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

<table>
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<tr>
<th>Submit</th>
<th>Received</th>
<th>Review Request</th>
<th>Assigned to Reviewer</th>
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<tr>
<td>1/03/2012</td>
<td>1/03/2012</td>
<td>2/09/2012</td>
<td>2/09/2012</td>
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</tbody>
</table>

Submission History (for amendments only): None

Applicant/Sponsor
Name: Dr. Reddy’s Laboratories, Ltd.,
Address: Bachelpally -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, 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 vial

5. METHOD(S) OF STERILIZATION: 

6. PHARMACOLOGICAL CATEGORY: antiemetic and antinauseant

B. SUPPORTING/RELATED DOCUMENTS: LOA, dated 5/23/2011, for 13 mm and 20 mm rubber stoppers. The letters for the 13 mm and 20 mm stoppers reference the located in record #713, pages 1-23, dated 10/20/2009.

DMF Review [redacted].doc performed on 8/05/2010, covers the submission for the located in Record 713, pages 1-23, submission date 10/20/2009. Revalidation is covered in DMF review [redacted].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
   (0/4)

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
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/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:

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<th>Content Parameter</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
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<tbody>
<tr>
<td>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?</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>2. Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?</td>
<td>X</td>
<td></td>
<td>2.3.P.2</td>
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<tr>
<td>3. Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?</td>
<td>X</td>
<td></td>
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<td>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?</td>
<td>X</td>
<td></td>
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<td>5. Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?</td>
<td>X</td>
<td></td>
<td>CCI: 3.2.P.2.4; PET not required.</td>
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<td>6. Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?</td>
<td>X</td>
<td></td>
<td>3.2.R.3.P</td>
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<td>7. Has the applicant submitted the results of analytical method verification studies?</td>
<td>X</td>
<td></td>
<td>3.2.R.3.P</td>
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<td>8. Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?</td>
<td>N/A</td>
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<td>9. Is this NDA fileable? If not, then describe why.</td>
<td>X</td>
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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
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/s/

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STEVEN P DONALD
02/13/2012

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STEPHEN E LANGILLE
02/16/2012