CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207963Orig1s000

MICROBIOLOGY/VIROLOGY REVIEW(S)

Product Quality Microbiology Review

18 May 2015

NDA: **207963**

Drug Product Name
Proprietary: Not applicable
Non-proprietary: Palonosetron Hydrochloride Injection, 0.125 mg/mL

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
7 August 2014	8 August 2014	12 August 2014	21 August 2014
27 February 2015	2 March 2015	N/A	N/A

Submission History (for 2nd Reviews or higher): Not applicable

Applicant/Sponsor
Name: Exela Pharma Sciences
Address: P.O. Box 818
1245 Blowing Rock Blvd.
Lenoir, N.C. 28645

Representative: Jonathan E. Sterling
Telephone: 828 758-5474

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended as Approvable Pending a Complete Response to Microbiology Deficiencies

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: 505(b)(2)

2. SUBMISSION PROVIDES FOR: [redacted] (b) (4) Hydrochloride Injection in 2 mL glass vials.

3. MANUFACTURING SITE: Exela Pharma Sciences
1325 William White Place
Lenoir, NC 28645
Registration # 3008563008

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Injectable
- Intravenous Injection
- 0.125 mg/mL as base

5. METHOD(S) OF STERILIZATION: [redacted] (b) (4).

6. PHARMACOLOGICAL CATEGORY: Prevention of nausea during chemotherapy.

B. SUPPORTING/RELATED DOCUMENTS: 26 November 2013 review of DMF 11648.

C. REMARKS: The application was submitted in a series of PDF files arranged in CTD format. An information request was emailed to the applicant on 28 January 2015. The response was received on 2 March 2015.

filename: 207963.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended as Approvable Pending a Complete Response to Microbiology Deficiencies.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -
The drug product is [redacted] (b) (4)

B. Brief Description of Microbiology Deficiencies -
The applicant failed to provide [redacted] (b) (4) for the bulk drug product.

C. Contains Potential Precedent Decision(s)- ☐ Yes ☒ No

III. Product Quality Microbiology Risk Assessment

A. Initial Product Quality Microbiology Risk Assessment

CQA	Risk Factor	Prob. of Occ. (O)	Modifier for O[3, 4, 5]	Severity of Effect (S)	Detect. (D)	Risk Priority Number[6] (RPN)	Additional Review Emphasis based on Risk (in addition to normal review process)
Ster.	[redacted] (b) (4)	6		5	5	150	Container closure integrity was tested on containers [redacted] (b) (4) .
Endo		2		4	4	32	
[redacted] (b) (4)							

(b) (4)

RPN <50 = Low Risk; RPN 50-120 = Moderate Risk; RPN >120 = High Risk

B. Final Risk Assessment – The failure to establish (b) (4) for the non-sterile drug product could result in significant microbial growth (b) (4).

IV. Administrative

A. Reviewer's Signature _____

Stephen E. Langille, Ph.D.
Acting Branch Chief, DMA Branch 3

B. Endorsement Block

Jessica Cole, Ph.D. – Quality Assessment Lead –
DMA Branch 3.

C. CC Block

N/A

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

STEPHEN E LANGILLE
05/18/2015

JESSICA COLE
05/18/2015