BIOSPECTRA
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STABILITY INDICATING REPORT: DEXTRAN SULFATE 8000

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1. PURPOSE:

1.1. The purpose of this Report is to gather insight into which Quality Control (QC) analyses are stability indicating through assessment of results on chemically and physically stressed material.

1.2. To determine which tests are stability indicating for Dextran Sulfate 8000 when the product is stressed in extreme conditions.

1.2.1. The first developmental lot of Dextran Sulfate 8000 was stressed in the following ways:

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1.2.1.4. pH

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2. SCOPE:

2.1. This Report applies to the stability testing of BioSpectra manufactured Dextran Sulfate 8000.

3. RESPONSIBILITIES:

3.1. The Associate Director of Product Life Cycle is responsible for the control, implementation, training, and maintenance of this procedure.

3.2. The QC Analysts and/or qualified designee were responsible for performing the testing stated in this report and recording all results in current laboratory documentation.

3.3. The Stability Manager is responsible for incorporating the findings of this report into the stability program for the applicable material.

4. REFERENCES:

4.1. BSI-ATM-0094, Analytical Method for the Quantification of Sulfur by Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) in Dextran Sulfate
4.2. BSI-PRL-0676, Stability Indicating Protocol: Dextran Sulfate 8000
4.3. BSI-SOP-0090, Lambda 25 UV/Vis Operation and Calibration
4.4. BSI-SOP-0098, Balance SOP
4.5. BSI-SOP-0126, Laboratory Notebooks
4.6. BSI-SOP-0134, Pipette SOP
4.7. BSI-SOP-0244, VWR Gravity Convection Oven Operation and Calibration (Model Number 414005-106)
4.8. BSI-SOP-0255, XL200 pH/mV/Conductivity Meter SOP
4.9. BSI-SOP-0289, Stability Indication Protocol
4.10. BSI-SOP-0486, Viscometer SOP
4.11. BSI-SOP-0490, MCP 5300 Polarimeter SOP
4.12. Current USP/ NF
4.13. ICH Q1A

5. EQUIPMENT:

5.1. Accelerated Stability Chamber
5.2. Analytical Balance
5.3. Avio 500 ICP-OES
5.4. Calibrated Pipettes
5.5. Calibrated Timer
5.6. Desiccator
5.7. Hot Plate
5.8. Lambda 25 UV/Vis Spectrophotometer
5.9. Lux Meter
5.10. MCP 5300 Polarimeter
5.11. pH Probe
5.12. Temperature Monitored Refrigerator
5.13. Ubbelohde Viscometer
5.14. VWR Gravity Convection Oven or equivalent
5.15. XL200 pH/mV/Conductivity Meter or equivalent

6. REAGENTS:

6.1. **0.1M Barium Chloride:** Dissolve 2.4 g of barium chloride dihydrate in purified water and dilute with purified water to make 100 mL.
6.2. **1% Acrinol:** Dissolve 1.0 grams of Acrinol Monohydrate in purified water and dilute with purified water to make 100 mL.
6.3. **1.0M Sodium Chloride:** Transfer 58.44 g of sodium chloride to a 1000 mL volumetric flask, dissolve, and dilute to volume with purified water.
6.4. **2N Sodium Hydroxide:** Dissolve 8 g of Sodium Hydroxide in purified water to make 100 mL. Preserve in polyethylene bottles.
6.5. **30% Hydrogen Peroxide:** Purchased Commercially.
6.6. **50% Sodium Hydroxide:** Purchased Commercially.
6.7. **Acrinol Monohydrate:** Purchased Commercially.
6.8. **Anhydrous Sodium Sulfate:** Purchased Commercially.
6.9. **Anthrone Powder:** Purchased Commercially.
6.10. **Anthrone Solution:** Prepare immediately before use. Weigh 90 – 100 mg of anthrone powder into a beaker, add 50 mL of concentrated sulfuric acid, dissolve, and mix thoroughly.

