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BIOBUFFER SOLUTIONS TESTING PROGRAM

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1. SCOPE:

1.1. This procedure outlines the require testing for the following products that will be sold as BioBuffer Solutions: L-Cystine DiHCl.

2. PURPOSE:

2.1. The purpose of this procedure is to provide instructions for the required testing upon receipt of the products detailed in section 1.

3. RESPONSIBILITIES:

3.1. It is the responsibility of the Director of Laboratory Testing, or qualified designee for the implementation, control, training, and maintenance of this procedure.
3.2. It is the responsibility of the Laboratory Services staff to comply with the requirements of the is procedure.

4. REFERENCES:

4.1. BSI-ATM-0024, L-Cystine Dihydrochloride Testing Methods
4.2. BSI-FRM-0455, LCYS-4250 L-Cystine diHCl Bio Pharma Summary Sheet
4.3. BSI-FRM-1214, LCYS-4250 L-Cystine diHCl Bio Pharma Reduced Testing Summary Sheet
4.4. BSI-FRM-1051, Raw Material Evaluation Request Form- L-Cystine DiHCl
4.5. BSI-LST-0150, L-Cystine Dihydrochloride Stability Data Card
4.6. BSI-MEM-1176, L-Cystine Dihydrochloride [redacted] Raw Material Evaluation Result Summary
4.7. BSI-SOP-0099, Sampling Matrix

5. PROCEDURE:

5.1. L-Cystine DiHCl Testing Requirements:

5.1.1. A minimum of 3 batches received will require Raw Material Evaluation testing on the Composite Sample, Commercialized Code (LCYS-4250) testing on the Composite Sample and the Individual Uniformity Samples.
5.1.1.1. Individual Uniformity is only required on 1 batch received.

Table 1. Example of Testing Matrix Validation Batches

Batch Receipt #	Lot Number	Composite Sample testing to RM Evaluation Form	Composite Testing to Commercialized Code (LCYS-4250)	Uniformity Testing to Commercialized Code (LCYS-4250)
1	1	X	X	X
2	2	X	X	
3	3	X	X	

5.1.2. After the minimum of 3 batches are tested and released to the above criteria, a reduced testing plan will be introduced on all new bulk shipments.

5.1.3. Reduced Testing Plan will be as follows:
5.1.3.1. Only one batch from the shipment will be fully tested to the Commercialized Code (LCYS-4250).
5.1.3.2. The remaining batches will require Stability Indicating Analysis in accordance with BSI-FRM-1214, LCYS-4250 L-Cystine diHCl Bio Pharma Reduced Testing Summary Sheet.

5.1.3.3. L-Cystine DiHCl Stability Indicating Analysis are as follows:

Table 2. Stability Indicating Analysis	
Analyses	**Specification**
Appearance and Color	White to Slightly Yellow Crystalline Powder
Assay (Dried Basis)	98.0 – 102.0%
Chloride	22.2 – 23.5%
Identification (IR)	Passes Test
Loss on Drying (105°C)	≤ 1.0%
Solubility	Passes Test
Specific Rotation (Free Basis) @20°C	-225.0° to -210.0°

Table 3. Example of Reduced Testing Matrix after Validation Batches			
Bulk Receipt #	**Lot Number**	**Non-Reduced Testing (LCYS-4250)**	**Reduced Testing (LCYS-4250)**
1	1	X	
1	2		X
1	3		X
1	4		X
1	5		X
2	1	X	
2	2		X
2	3		X

5.2. Stability Program Requirements:

5.2.1. The first 3 Raw Material Evaluation batches will be placed in the BioSpectra Stability Program.

5.2.2. After the first 3 Raw Material Evaluation batches, 1 batch per year will be placed in the Stability Program, if received during that year.