BIOSPECTRA
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DEGRADATION AND IMPURITY PROFILE REPORT: MOPS – S01

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1. PURPOSE AND SCOPE:

1.1. The impurity profiling of MOPS was intended to identify and possibly quantify impurities found in the MOPS product manufactured and purified at BioSpectra.

1.1.1. In the case where an impurity was found, a limit was set to the maximum allowable for establishing as pure of a product as possible. In the case where a limit could not be set, a procedure was written and followed, to identify if the possible impurity was present or not (i.e. an identity test, which is qualitative.)

1.1.2. The profiling results and data allowed BioSpectra to further understand the purity and characteristics of MOPS.

1.1.3. The four stages of MOPS that were tested are Raw Material, Mother Liquor, Wet Crystals and the Finished Goods.

1.1.4. The tests to determine the presence of impurities and degradation products were as follows:

1.1.4.1. Appearance and Color

1.1.4.1.1. Raw Material and Finished Goods First Batch Beginning Drum

1.1.4.2. Absorbance Scan 1M:

1.1.4.2.1. Raw Material and Finished Goods First Batch Beginning Drum

1.1.4.3. Absorbance 1M:

1.1.4.3.1. Raw Material and Finished Goods First Batch Beginning Drum

1.1.4.4. Assay

1.1.4.4.1. All four stages

1.1.4.5. Identification (IR)

1.1.4.5.1. All four stages.

1.1.4.6. pH of a 1% Solution

1.1.4.6.1. Raw Material and Finished Goods First Batch Beginning Drum

1.1.4.7. Loss on Drying

1.1.4.7.1. Raw Material and Finished Goods First Batch Beginning Drum.

1.1.4.8. Elemental Impurities with addition of Iron

1.1.4.8.1. All four stages.

2. RESPONSIBILITIES:

2.1. The Laboratory Manager is responsible for control, training, implementation and maintenance of the procedure.

2.2. The Laboratory Systems Supervisor or designee is responsible for ensuring the completion of the Degradation and Impurity Profiling Report.

2.3. The Laboratory Analysts are responsible for performing the testing stated in the Protocol and recording all results in the appropriate laboratory documentation.

3. REFERENCES:

3.1. BSI-ATM-0008, MOPS Testing Methods

3.2. BSI-ATM-0073, Analytical Method of Analysis: Guanidine Thiocyanate, MOPS, and Urea via ICP-MS

3.3. BSI-PRL-0196, Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade

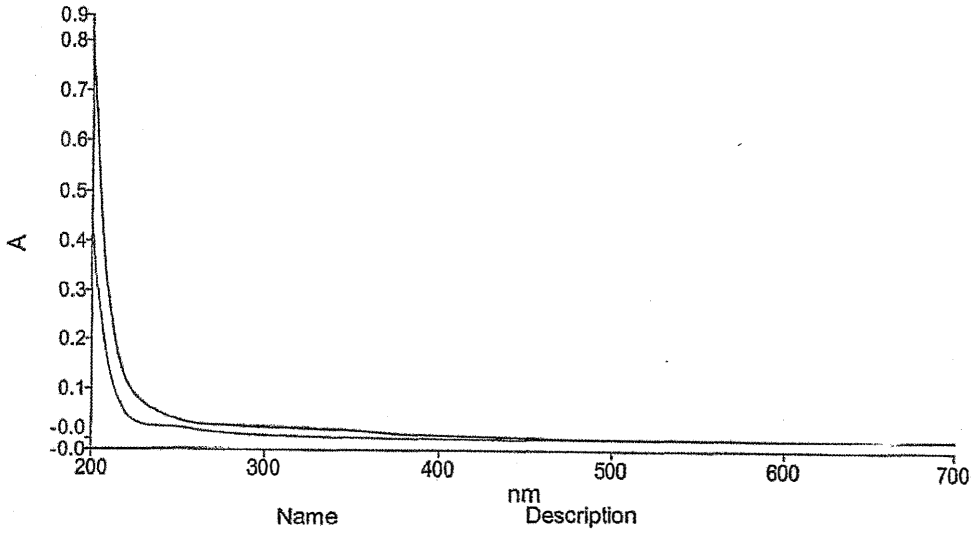
3.4. BSI-PRL-0525, MOPS Bio Excipient Grade S01, Process Validation Protocol

3.5. BSI-SOP-0102, Degradation and Impurity Profiling SOP

4. RESULTS:

4.1. ABSORBANCE SCAN (1M) :

4.1.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Absorbance Scan (1M) analysis are detailed in the image below.



