BIOBUFFER SOLUTIONS

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

BioBuffer Solutions Testing Program

TABLE OF CONTENTS

1. SCOPE:

1.1. This procedure outlines the require testing for the following products that will be sold as BioBuffer Solutions: L-Cystine DiHCl, L-Arginine HCl, Bis Tris HCl, L-Glutamine, L-Histidine Monochloride Monohydrate.

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.
3.3. It is the responsibility of Quality Assurance personnel to comply with the requirements of the is procedure.

4. REFERENCES:

4.1. BSI-ATM-0024, L-Cystine Dihydrochloride Testing Methods
4.2. BSI-ATM-0114, L-Arginine HCl Testing Methods
4.3. BSI-FRM-0455, LCYS-4250 L-Cystine diHCl Bio Pharma Summary Sheet
4.4. BSI-FRM-0482, LARH-4220 L-Arginine HCl Bio Pharma Summary Sheet
4.5. BSI-LST-0009, Supplier, Manufacturer, and Service Provider List
4.6. BSI-RPT-0334, Stability Indicating Report: L-Cystine diHCl Bio Contract Grade
4.7. BSI-RPT-1551, Stability Indicating Report: L-Arginine HCl
4.8. BSI-SOP-0057, Supplier, Manufacturer, and Service Provider Qualification Master Plan
4.9. BSI-SOP-0099, Sampling Matrix

5. PROCEDURE:

5.1. Testing and Reporting Requirements:

5.1.1. A minimum of 3 batches received will require Raw Material Evaluation testing on the Composite Sample, Commercialized Code 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	Uniformity Testing to Commercialized Code
1	1	X	X	X
2	2	X	X	
3	3	X	X	

5.1.2. After successful uniformity and the minimum of 3 batch testing, reporting of results, and release of the raw material according to the criteria above, a reduced sampling plan will be introduced on all new bulk shipments.

5.1.2.1. Upon request, pre-shipment samples may be obtained from the Approved Supplier, provided they are accompanied with chain of custody information detailing the sampling. These samples may be utilized for analysis by outside service provider(s) with results reported on the CoA for the particular lot.

5.1.3. Results from the analyses performed on the composite sample will be reported on the CoA.

5.1.3.1. Pre-shipment sample testing results can be reported on the CoA for the following analyses (if applicable):

5.1.3.1.1. Microbial Content

5.1.3.1.2. Endotoxin

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.