BIOSPECTRA

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Date	Time	Group	Name
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10-Aug-2021	09:05:38 PM	EDITOR	Meissner, Dora

BioSpectra Validation External Report

Validation Report for the manufacture of:

SODIUM DECANOATE

To be manufactured as the following codes:

NDEC-3200 THROUGH NDEC-32XX

To be manufactured at:

BIOSPECTRA, INC., 100 MAJESTIC WAY BANGOR, PENNSYLVANIA, 18013

In compliance with the standards of:

ICH Q7 GOOD MANUFACTURING PRACTICE GUIDE

Manufactured to be suitable for use as:

EXCIPIENT

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1. INTRODUCTION

The Validation of a manufacturing process used to produce Excipients is a requirement under ICH Q7 Good Manufacturing Practice Guide. This validation (considered a revalidation) protocol describes the process as performed using, Process Suite E06 of Zone E of the Bangor, PA facility. This process Suite is intended to manufacture excipients in accordance with ICH Q7. The FDA defines validation, specifically process validation as:

"The collection and evaluation of data, from the process design state through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product."

This Sodium Decanoate Validation Study was a concurrent validation to ensure that the Sodium Decanoate process conforms to the pre-established critical process parameters associated with the scale up of the process. This concurrent validation study allows for the release of the validation batch for commercial distribution based on approval of the executed batch record and documented evidence that the batch conforms to the finished goods specifications before release. This validation required three batches of Sodium Decanoate to be manufactured.

2. OBJECTIVE

The objective of this External Validation Report is to verify and assure that the manufacturing process for Sodium Decanoate consistently produces material that meets a set of pre-determined specifications. This validation was performed due to process suite change to increase batch capacity.

This validation included three batches of Sodium Decanoate, manufactured according to the current revision of the Batch Record. This validation report will summarize the manufacture of each batch within the validation study. As stated in the protocol, representative samples were submitted to the QC Laboratory and were tested against Finished Good specifications. This was conducted to verify that the process is capable of consistently producing material that meets Finished Good Specifications.

3. SCOPE:

This Report applies to each validation batch of Sodium Decanoate, Bio Excipient Grade, within this validation study. This batch process includes the following process steps: batch solution creation, purification, spray drying, tray drying (as needed), packaging and testing of the finished good. Specifications and approval requirements for all Raw Materials (RM) and components have been created; therefore, these RM and components are not covered by this Report except that only approved RM and components were used.

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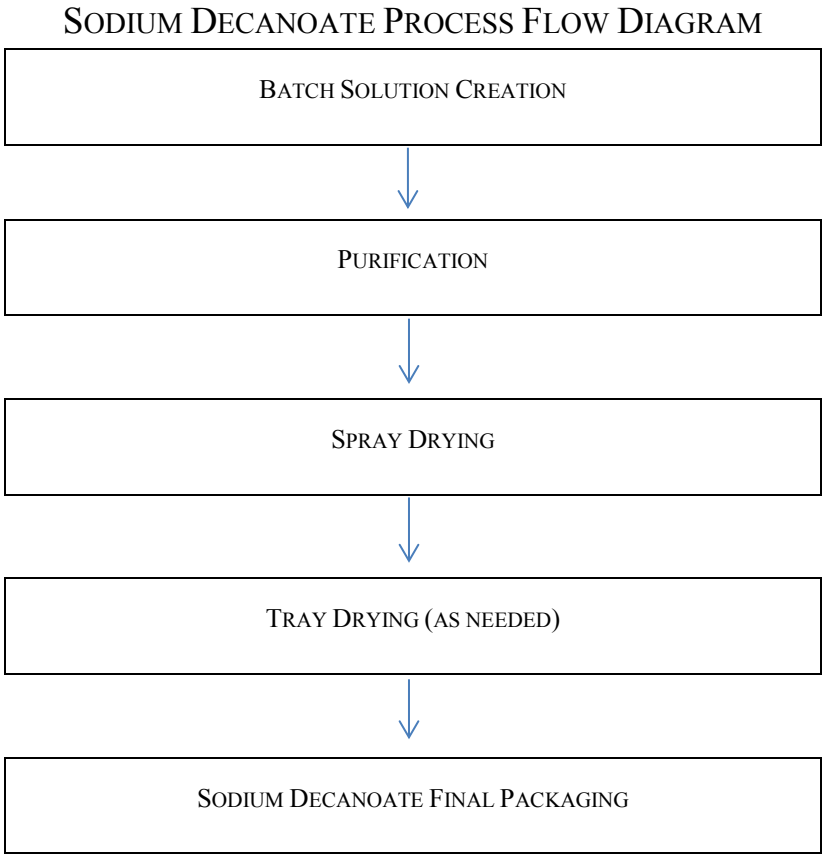
4. EXECUTIVE SUMMARY

