction Parameters

1. N/A			
2. Extracts to be used for testing:	0.9% NaCl	Cottonseed Oil	Alcohol/0.9%NaCl
	Polyethylene Glycol	Other:	
3. Extract Conditions:	121 ± 1°C for 1 hr ± 2 min	70 ± 2°C for 24 hrs. ± 15 min.	
	50 ± 2°C for 72 hrs ± 30 min	Other:	

E. Additional Comments:

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The undersigned assures the test facility that the information provided on this form is accurate and true. The undersigned confirms that this is a GLP designated study which should be listed on the test facility master schedule.

Sponsor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Title: \_\_\_\_\_

Phone#: \_\_\_\_\_ Fax#: \_\_\_\_\_