6.11. **Barium Chloride Dihydrate:** Purchased Commercially.
6.12. **Barium Chloride TS (~0.5M):** Dissolve 30 g of barium chloride dihydrate in water to make 250 mL.
6.13. **Dextrose (D-Glucose) Certified Reference Standard (CRS):** Purchased Commercially.
6.14. **Glacial Acetic Acid:** Purchased Commercially.
6.15. **Hydrochloric Acid, concentrated:** Purchased Commercially.
6.16. **Hydrochloric Acid, Dilute (~10%):** Dilute 23.6 mL of concentrated hydrochloric acid with water to make 100 mL.
6.17. **Purified Water:** In-House or Purchased Commercially.
6.18. **Sodium Chloride:** Purchased Commercially.
6.19. **Sodium Hydroxide, pellets:** Purchased Commercially.
6.20. **Sulfate Standard Solution (0.2% SO_4^{2-} Solution):** Dissolve 0.296 g of anhydrous sodium sulfate in purified water and dilute with purified water to 100 mL.
6.21. **Sulfuric Acid, concentrated:** Purchased Commercially.

7. PROCEDURE:

7.1. Stress Procedures:

7.1.1. Control:

7.1.1.1. Refer to original testing results for Dextran Sulfate 8000 developmental lot DXSE-0123-00001. No stress applied to the material.

7.1.2. Thermal Stress:

7.1.2.1. Transferred 100.44 grams of the crystal to a suitable tray and evenly spread to increase exposure area.

7.1.2.2. Heated sample between 100-105°C for 13.3 hours to stress.

7.1.2.3. Froze sample for 13.5 hours after heat exposure.

7.1.2.4. Brought sample back to room temperature before analysis.

7.1.3. Acid Stress:

7.1.3.1. Applied 2.5 mL of concentrated hydrochloric acid per 100 g of sample; mixed the acidic mixture thoroughly in a suitable container.

7.1.3.2. Dried the sample using a well-ventilated tray and used a mortar and pestle to homogenize after drying. Note: HCl is very caustic and corrosive, use proper PPE while handling.

7.1.4. Basic Stress:

7.1.4.1. Applied 2.5 mL of 50% sodium hydroxide per 100 g of sample; mixed the basic mixture thoroughly in a suitable container.

7.1.4.2. Dried the sample using a well-ventilated tray and used a mortar and pestle to homogenize after drying. Note: NaOH is very caustic, use proper PPE while handling.

7.1.5. Oxidative Stress:

7.1.5.1. Applied 2.5 mL of 30% hydrogen peroxide per 100 g of sample. Mixed the mixture thoroughly and allowed to react in an open container or vessel.

7.1.5.2. Once reaction (if any) has ceased, transferred material to a well-ventilated tray, dried the sample and used a mortar and pestle to homogenize after drying. Note: Hydrogen peroxide is very reactive, read and understand the SDS before use and understand proper disposal and hazards associated with strong oxidizers.

7.1.6. Humidity/Hydrolytic Stress:

7.1.6.1. Transferred material to a suitable tray and evenly spread to increase exposure area.

7.1.6.2. Contacted Stability management to place the material, covered loosely, into the accelerated stability chamber and record conditions.

7.1.6.3. Allowed sample 27.07 hours exposure to accelerated conditions before removingfor testing.

7.1.7. Photolytic Stress:

Exposed sample to approximately 1.4 million lux hours of light.

8. ANALYTICAL PROCEDURES:

8.1. APPEARANCE

8.1.1. Place 10 grams of sample in a clean, dry, glass beaker.
8.1.2. In an area with sufficient lighting, view the sample from all sides.
8.1.3. The sample should be white to light yellow in color and characteristic of a powder.

Sample ID	Result (White to light yellow powder)	Disposition
Control	White powder	Stability Indicating
Thermal Stress	White to light yellow powder	
Acid Stress	White to light yellow powder; orange crystal present	
Base Stress	White to light yellow powder; brown crystal present	
Oxidative Stress	White to light yellow powder	
Humidity/Hydrolytic Stress	White to light yellow powder	
Photolytic Stress	White to light yellow powder	

8.2. CLARITY (20% SOLUTION AT 360nm)

8.2.1. Prepare a 20% solution of the specified sample.
8.2.1.1. Accurately weigh 5.0 grams of sample.
8.2.1.2. Transfer accurately weighed sample to a graduated cylinder and dilute to 25 mL with purified water.
8.2.1.3. Swirl to dissolve completely.
8.2.2. Refer to Lambda 25 UV/Vis Operation and Calibration SOP to measure the absorbance of the sample with a 1cm pathlength at 360 nm.