The Validation Study for Sodium Decanoate was performed due to change control referenced as BCC21-15. This change was approved for the process scale-up and move from N05 to E06. The process steps remained the same except for the scale up activities and equipment used. This information is detailed in the supplied change notification and approved change control form.

The Sodium Decanoate manufacturing process is a manufacturing/purification process with Critical Process Parameters as detailed in the Validation Protocol. The CPP were developed based on the FMEA analysis conducted for the process and were found to be in accordance with BioSpectra's Manufacturing Process Validation Master Plan. The utilities and process used in the manufacture of this product have been qualified in accordance with BioSpectra's Equipment Qualification Master Plan. The manufacturing of each batch for this validation study was deemed successful and these batches will be released in accordance with the Validation plan and the approval of all related manufacturing and Quality Control documentation.

5. PROCESS FLOW DIAGRAM



6. MANUFACTURING OBSERVATIONS

The Sodium Decanoate batches that were manufactured in accordance with the current Sodium Decanoate Bio Excipient Grade Batch Record DCN:21-001782 v.1.0 and have met the requirements. The manufacturing observations for all validation batches are listed in Table 1 below.

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TABLE 1: MANUFACTURING OBSERVATION FOR VALIDATION BATCHES

Process Step/Additional Analysis	Acceptance Criteria	Validation Batch 1: NDEC-0121-0133-PV Start Date: 3/23/21 End Date: 4/11/21	Validation Batch 2: NDEC-0121-00001-PV Start Date: 4/12/21 End Date: 5/1/21	Validation Batch 3: NDEC-0121-00002-PV Start Date: 5/4/21 End Date: 5/28/21
Batch Creation	Charge material to build solution of required concentration for Purification	Material charged to build desired solution concentration and prepared for purification	Material charged to build desired solution concentration and prepared for purification	Material charged to build desired solution concentration and prepared for purification
Purification	Purify using 3-stage filtration	3-stage purification met requirements	3-stage purification met requirements	3-stage purification met requirements
Spray Drying	Meet the Inlet Temperature, Pump Feed Rate and Air Pressure requirements	Met Requirements for Validation	Met Requirements for Validation	Met Requirements for Validation
Tray Drying (if needed)	Tray drying as needed. Time: Monitor	Tray Drying not Required	Tray Drying not Required	Tray Drying not Required
In-process Moisture	Manufacturing: MF-50 Moisture balance: 1.5-2.5% QC Karl Fischer: 1.5-3.0%	MF-50: 2.05% Karl Fischer: 2.17%	MF-50: 2.00% KF: 2.21%	MF-50: 1.90% KF: 1.95%
Yield	Final Batch Yield Monitor	34.8 kgs were manufactured	40.1 kgs were manufactured	35.0 kgs were manufactured

7. ANALYSIS

The validation batches for Sodium Decanoate met the analytical requirements associated with the validation Critical Quality Attributes (CQA) and the Product Code, Historic Code/Current Code: ND3220/NDEC-3220. The results can be found in Table 2 and Table 3.

