

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-915

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

20-December-2005

NDA: 21-915

Drug Product Name

Proprietary:

Ondansetron Injection, USP in
PL 2408 Plastic Container

Non-proprietary:

Ondansetron Injection, USP

Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter March 30, 2005

Stamp April 1, 2005

Consult Sent May 19, 2005

Assigned to Reviewer May 20, 2005

Submission History (for amendments only) Not applicable

Applicant/Sponsor

Name:

Baxter Healthcare Corporation

Address:

1620 Waukegan Road

McGaw Park, IL 60085

Baxter Registration Number

1423500

Representative:

Vicki Drews

Telephone:

(847) 473-6296

Name of Reviewer:

Stephen E. Langille, Ph.D.

Conclusion:

Approvable pending revision

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original submission
2. **SUBMISSION PROVIDES FOR:** Parametric release of the drug product in a PL2408 plastic container.
3. **MANUFACTURING SITE:** Baxter Healthcare
Jayuya, Puerto Rico
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Aqueous injection
 - Intravenous
 - 8 mg/50 mL and 32 mg/50 mL
5. **METHOD(S) OF STERILIZATION:** Terminal sterilization – moist heat
6. **PHARMACOLOGICAL CATEGORY:** Antiemetic
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF 11619
- C. **REMARKS:** Baxter seeks approval for parametric release of Ondansetron for Injection.

filename: N021915r1.doc

**APPEARS THIS WAY
ON ORIGINAL**

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
NDA 21-915 is approvable pending the resolution of product quality 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 -**
Baxter seeks approval for parametric release of Ondansetron Injection packaged in 50 mL dual port PL2408 containers.
- B. Brief Description of Microbiology Deficiencies -**
The applicant failed to provide adequate information regarding:
- The WFI system
 - Historical sterility data for products manufactured in the 50 mL PL 2408 containers
 - Sterilization validation information
 - Biological indicator data
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Failure to address the microbiology deficiencies could result in endotoxin and/or microbial contamination of the drug product.

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Bryan Riley, Ph.D.
- C. CC Block**
N/A

6 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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

/s/

Stephen Langille
12/20/2005 03:09:33 PM
MICROBIOLOGIST

Bryan Riley
12/20/2005 03:16:40 PM
MICROBIOLOGIST

Product Quality Microbiology Review

24-January-2006

NDA: 21-915-BL

Drug Product Name

Proprietary:

Ondansetron Injection, USP in
PL 2408 Plastic Container

Non-proprietary:

Ondansetron Injection, USP

Drug Product Priority Classification: N

Review Number: 2

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
January 23, 2006	January 23, 2006	January 23, 2006	January 23, 2006

Submission History (for amendments only)

Submission Date(s)	Microbiology Review #	Review Date(s)
March 30, 2005	1	December 21, 2005

Applicant/Sponsor

Name:

Baxter Healthcare Corporation

Address:

1620 Waukegan Road

McGaw Park, IL 60085

Baxter Registration Number
1423500

Representative:

Vicki Drews

Telephone:

(847) 473-6296

Name of Reviewer:

Stephen E. Langille, Ph.D.

Conclusion:

Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Amendment to the original submission
 2. **SUBMISSION PROVIDES FOR:** Parametric release of the drug product in a PL2408 plastic container.
 3. **MANUFACTURING SITE:** Baxter Healthcare
Jayuya, Puerto Rico
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Aqueous injection
 - Intravenous
 - 8 mg/50 mL and 32 mg/50 mL
 5. **METHOD(S) OF STERILIZATION:** Terminal sterilization – moist heat
 6. **PHARMACOLOGICAL CATEGORY:** Antiemetic
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF 11619
- C. **REMARKS:** Baxter seeks approval for parametric release of Ondansetron for Injection.

filename: N021915R2.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 21-915 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 -**
Baxter seeks approval for parametric release of Ondansetron Injection packaged in 50 mL dual port PL2408 containers.
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille, Ph.D.
- B. Endorsement Block** _____
James McVey
- C. CC Block**
N/A

3 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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

/s/

Stephen Langille
1/24/2006 11:23:03 AM
MICROBIOLOGIST

James McVey
1/26/2006 07:36:24 AM
MICROBIOLOGIST