Sample ID	Result (NMT 0.9 OD Unit)	Disposition
Control	0.1439	Stability Indicating
Thermal Stress	0.1141	
Acid Stress	0.0856	
Base Stress	2.8228	
Oxidative Stress	0.0858	
Humidity/Hydrolytic Stress	0.1220	
Photolytic Stress	0.0975	

8.3. FREE INORGANIC SULFATE

8.3.1. Standard Preparation:
8.3.1.1. Pipette 5 mL of Sulfate Standard Solution (0.2% SO_4^{2-} Solution) into a test tube.
8.3.2. Sample Preparation:
8.3.2.1. 1% Dextran Sulfate Sample Stock Solution
8.3.2.1.1. Weigh out 1.0 grams of sample, transfer to a 100 mL volumetric flask, dissolve in purified water, dilute to volume with purified water, and mix well.
8.3.2.1.2. Note: A 1% Dextran Sulfate Sample Solution is also used in the pH test and the dextran sulfate identification tests. A stock solution may be prepared and used in any of these tests as long as it is treated as expiring in 48 hours.
8.3.2.2. Pipette 5 mL of 1% Dextran Sulfate Sample Stock Solution into a test tube.

8.3.3. Procedure:

8.3.3.1. To the standard and samples, add 0.5 mL of hydrochloric acid, dilute (~10%) and 1 mL of 0.1M Barium Chloride.

8.3.3.2. Mix well and allow to stand at room temperature for 15 minutes.

8.3.3.3. If the turbidity of the sample preparation does not exceed that produced by the standard, the sample passes test.

Sample ID	Result (NMT 0.2%)	Disposition
Control	<0.2%	Not Stability Indicating
Thermal Stress	<0.2%	
Acid Stress	<0.2%	
Base Stress	<0.2%	
Oxidative Stress	<0.2%	
Humidity/Hydrolytic Stress	<0.2%	
Photolytic Stress	<0.2%	

8.4. GLUCOSE CONTENT

8.4.1. Sample Preparation:

8.4.1.1. Sample Stock Solution (5 mg/mL Dextran Sulfate): Weigh out 1.0 grams of Dextran Sulfate sample into a 200 mL volumetric flask. Fill ~3/4 full with purified water and swirl to dissolve. Fill to volume with purified water and mix by inversion.

8.4.1.2. Sample Test Solution (0.05 mg/mL Dextran Sulfate): Pipette 1.0 mL of Sample Stock Solution into a 100 mL volumetric flask, fill to volume with purified water, and mix by inversion.

8.4.2. Standard Preparation:

8.4.2.1. Glucose Standard Stock Solution (440 µg/mL Glucose): Weigh out 110 mg equivalent of Dextrose (D-Glucose) CRS into a 250 mL volumetric flask. Fill ~3/4 full with purified water and swirl to dissolve. Fill to volume with purified water and mix by inversion. Refer to the Dextrose (D-Glucose) CRS Certificate of Analysis values for purity corrections:

$$Dextrose\ CRS\ Weight\ (mg) = \frac{\left(\frac{0.440\ mg}{mL}\right) \times \left(Final\ Volume\ (mL)\right)}{Dextrose\ CRS\ Purity\ \left(\frac{mg}{mg}\right)}$$

8.4.2.2. Calibration Standards: Per the "Glucose Calibration Standard Preparations" Table, pipette Glucose Standard Stock Solution into a 100mL volumetric flask, fill to volume with purified water, and mix by inversion.

Glucose Calibration Standard Preparations			
Standard ID	**Glucose Concentration (µg/mL)**	**Glucose Standard Stock Solution Amount (mL)**	**Final Volume (mL)**
1	13.2 µg/mL	3.0 mL	100 mL
2	33.0 µg/mL	7.5 mL	100 mL
3	52.8 µg/mL	12.0 mL	100 mL

8.4.3. Procedure:

8.4.3.1. Pipetted 0.50 mL of each glucose calibration standard, sample test solution, and a blank (purified water) into microcentrifuge tubes.