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TABLE 2: ANALYTICAL RESULTS FOR THE VALIDATION CRITICAL QUALITY ATTRIBUTES

CQA	Specification	NDEC-0121-0133-PV	NDEC-0121-00001-PV	NDEC-0121-00002-PV
Assay	97.0% to 103.0%	101.1%	99.4%	99.8%
Identification (IR)	Passes Test	Passes Test	Passes test	Passes Test
Loss on Drying	3.0% maximum	2.6%	2.3%	2.2%
pH (10%)	9.0 to 11.0	9.9 @ 24.3°C	9.9 @ 26.6°C	9.9 @ 24.9°C
Single Impurities (GC)	< 1.0%	0.1%	0.1%	0.1%
Water (KF)	1.5% to 3.0%	2.6%	2.3%	2.4%

TABLE 3: ANALYTICAL OBSERVATIONS FOR HISTORIC CODE/CURRENT CODE: ND3220/NDEC-3220

Finished Goods Analysis	Specification NDEC-3220	Validation Batch 1: NDEC-0121-0133-PV	Validation Batch 2: NDEC-0121-00001-PV	Validation Batch 3: NDEC-0121-00002-PV
		Manufacturing Date:	Manufacturing Date:	Manufacturing Date:
		3/23/21-4/11/21	4/12/21-5/1/21	5/4/21-5/28/21
Appearance	White to off white powder	White to Off-White powder	White to Off-White powder	White to Off-White powder
Assay (Dried Basis)	97.0%-103.0%	101.1%	99.4%	99.8%
Identification (IR)	Matches the Reference Standard	Matches the Reference Standards	Matches the Reference Standards	Matches the Reference Standards
Single Impurities (GC)	≤ 1.0%	0.1%	0.1%	0.1%
Loss on Drying	3.0% max.	2.6%	2.3%	2.2%
pH (10%)	9.0-11.0	9.9	9.9	9.9
Sodium	Passes Test	Passes Test	Passes Test	Passes Test
Solubility in Water	Passes Test	Passes Test	Passes Test	Passes Test
Water (KF)	1.5%-3.0%	2.6%	2.3%	2.4%

8. ADDITIONAL INFORMATION

8.1. Degradation and Impurity Profile

8.1.1. A Degradation and Impurity profile is being performed for this validation.

8.2. Stability Study

8.2.1. The Stability Analysis for Sodium Decanoate consists of an evaluation of the following analyses detailed in Table 4. These analyses were selected based on a combination finished goods requirements and Stability Indicating Protocol. The analyses listed below will be performed for each validation batch and 1 batch per year manufactured. Each

batch placed on the Long-Term Stability Program will undergo stability analysis at intervals 0, 3, 6, 9, 12, 18, 24, 36, 48, and 60-month.

TABLE 4: STABILITY ANALYSIS

Analysis	Specification
Appearance	White to off-white powder
Assay (Dried Basis)	97.0-103.0%
Identification (IR)	Passes Test
Loss on Drying (LOD)	3.0% max
Single Impurities (GC)	<1.0%
Solubility in Water	Passes Test
Water (Karl Fisher)	1.5-3.0%

9. CONCLUSION

BioSpectra has manufactured and validated the Sodium Decanoate, Historic Code/Current Code: ND3220/NDEC-3220 to be compliant with key compliance grades up to and including the Bio Excipient grade. This Bio Excipient Grade classification requires that the excipient be manufactured in accordance with ICH Q7 GMP guidelines to be suitable for use as a GMP manufactured Excipient. The results obtained during this validation study and subsequent analysis provide evidence that the Sodium Decanoate manufactured using the approved process will consistently meet the approved specifications for this product number. The utilities and process used in the manufacture of this product have been qualified in accordance with BioSpectra's Equipment Qualification Master Plan. The results reported from the validation batches of Sodium Decanoate for this Validation Study provided the evidence necessary to confirm that the approved change for process scale up and process suite change has not impacted the quality and physical characteristics of Sodium Decanoate. The Sodium Decanoate manufacturing process, using Process Suite E06, can be considered an approved, validated process capable of consistently producing Bio Excipient Grade material that meets Finished Good Specifications, NDEC-3220.

All Raw Materials used for the processing of Sodium Decanoate were approved before use in accordance with RM specifications. The Validation samples of Sodium Decanoate were placed into Long-Term Stability and will be reported on annually. The Stability Study does not impact the current retest date or previous stability studies.