

**CBER DMPQ CMC/Facility BLA Review Memorandum**

**BLA STN 125720/0**

**valoctocogene roxaparvovec**

**Brad Dworak, Ph.D., Reviewer, MRB1/DMPQ**

1. **BLA#:** STN 125720/0

2. **APPLICANT NAME AND LICENSE NUMBER**

BioMarin Pharmaceutical Inc. License #1649

3. **PRODUCT NAME/PRODUCT TYPE**

BMN 270 / Valoctocogene Roxaparvovec / AAV5-hFVIII-SQ

4. **GENERAL DESCRIPTION OF THE FINAL PRODUCT**

- a. Gene Therapy
- b. Solution for Intravenous Infusion
- c. 2E13 vector genomes per milliliter (vg/ml); 8 ml extractable volume
- d. Intravenous (IV) Infusion
- e. Indicated for the treatment of adults with severe Hemophilia A (HA; congenital factor VIII deficiency) (b) (4) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA approved test.

5. **MAJOR MILESTONES**

Original ADD: March 31, 2023

Inspection conducted from December 5-9, 2022

Major amendment issued March 6, 2023 due to substantial amount of new data submitted largely regarding clinical issues

ADD date was revised to June 30, 2023

6. **DMPQ CMC/FACILITY REVIEW TEAM**

Reviewer/Affiliation	Section/Subject Matter
Brad Dworak, OCBQ/DMPQ/MRB1	Drug substance Drug product

7. **INTER-CENTER CONSULTS REQUESTED**

Reviewer/Affiliation	Section/Topic	In agreement with consult recommendations (Yes/No <sup>1</sup> )
N/A	N/A	N/A

<sup>1</sup> In case there is a disagreement with the consult review, the reasons and final resolution of the disagreement should be provided in Section 10. **REVIEWER EXECUTIVE SUMMARY and RECOMMENDATION**

**8. SUBMISSION(S) REVIEWED**

Date Received	Submission	Comments/ Status
September 29, 2022	STN 125720/69	CR response
December 20, 2022	STN 125720/76	Response to inspection observations
April 24, 2023	STN 125720/101	Response to IR regarding packaging and labeling sites

**9. Referenced REGULATORY SUBMISSIONS (e.g., IND BLA, 510K, Master File, etc.)**

Document as in the example below:

Submission Type & #	Holder	Referenced Item	Letter of Cross-Reference	Comments/Status
BLA STN 125720/0	BioMarin Pharmaceutical Inc.	Original BLA submission	N/A	N/A

**10. REVIEWER SUMMARY AND RECOMMENDATION****A. EXECUTIVE SUMMARY**

The original BLA was received on December 23, 2019. BioMarin submitted Amendment #69 which included responses to the two DMPQ deficiencies (item #s 4 and 12) outlined in the CR letter issued on August 18, 2020. These deficiencies addressed the inadequacy of the (b) (4) qualification and validation of cold storage rooms (the deficiencies are listed below for reference). Other non-CR items identified in the original review memo were adequately addressed on the inspection and in this submission.

A pre-license inspection (PLI) was not performed under the original BLA review cycle due to the inadequacy of the data submitted to support approval. It was performed after the agency received a complete response with adequate data that addressed the deficiencies identified in the CR letter (21 CFR 601.3(a)(2)). Therefore, the PLI was conducted under the review period for the BLA CR

Response. The scope of the inspection (see information below) as performed in December 2022 covered the majority of the non-CR items, including those related to:

- quality systems
- facility cleaning
- cross-contamination measures
- environmental monitoring program, results, and trending data
- utilities
- smoke studies
- equipment qualification, operation, and cleaning
- material flow and viral boundaries
- batch numbering schema and genealogy.

The remaining non-CR items not addressed during the inspection were reviewed in this memo, which include:

- (b) (4) sample exceeded the (b) (4) limit
- (b) (4) limits to light exposure
- Deviation #191396 regarding (b) (4) time being exceeded

Other than the identified CR and non-CR items previously identified above, the substantial portion of the BLA under DMPQ purview remains consistent with the information already reviewed in the original BLA. However, in this amendment the firm reported minor changes and updates to the manufacturing and facility conditions including up-to-date stability data. These changes were reviewed as being within the scope of DMPQ purview and include the following:

Updated information

- Updated facility diagrams for Material and Waste Flow.
- New (b) (4) configuration
  - updated validation report (PVR-240187)
  - updated (b) (4) configuration and simulation validation report (PVR-240216)
  - updated section 3.2.P.3.5.8.1 (b) (4) Sanitization for clarification
- Updated shipping validation report PQR-240111 to include (b) (4) the Global finished goods shipment configuration
- Updated DP stability claim and stability data sections

- Validation that the (b) (4) can be used for up to (b) (4) of the (b) (4) (PVR-240260). (Note, this was previously removed in the original review as the validation for this type of (b) (4) was missing.)
- The list of manufacturers was updated to include current site contact names. Also, the BioMarin (b) (4) (b) (4) site was removed altogether and no longer will be doing release testing.