	Sample ID	Description
	MOPS-0222-00075-PV Drum 1.Sample	
	RMAT-0122-0033.Sample	
	RMAT-0122-0034.Sample	

4.1.2. No observable peaks were present in the finished good or raw materials.

4.2. ABSORBANCE (1M) :

4.2.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Absorbance (1M) analysis are detailed in the table below.

4.2.2. The absorptivity of the finished goods was less than that of the raw materials.

TABLE 1: ABSORBANCE (1M)

Lot Number	Stage of Material	Abs. @ 250 nm	Abs. @ 260 nm	Abs. @ 280 nm
RMAT-0122-0033	Raw Material	0.0343	0.0280	0.0259
RMAT-0122-0034		0.0300	0.0243	0.0217
MOPS-0222-00075-PV Beginning Drum	Finished Goods	0.0091	0.0069	0.0050

4.3. **APPEARANCE AND COLOR:**

4.3.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Appearance and Color analysis are detailed in the table below.

TABLE 2: APPEARANCE AND COLOR

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	White/Powder
RMAT-0122-0034			White/Powder
MOPS-0222-00075-PV Beginning Drum	Finished Goods	White/Crystals	White/Crystals

4.4. **ASSAY:**

4.4.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Assay analysis are detailed in the table below.

TABLE 3: ASSAY

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	99.73%
RMAT-0122-0034			100.15%
PMAT-0222-00460-PD	Mother Liquor		59.37%
MOPS-0222-00075-PV First Basket, Bottom	Wet Crystal		91.45%
MOPS-0222-00075-PV Beginning Drum	Finished Goods	99.5% min.	100.4%

4.5. **IDENTIFICATION (IR):**

4.5.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Identification (IR) analysis are detailed in the table below.

TABLE 4: IDENTIFICATION (IR)

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	0.991803
RMAT-0122-0034			0.997697
PMAT-0222-00460-PD	Mother Liquor		0.956851
MOPS-0222-00075-PV First Basket, Bottom	Wet Crystal		0.562942
MOPS-0222-00075-PV Beginning Drum	Finished Goods	Passes Test	Passes Test (0.996054)

4.6. **PH OF A 1% SOLUTION** :

4.6.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of pH of a 1% Solution analysis are detailed in the table below.

TABLE 5: pH OF A 1% SOLUTION

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	4.25 @ 23.0°C
RMAT-0122-0034			4.36 @ 23.1°C
MOPS-0222-00075-PV Beginning Drum	Finished Goods	3.0-4.5	4.3 @ 23.0°C

4.7. **LOSS ON DRYING** :

4.7.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Loss on Drying analysis are detailed in the table below.

TABLE 6: LOSS ON DRYING

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	0.2506%
RMAT-0122-0034			0.4307%
MOPS-0222-00075-PV Beginning Drum	Finished Goods	1.0% max.	<1.0%

4.8. **ELEMENTAL IMPURITIES WITH ADDITON OF FE** :

4.8.1. Refer to Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade DCN: BSI-PRL-0196 for sample preparation and analysis. The results of Elemental Impurities with Addition of Fe analysis are detailed in the table below.

TABLE 7: ELEMENTAL IMPURITIES WITH ADDITION OF FE

Lot Number	Stage of Material	Specification	Result
RMAT-0122-0033	Raw Material	Monitor	Refer to Elemental Impurity Assessment: MOPS Suite 1 Process Validation DCN: BSI-RPT-1135
RMAT-0122-0034			
PMAT-0222-00460-PD	Mother Liquor		
MOPS-0222-00075-PV First Basket, Bottom	Wet Crystal		
MOPS-0222-00075-PV Beginning Drum	Finished Goods	As: ≤5 ppm Cu: ≤5 ppm Fe: ≤5 ppm Pb: ≤5 ppm	

5. CONCLUSION:

5.1. All samples met the specifications for the required analyses as dictated in the Degradation and Impurity Profile Protocol: MOPS Bio Excipient Grade.

5.2. It can be concluded that there are no additional identifiable impurities present in the MOPS material at any stage of the process at this time.