8.4.3.2. Anthrone Solution Preparation:

8.4.3.2.1. Note: Prepare immediately before use.

8.4.3.2.2. Weigh 90 – 100 mg of Anthrone Powder into a beaker. Add 50 mL of concentrated sulfuric acid, dissolve, and mix thoroughly.

8.4.3.3. Slowly and carefully add 1.0 mL of Anthrone Solution into each of the microcentrifuge tubes, mix, and immediately place the microcentrifuge tubes in a hot bath for 9 minutes.

8.4.3.3.1. Note: Mixing of the samples and anthrone solution is extremely exothermic.

8.4.3.4. After 9 minutes, remove the microcentrifuge tubes from the hot bath and place on ice or in a temperature monitored refrigerator for 5 minutes.

8.4.3.5. After 5 minutes remove the microcentrifuge tubes from ice or a temperature monitored refrigerator and allow to come to room temperature.

8.4.4. Quantitative Reporting:

8.4.4.1. Calibrate the UV/Vis Spectrophotometer by ensuring that the Blank is assigned as "Blank," the Calibration Standard IDs 1 through 3 are assigned as "Standard," and all samples are assigned as "Sample" in the "Type" column on the "Sample Info" window of the PerkinElmer UV WinLab software.

8.4.4.2. Input the Calibration Standards concentrations in parts per million (ppm) into the "Concentration" column on the "Sample Info" window of the PerkinElmer UV WinLab software.

8.4.4.3. Measure the absorbance of the standards and samples at 625 nm as per the Lambda 25 UV/Vis Operation and Calibration SOP.

8.4.5. Result Reporting:

8.4.5.1. System Suitability

8.4.5.1.1. The Calibration Coefficient (r^2) of the calibration curve must be NLT 0.99.

8.4.5.2. The Glucose Content is determined using the following equations:

8.4.5.2.1. Dextran Sulfate Concentration (ppm) on the Dried Basis:

$$Dextran\ Sulfate\ Concentration\ (Dried\ Basis)(ppm) = \frac{Sample\ Weight\ (g) \times \left(100 - LOD\ (\%)\right)}{2}$$

8.4.5.2.2. Glucose Content (%w/w):

$$Glucose\ Content\ \left(\%\frac{w}{w}\right) = \frac{Glucose\ Concentration\ (ppm)}{Dextran\ Sulfate\ Concentration\ (Dried\ Basis)(ppm)} \times 100$$

Sample ID	Result (35%-48%)	Disposition
Control	39.4502%	Not Stability Indicating
Thermal Stress	38.4159%	
Acid Stress	38.2227%	
Base Stress	37.8871%	
Oxidative Stress	38.3377%	
Humidity/Hydrolytic Stress	37.5509%	
Photolytic Stress	39.0816%	

8.5. **IDENTIFICATION TEST**

8.5.1. **Note:** The Identification Test consists of three separate tests: Acrinol, Sulphate, and Dextran Identification. All three separate identification tests must pass to report the Identification Test as passes.

8.5.2. **Acrinol Identification:**

8.5.2.1. Sample Preparation (5% Dextran Sulfate Sample Solution):

8.5.2.1.1. Weigh out 5.0 grams of sample, transfer to a 100 mL volumetric flask, dissolve in purified water, dilute to volume with purified water, and mix well.

8.5.2.2. Procedure:

8.5.2.2.1. Into two (2) clean test tubes add 1.0 mL of 1% Acrinol, 5.0mL of 5% Dextran Sulfate Sample Solution, and mix well.

8.5.2.2.2. A yellow flocculent precipitate should form in both test tubes.

8.5.2.2.3. To one test tube add a few drops of hydrochloric acid, dilute (~10%) and mix well.

8.5.2.2.4. To the other test tube, add a few drops of 2N sodium hydroxide and mix well.

8.5.2.2.5. The yellow flocculent precipitate should be almost insoluble in either acid or alkali to report as passes test.