#### CR items

For reference, the DMPQ CR deficiency items were as follows:

CR Item #4: Your application did not contain sufficient information to assess the qualification of the (b) (4) used for sterilization of the materials that contact the final sterilized product. Please provide the following information:

- a. A summary of results of the (b) (4), including a diagram and identification of the (b) (4).
- b. Locations of (b) (4) placements in the (b) (4) patterns and rationale for selection of monitoring locations.
- c. Name, lot number, labeled population, and expiration date for the (b) (4) used in the studies.
- d. The summarized data collected during (b) (4) tests, and your specifications regarding (b) (4) differences allowed between (b) (4) (b) (4).
- e. If applicable, a summary along with the results of the validation performed for a minimum (b) (4) configuration.

The firm updated section 3.2.P.3.5 and added (b) (4) validation and associated (b) (4) data, including providing qualification report PVR-121352 *Final Report for (b) (4) Sterilization*.

CR Item #12: Please describe and clarify the storage locations for the FBDS (b) (4). Please include qualification summary reports demonstrating adequacy of the storage environment and conditions for these locations.

The firm updated section 3.2.A.1 Facilities and Equipment including Table 3.2.A.1.3.1.1.5 to include storage unit locations and corresponding qualification summary reports demonstrating adequacy of the storage environment.

#### Inspection

A CBER-lead PLI inspection took place from December 5-9, 2022, at the BioMarin site in Novato, CA. An FDA Form 483 was issued to the firm with a total of two (2) observations. These observations were adequately addressed and are outlined in the 483-response memo.

## B. RECOMMENDATION<sup>2</sup>

**Approval** is recommended pursuant to the information provided in the original BLA submission in 2020 and amendments.

## II. COMPLETE RESPONSE (CR)

N/A

## III. SIGNATURE BLOCK

Reviewer/Title/Affiliation	Concurrence	Signature and Date
Brad Dworak, Ph.D.	Concur	
Lori Peters, Branch Chief	Concur	
Carolyn Renshaw, Division Director	Concur	

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<sup>2</sup> The review recommendations as indicated by the reviewer's signature for the CTD sections/subject matter is identified in section 6.

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### **Module 3**

#### **3.2.S DRUG SUBSTANCE<sup>3</sup>**

Refer to 125720/0 DMPQ original BLA review memo.

##### **3.2.S.2 Manufacture**

###### **3.2.S.2.1 Manufacturer(s)**

See section 3.2.A.1 for a complete list of drug substance manufacturers.

###### **3.2.S.2.2 Description of Manufacturing Process**

###### **❑ Manufacturing process steps**

Defer to original review memo.

###### **3.2.S.2.3 Control of Materials**

###### **❑ Critical Components**

Defer to original review memo.

###### **3.2.S.2.4 Controls of Critical Steps and Intermediates**

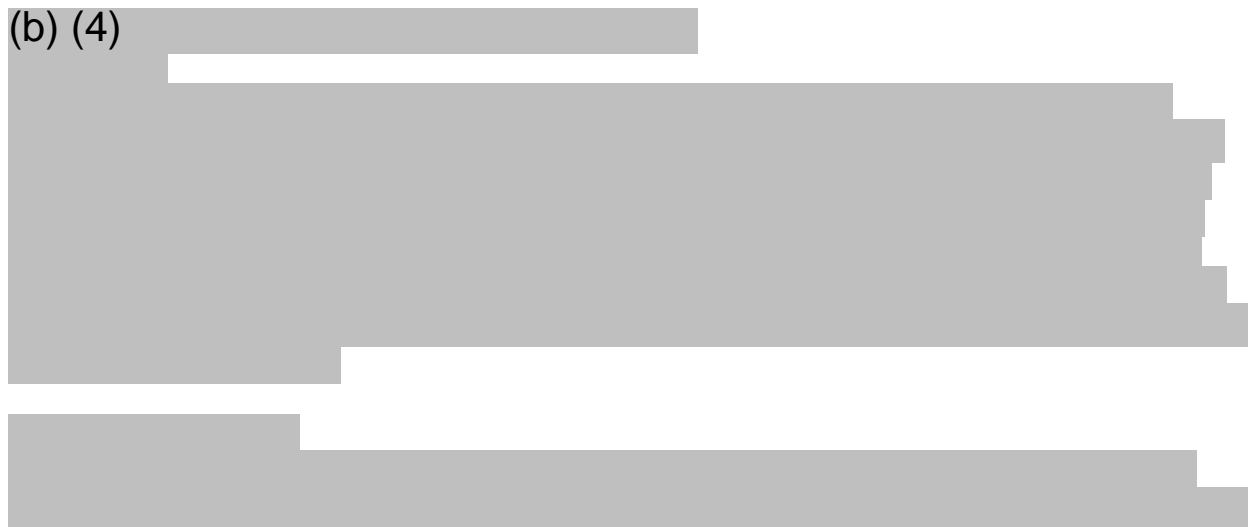
Defer to original review memo.

