

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-246

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

29 August 2008

NDA: 22-246/N-000

Drug Product Name

Proprietary: N/A

Non-proprietary: Metoclopramide Orally
Disintegrating Tablets

Drug Product Priority Classification: S.

Review Number: 1.

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
05 NOV 2007	06 NOV 2007	15 NOV 2007	15 NOV 2007

Applicant/Sponsor

Name: Wilmington Pharmaceuticals, LLC.

Address: 1213 Culbreth Dr.

Suite 230

Wilmington, NC. 28405

Representative: Eugene T. Haley

Telephone: 910-509-0097

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommended for approval.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA.
 - 2. SUBMISSION PROVIDES FOR:** A new drug product.
 - 3. MANUFACTURING SITE:**
Catalent Pharma Solutions
Frankland Rd
Blagrove
Swindon, SN5 8RU
UK
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Freeze dried tablet.
 - Oral.
 - 5 mg & 10 mg.
 - 5. METHOD(S) OF STERILIZATION:** The product is not sterile.
 - 6. PHARMACOLOGICAL CATEGORY:** Indicated for the treatment of GERD.
- B. SUPPORTING/RELATED DOCUMENTS:** None.
- C. REMARKS:**
The submission is provided in paper (a desk copy totaling 19 volumes).

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – NDA 22-246 is recommended for approval on the basis of product quality microbiology.
- 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 manufacturing process includes the following 5 stages:

(b) (4)



- B. Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. Reviewer's Signature** _____
John W. Metcalfe, Ph.D.
- B. Endorsement Block** _____
Stephen Langille, Ph.D.
- C. CC Block**
N/A

5 Pages Withheld as b(4) Trade Secret/Confidential



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this page is the manifestation of the electronic signature.**

/s/

John Metcalfe
9/8/2008 09:45:51 AM
MICROBIOLOGIST

Stephen Langille
9/8/2008 10:14:53 AM
MICROBIOLOGIST