Sample ID	Result (Pass)	Disposition
Control	Pass	Not Stability Indicating Note: Recommended to be included with stability test program for identification confirmation of each pull.
Thermal Stress	Pass	
Acid Stress	Pass	
Base Stress	Pass	
Oxidative Stress	Pass	
Humidity/Hydrolytic Stress	Pass	
Photolytic Stress	Pass	

8.5.3. **Dextran Identification:**

8.5.3.1. Sample Preparation (1% Dextran Sulfate Sample Solution):

8.5.3.1.1. Weigh out 1.0 grams of sample, transfer to a 100 mL volumetric flask, dissolve in purified water, dilute to volume with purified water, and mix well.

8.5.3.2. Anthrone Solution Preparation:

8.5.3.2.1. Note: Prepare immediately before use.

8.5.3.2.2. Weigh 90 – 100 mg of Anthrone Powder into a 100 mL beaker. Add 50 mL of concentrated sulfuric acid, dissolve, and mix thoroughly.

8.5.3.3. Procedure:

8.5.3.3.1. Into a test tube, pipette 1.0 mL of 1% Dextran Sulfate Solution and 5.0 mL of Anthrone Solution and mix well.

8.5.3.3.2. Heat the tube in a boiling water bath for 10 minutes.

8.5.3.3.3. The solution should turn green then a blue-green color.

8.5.3.3.4. To the test tube add a few drops of Glacial Acetic Acid.

8.5.3.3.5. The blue-green color does not change with the addition of Glacial Acetic acid to report as passes test.

Sample ID	Result (Pass)	Disposition
Control	Pass	Not Stability Indicating Note: Recommended to be included with stability test program for identification confirmation of each pull.
Thermal Stress	Pass	
Acid Stress	Pass	
Base Stress	Pass	
Oxidative Stress	Pass	
Humidity/Hydrolytic Stress	Pass	
Photolytic Stress	Pass	

8.5.4. **Sulphate Identification:**

8.5.4.1. Pipette 10 mL of purified water into a beaker containing a stir bar.

8.5.4.2. Slowly and with caution add 10 mL of concentrated hydrochloric acid to the beaker.

8.5.4.3. Place the beaker on a hot plate and stir using the magnetic stir bar.

8.5.4.4. Weigh out 1.00 grams of sample and transfer to the beaker.

8.5.4.5. Heat the beaker to boiling with continuous mixing for two (2) minutes then allow to cool to room temperature.

8.5.4.6. Add a few drops of barium chloride TS (~0.5M).

8.5.4.7. A heavy precipitate of barium sulfate should form to report as passes test.

Sample ID	Result (Pass)	Disposition
Control	Pass	Not Stability Indicating Note: Recommended to be included with stability test program for identification confirmation of each pull.
Thermal Stress	Pass	
Acid Stress	Pass	
Base Stress	Pass	
Oxidative Stress	Pass	
Humidity/Hydrolytic Stress	Pass	
Photolytic Stress	Pass	

8.6. **LOSS ON DRYING**

8.6.1. Dry an LOD vial in the oven at 105 ± 2°C for 30 minutes.

8.6.2. Cool for 15 minutes in a desiccator, weigh the LOD vial, and record results.

8.6.3. If the substance to be tested is in the form of large crystals, reduce the particle size to about 2 mm by quickly crushing before weighing.

8.6.4. Transfer 1.0 – 1.5 grams of the sample to the LOD vial and accurately weigh the vial and contents. By gentle, sidewise shaking, distribute the sample as evenly as possible in the LOD vial to a depth of about 5mm.

8.6.5. Place the LOD vial containing the sample into the oven and dry at 105 ± 2°C for 5 hours.

8.6.6. Remove LOD vial from the oven and allow to cool in the desiccator for 15 minutes.

8.6.7. Reweigh the LOD vial and sample.

8.6.8. Calculate the %LOD as follows:

$$\%LOD = \frac{Inital\ Sample\ Weight\ (g) - Final\ Sample\ Weight\ (g)}{Initial\ Sample\ Weight\ (g)} \times 100$$

Sample ID	Result (NMT 10%)	Disposition
Control	7.54%	Stability Indicating
Thermal Stress	1.35%	
Acid Stress	8.85%	
Base Stress	7.76%	
Oxidative Stress	8.74%	
Humidity/Hydrolytic Stress	11.02%	
Photolytic Stress	8.64%	

8.7. **pH (1% SOLUTION)**

8.7.1. Weigh out 1.0 grams of sample, transfer to a 100 mL volumetric flask, dissolve in purified water, dilute to volume with purified water, and mix well.