##### **Overall assessment**

This section was deemed acceptable previously.

###### **3.2.S.2.5 Process Validation and/or Evaluation**

(b) (4)





2 pages have been determined to be not releasable: (b)(4)

### **3.2.S.7 Stability**

#### **3.2.S.7.1 Stability Summary and Conclusion and 3.2.S.7.3 Stability Data**

New data is deferred to the OTP reviewer. There are no specifications for (b) (4)

### **3.2.P DRUG PRODUCT<sup>4</sup>**

#### **3.2.P.1 Description and Composition of the Drug Product**

Please reference original review memo.

#### **3.2.P.2.5 Microbiological Attributes**

Original DMPQ review memo can be referenced.

#### **3.2.P.3 Manufacture**

##### **3.2.P.3.1 Manufacturer(s)**

Refer to section 3.2.A.1 for a complete list of all manufacturing facilities.

##### **3.2.P.3.3 Description of Manufacturing Process**

Description has not changed in this amendment.

##### **3.2.P.3.4 Controls of Critical Steps and Intermediates**

Controls have not changed in this amendment.

##### **3.2.P.3.5 Process Validation and/or Evaluation**

#### **Updated (b) (4)**

The firm mentions that as a response to observations from a (b) (3) (A) inspection, the (b) (4) was modified from a (b) (4) design to a (b) (4) design. This redesign project also included the redevelopment of the (b) (4). The reengineering and redevelopment of the (b) (4) further minimized the number of (b) (4) between raw materials and the (b) (4). In order to demonstrate the capability of the revised (b) (4) to provide sterility assurance, (b) (4) process simulation of the defined, routine DP manufacturing process was required.

Thus, (b) (4) was performed on June 16, 2020, using (b) (4) per the process validation protocol. The process simulation run incorporated all inherent and corrective interventions in order to demonstrate that the DP manufacturing process in the manufacturing facility can maintain a state of control and result in sterile DP after the revisions to the (b) (4) (b) (4) for drug product operations) were implemented.

The process simulation was conducted using the same manufacturing suites, types of interventions, and acceptance criteria as those used for routine DP production that was prior reviewed in the original BLA.

## RESULTS

Results of the process simulation run are below:

(b) (4)

(b) (4)

(b) (4)

### Visual inspection results

A total of (b) (4) vials were filled and passed visual inspection and container closure integrity (acceptance criteria is (b) (4) vials). All vials were (b) (4) and none exhibited contamination. All (b) (4) vials passed testing.

### Environmental monitoring results

The filling manufacturing area (room (b) (4)) EM results passed the acceptance criteria for (b) (4) for the (b) (4) of the run. No (b) (4) were observed.

The (b) (4) EM results were also passing for (b) (4) during the (b) (4) operations. (b) (4) samples for (b) (4) and (b) (4) were also within the acceptance criteria. No (b) (4) were observed.

### Personnel monitoring results

All results were within the acceptance criteria for (b) (4) with a maximum count of (b) (4). The (b) (4) personnel monitoring samples with microbial counts were submitted for microbial organism identification. Two species were identified. The (b) (4) species are mostly found in soil and the (b) (4) species are commonly found in soil and water environments. The firm mentions probable root cause of these microbial organisms' recoveries is personnel gowning technique or improper aseptic techniques.


