

**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:** (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:** (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 (b) (4)
- B. Brief Description of Microbiology Deficiencies** -
The applicant failed to provide (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


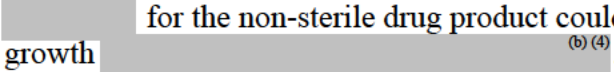
CQA	Risk Factor	Prob. of Occ. (O)	Modifier for O ^(3, 4, 5)	Severity of Effect (S)	Detect. (D)	Risk Priority Number ⁶ (RPN)	Additional Review Emphasis based on Risk (in addition to normal review process)
Ster.	(b) (4)	6		5	5	150	Container closure integrity was tested on containers (b) (4)
Endo		2		4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





(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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/s/

STEPHEN E LANGILLE
05/18/2015

JESSICA COLE
05/18/2015