8.7.2. Follow the appropriate SOP for pH calibration and measurement.

Sample ID	Result (5.0 – 7.5)	Disposition
Control	6.87 @ 23.0°C	Stability Indicating
Thermal Stress	6.75 @ 23.2°C	
Acid Stress	3.01 @ 23.2°C	
Base Stress	7.57 @ 23.2°C	
Oxidative Stress	6.85 @ 23.1°C	
Humidity/Hydrolytic Stress	6.90 @ 23.2°C	
Photolytic Stress	6.89 @ 23.2°C	

8.8. **SPECIFIC ROTATION $[\alpha]_D^{20}$**

8.8.1. Sample Preparation (5% Dextran Sulfate Solution):

8.8.1.1. Transfer 5.0 grams of sample to a 100 mL volumetric flask, dissolve, and dilute to volume with purified water. Mix thoroughly.

8.8.2. Optical Zero Reference: Purified Water.

8.8.3. Analysis: Perform at 20°C.

8.8.4. Refer to the MCP 5300 Polarimeter SOP for instrument analysis.

Sample ID	Result (+75° to +105°)	Disposition
Control	+87.19°	Not Stability Indicating
Thermal Stress	+87.04°	
Acid Stress	+84.97°	
Base Stress	+86.27°	
Oxidative Stress	+86.77°	
Humidity/Hydrolytic Stress	+85.34°	
Photolytic Stress	+86.04°	

8.9. **SPECIFIC VISCOSITY (IN 1.0M NaCl AT 25°C)**

8.9.1. Note: Solutions may be scaled as needed.

8.9.2. 1.0M Sodium Chloride Preparation:

8.9.2.1. Transfer 58.44 grams of sodium chloride to a 1000 mL volumetric flask, dissolve, and dilute to volume with purified water.

8.9.3. Sample Preparation (1% Dextran Sulfate in 1.0M Sodium Chloride):

8.9.3.1. Using an analytical balance, weigh 1.0 grams of sample, transfer to a 100 mL volumetric flask, dissolve, and dilute to volume with 1.0M sodium chloride.

8.9.4. Analysis:
8.9.4.1. Perform analysis at 25°C.
8.9.4.2. Refer to the Viscometer SOP for manual viscometer analysis, only efflux time is required for result reporting.
8.9.4.3. Calculate the Specific Viscosity using the following calculation:

$$Specific\ Viscosity = \frac{\left(\left(\frac{Efflux\ Time\ of\ Sample\ (seconds)}{Efflux\ Time\ of\ 1.0M\ NaCl\ (seconds)}\right) - 1\right)}{Sample\ Weight\ (g) - \left(Sample\ Weight\ (g) \times \left(\frac{LOD\ (\%)}{100}\right)\right)}$$

Sample ID	Result (0.018 – 0.032)	Disposition
Control	0.025	Not Stability Indicating
Thermal Stress	0.028	
Acid Stress	0.028	
Base Stress	0.029	
Oxidative Stress	0.024	
Humidity/Hydrolytic Stress	0.024	
Photolytic Stress	0.028	

8.10. **TOTAL SULPHUR CONTENT**
8.10.1. Refer to Analytical Method for the Quantification of Sulfur by Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) in Dextran Sulfate (DCN: BSI-ATM-0094), for sample preparation and analysis.

Sample ID	Result (17.0-20.0%)	Disposition
Control	18.36%	Not Stability Indicating
Thermal Stress	17.75%	
Acid Stress	17.83%	
Base Stress	17.22%	
Oxidative Stress	17.95%	
Humidity/Hydrolytic Stress	17.18%	
Photolytic Stress	17.46%	

9. CONCLUSION:

9.1. The analyses recommended for the Dextran Sulfate 8000 stability test program are as follows:
9.1.1. Appearance
9.1.2. Clarity of Solution
9.1.3. Loss on Drying
9.1.4. pH (1% Solution)
9.1.5. Identity, not stability indicating but must be performed on stability
9.2. Additional analyses for Dextran Sulfate 8000 stability test program are as follows:
9.2.1. Total Bioburden