Also, the firm mentioned that there was minimal risk that the low levels of microbial recoveries (below alert and action limits) would negatively impact the process simulation run as the process is designed to prevent personnel interaction with the product. Filled vials are fully stoppered and capped prior to exiting the (b) (4) and no microbial growth was detected from the process simulation vials.

#### **Reviewer Comment**

No microbial growth was observed in any of the (b) (4) filled vials from the process simulation run. All other results passed the acceptance criteria. Therefore, this process simulation run with the updated (b) (4) appears to be acceptable.

### Process validation of the (b) (4) for the revised (b) (4)

(b) (4)



3 pages have been determined to be not releasable: (b)(4)

(b) (4)

#### **Reviewer Comment**

Regarding the above deviation, (b) (4)

For this validation, all acceptance criteria were met and considered reasonable for product safety regarding (b) (4). Therefore, these results appear to be acceptable.

#### **Shipping Qualification of (b) (4) Container**

##### Description

The (b) (4) shipping container was added as another option to be used for shipping of the finished product. Drug product (DP) is filled at the BioMarin (b) (4) site and shipped to (b) (4) (known as (b) (4) for labelling and secondary packaging. The finished goods are packed as one labelled vial into a one-unit carton, along with one leaflet and two seals per carton. The current qualified shipping container (b) (4) when packed, requires a pallet jack or a minimum of two persons to lift. The (b) (4) and can be managed by a single person.

Product quality and CCI testing have been previously completed in the original submission and found to be adequate for these shipping durations and conditions during flight and ground transport. As the (b) (4) is provided as an alternate shipping container, the new shipping qualification studies was based on the adequacy of this container under the same conditions as previously tested, including visual inspection of the vials and review of the temperature logs after reaching final destination. As the visual inspection results were passing (see below), the container closure was still considered adequate therefore not required to be retested or revised for this new shipping container. Pre-and post-shipment visual inspections and maintaining temperature below -60°C for the duration of transit were completed in the new qualification.

The shipping lane from BioMarin, (b) (4) to BioMarin, Novato, CA, USA is considered worst-case lane for last mile distribution as it consists of (b) (4) transport, requiring a (b) (4) with customs clearance processing upon arrival at the destination (b) (4) filled vials with commercially representative packaging were used for this qualification.

#### Load configurations

(b) (4)

#### Acceptance criteria

- Pre and post shipment visual inspections are completed
- Real world destination shipments are completed, and temperature remained  $\leq -60^{\circ}\text{C}$  for the duration of the shipment.

#### Summary of results

Qualification Activity	Results	Acceptance Criteria Met (Yes/No)
Destination Shipment	(b) (4)	Yes
Pre and Post Shipment Visual Inspection	(b) (4)	Yes

#### **Reviewer Comment**

The shipping validation included worst-case conditions including testing the maximum and minimum load configurations at the longest shipping duration. All acceptance criteria were met. Therefore, this validation appears to be acceptable.

## **Overall updates to shipping validation**

### **Shipping configurations**

Updated testing for shipment of the (b) (4) DP and packaged vials has been conducted for the (b) (4) shipping container for temperatures < -60°C for up to (b) (4), respectively, prior to (b) (4). The (b) (4) was qualified for packaged vials detailed in the above section and summarized below with the other shipping options.

The (b) (4) shippers can be used interchangeably for (b) (4) DP and packaged vial transport. The shippers are considered comparable based on dimensions, materials of construction (b) (4) and operational qualification results. Additionally, both shippers use the same partitions and payload box for transportation.

### **Results**

The (b) (4) undergone (b) (4) for the (b) (4) DP and packaged vials.

The (b) (4) undergone (b) (4) for the packaged vials.

### **Reviewer Comment**

All results were passing for these tests at minimum and maximum load configurations. Therefore, the overall shipping validation appears to be acceptable.

## **Vial Label Adhesion Qualification**

### **Description**

A study was performed to evaluate the impact of transport on vial label adhesion for vials labeled by the (b) (4) labeling process. Vials were labeled and secondary packaged using the validated (b) (4) labeling process at (b) (4), then shipped from the labeling site to BioMarin. Upon receipt, 100% of vials were visually inspected for label adhesion. All vials passed the acceptance criteria for label adhesion.

