

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203050Orig1s000

MICROBIOLOGY/VIROLOGY REVIEW(S)

Product Quality Microbiology Review

2/23/2012

NDA: 203050

Drug Product Name

Proprietary: None

Non-proprietary: Palonosetron Hydrochloride Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
1/03/2012	1/03/2012	2/09/2012	2/09/2012

Submission History (for amendments only): None

Applicant/Sponsor

Name: Dr. Reddy's Laboratories, Ltd.,

Address: Bachepally -502 325, India

Representative: Kimberly Ernst., Associate Director, Global Regulatory Affairs, Dr. Reddy's Laboratories, Inc., 200 Sommerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, NJ 08807

Telephone: 908 203 4980

Name of Reviewer: Steven P. Donald, M.S.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** Manufacture of a sterile drug product.
 3. **MANUFACTURING SITE:** Gland Pharma Ltd, (b) (4)
(b) (4) 00043.
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Injectable, IV, 0.075 mg/1.5mL in a 2 ml/13 mm glass vial and 0.25 mg/5 mL in a 5 ml/20 mm glass vial; single (b) (4) vial
 5. **METHOD(S) OF STERILIZATION:** (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** antiemetic and antinauseant
- B. **SUPPORTING/RELATED DOCUMENTS:** LOA, dated 5/23/2011, for 13 mm and 20 mm (b) (4) rubber stoppers. The letters for the 13mm and 20mm stoppers reference the (b) (4) located in record #713, pages 1-23, dated 10/20/2009.
- DMF Review (b) (4).doc performed on 8/05/2010, covers the submission for the (b) (4) located in Record 713, pages 1-23, submission date 10/20/2009. Revalidation is covered in DMF review (b) (4).doc, dated 9/01/2011. These DMF reviews were both performed by the Office of Generic Drugs Microbiology group and are both found "adequate".
- C. **REMARKS:** None

filename: N203050r1.doc

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
NDA 203050 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A**

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –** The bulk drug solution is
 (b) (4)
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies – N/A**

III. Administrative

- A. Reviewer's Signature** _____
Steven P. Donald, M.S.
- B. Endorsement Block** _____
Stephen E. Langille, PhD
Senior Microbiology Reviewer
- C. CC Block**
N/A

23 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page



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

/s/

STEVEN P DONALD
03/20/2012

STEPHEN E LANGILLE
03/20/2012

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 203050

Applicant: Dr. Reddy's
Laboratories, Inc

Letter Date: 1/3/2012

Drug Name: Palonosetron
Hydrochloride

NDA Type: 505 (b)(2)

Stamp Date: 1/3/2012

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		2.3.P.2
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		(b) (4)
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		CCI: 3.2.P.2.4; PET not required.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		3.2.R.3.P
7	Has the applicant submitted the results of analytical method verification studies?	X		3.2.R.3.P
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	N/A		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: None

Steven P. Donald, M.S.

2/10/2012

Reviewing Microbiologist

Date

Stephen E. Langille, Ph.D.

2/10/2012

Microbiology Secondary Reviewer/Team Leader

Date

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

/s/

STEVEN P DONALD
02/13/2012

STEPHEN E LANGILLE
02/16/2012