Shipping Configuration	Component	Inspection Criteria	Quantity Inspected (Labeled Vial)	Post-Shipment Visual Inspection Results (Pass/Fail)
Finished Goods (b) (4)	Vial Label	The vial label is free from wrinkles, peeling and is intrinsic to the vial.	(b) (4) (Max shipper load)	All vial labels pass



Shipping Configuration	Component	Inspection Criteria	Quantity Inspected (Labeled Vial)	Post-Shipment Visual Inspection Results (Pass/Fail)
Finished Goods – (b) (4)	Vial Label	The vial label is free from wrinkles, peeling and is intrinsic to the vial.	(b) (4) (Max shipper load)	All vial labels pass

**Reviewer Comment**

The report included the visual inspection of labels in a maximum shipping load and indicated that all labels were readable and free of wrinkles and peel. Therefore, this study appears to be acceptable.

**Non-CR item: Deviation 191396** (b) (4) exceeded (b) (4)

**Reviewer Comment**

This deviation report was reviewed, and determined that for lot (b) (4), the (b) (4) total time was (b) (4), exceeding the limit of (b) (4). (b) (4) testing of the (b) (4) passed. The root cause was due to delays of the (b) (4) unable to be secured in a timely manner on the (b) (4). Sterility samples for this lot passed with no growth. The (b) (4) issue was handled in a separate deviation. As the other (b) (4) PPQ lots were under the (b) (4) time, and since this lot passed sterility sampling with no growth, it appears acceptable as there is low risk to the product safety.

**Overall Reviewer's Assessment of Section 3.2.P.3.5:**

The shipping re-qualification and (b) (4) re-qualification were reviewed and appear to be acceptable. The non-CR items also were found to be acceptable.

**3.2.P.5 Control of Drug Product****3.2.P.5.1 and 3.2.P.5.6 Specification(s) and Justification of Specification(s)**

Original DMPQ review memo can be referenced.

**3.2.P.5.2 and 3.2.P.5.3 Analytical Procedures and Validation of Analytical Procedures**

Original DMPQ review memo can be referenced.

**3.2.P.5.4 Batch Analyses**

Original DMPQ review memo can be referenced.

### Overall Reviewer's Assessment of Sections 3.2.P.5.4

The information appears acceptable based on the original BLA review.

### 3.2.P.7 Container Closure System

No changes to the container closure system were mentioned. Original review memo can be referenced.

### 3.2.P.8 Stability

#### 3.2.P.8.1 Stability Summary and Conclusion and 3.2.P.8.3 Stability Data

Updated stability data for primary stability lots in commercial production process (b) (4) are available in this supplement for the 24, 30, and 36-month timepoints. All results for container closure integrity testing are in the table below:

Lot	12 months	24 months	30 months	36 months
(b) (4)				

### Overall Reviewer's Assessment of Section 3.2.P.8.1:

#### Reviewer Comment

The proposed assigned shelf life of the product is 24 months at  $\leq -60^{\circ}\text{C}$ . Lot (b) (4) at 30-months was not recorded. However, the 36-month time point was available. Because this time point exceeds the proposed shelf life by 6 months, this result did not result in an impact on safety profile. Therefore, the updated stability data for container closure integrity testing appear to be acceptable.

### 3.2.A APPENDICES




#### (b) (4) VALIDATION

#### Reviewer Comment



The firm provided more information below to address CR deficiency items #4a-e outlined in the executive summary above. The firm updated section 3.2.P.3.5 and provided a red-lined version as well.

Description

(b) (4)



(b) (4)



2 pages have been determined to be not releasable: (b)(4)

(b) (4)

**Reviewer Comment**

All acceptance criteria were met for these results. The firm adequately responded to all items pertaining to CR item #4. Therefore, this response and results appear to be acceptable.

**Equipment Qualification for Cold Storage**

The firm provided an updated Table 3.2.A.1.3.1.1.5.1 to include cold storage locations and equipment IDs:

(b) (4)

The IQ/OQ qualification reports for all these equipment were provided. IQ/OQ consisted of surface compatibility for cleaning, alarm limit functioning, temperature control, connection to the (b) (4) for temperature recording, data integrity controls, security, and

changing of setpoints including admin access.

**Reviewer Comment**

All qualification reports were reviewed and passed the acceptance criteria. Therefore, this response to the CR deficiency appears to be acceptable.




**Updated Waste and Material Diagrams**

**Reviewer Comment**

These diagrams were re-reviewed with respect to the viral boundaries of the manufacturing areas. Waste and material flow paths appeared to be congruent to the Material and Waste Air Lock IN and OUT areas. As there has been no other changes to the facility spaces and classifications, this appears to be acceptable.

**Updated Manufacturer Sites**

Manufacturing/ Testing activities and facilities	Inspection? Waiver? Not required?	Compliance check required for approval?	RMS-BLA entry required?	Comments
<p><b>Facility:</b> BioMarin Pharmaceutical Inc. (b) (4) Novato Campus Novato, California, 94949, U.S.A.</p> <p><b>FEI:</b> 3004079983</p> <p><b>Activity:</b> <b>DS:</b></p> <ul style="list-style-type: none"> <li>• (b) (4) Manufacturer</li> <li>• (b) (4) storage</li> <li>• (b) (4) Drug Substance and Intermediate storage</li> <li>• Release testing (b) (4)</li> <li>• In-Process testing (b) (4)</li> <li>• Stability testing (b) (4)</li> </ul> <p><b>DP:</b></p> <ul style="list-style-type: none"> <li>• FDP Manufacturer</li> <li>• Release testing (Physicochemical, Microbiological, Biological)</li> <li>• In-Process testing (b) (4)</li> <li>• Stability testing (Physicochemical, Biological)</li> <li>• Filling</li> <li>• Primary Labeling ((b) (4) labeling of vials - Primary and only site)</li> <li>• Storage</li> </ul>	Inspection	Yes	Yes	<p><b>Inspections:</b> 12/2022 – CBER PLI inspection - VAI</p>

Manufacturing/ Testing activities and facilities	Inspection? Waiver? Not required?	Compliance check required for approval?	RMS-BLA entry required?	Comments
<b>Facility:</b> (b) (4)  <b>FEI:</b> (b) (4) <b>Activities:</b> <b>DP:</b> <ul style="list-style-type: none"> <li>Primary Labeling (b) (4) labeling of vials - Primary and only site)</li> <li>Secondary Packaging (Both (b) (4) labeled vials – Primary and only site)</li> </ul>	Waiver	Yes	Yes	<b>Inspections:</b> (b) (3) (A) - VAI (b) (4) – ORA/OPQO PAI surveillance inspection – VAI
<b>Facility:</b> (b) (4)  <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DS:</b> <ul style="list-style-type: none"> <li>(b) (4) storage</li> </ul> <b>DP:</b> <ul style="list-style-type: none"> <li>Microbial testing</li> <li>Sterility Release testing</li> </ul>	Waiver	Yes	Yes	<b>Inspectional History:</b> (b) (4)- DND/BE/OSIS/GLP – establishment inspection - VAI (b) (4) – ORA/OBPO surveillance inspection – VAI
<b>Facility:</b> (b) (4)  <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DP:</b> <ul style="list-style-type: none"> <li>Chemical/Physical Testing for Release and Stability</li> <li>(b) (4)</li> </ul>	Waiver	Yes	Yes	<b>Inspectional History:</b> (b) (4) – CDRH BIMOW unannounced GLP inspection - NAI (b) (4) – ORA/OBPO surveillance - NAI (b) (4) – NAI (GMP)



Manufacturing/ Testing activities and facilities	Inspection? Waiver? Not required?	Compliance check required for approval?	RMS-BLA entry required?	Comments
<b>Facility:</b> (b) (4) (b) (4) <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DP:</b> <ul style="list-style-type: none"> <li>Sterility release testing</li> </ul>	Waiver	Yes	Yes	<b>Inspectional History:</b> (b) (3) (A) surveillance inspection - VAI (b) (4) – ORA/OBPO surveillance inspection - VAI
<b>Facility:</b> (b) (4) (b) (4) <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DP:</b> <ul style="list-style-type: none"> <li>storage</li> </ul>	Not required	Not required	Yes	
<b>Facility:</b> (b) (4) (b) (4) <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DS:</b> <ul style="list-style-type: none"> <li>in-process (b) (4) testing</li> </ul>	Not required	Not required	Yes	
<b>Facility:</b> (b) (4) (b) (4) <b>FEI:</b> (b) (4) <b>Activity:</b> <b>DS:</b> <ul style="list-style-type: none"> <li>In-process (b) (4)</li> </ul>	Not required	Not required	Yes	

**Overall Reviewer's Assessment of Section 3.2.A.1:**

This section appears to be acceptable.

**3.2.R Regional Information (USA)****❑ Executed Batch Records**

For reference only – DMPQ is not responsible for reviewing batch records.

- ❑ **Combination Products**
  - N/A
- ❑ **Comparability Protocols**  
N/A

**Other eCTD Modules**

**Module 1**

**A. Environmental Assessment or Claim of Categorical Exclusion**

- The Environmental Assessment (EA) or Claim of Categorical Exclusion are reviewed and documented by OTP for this BLA.