CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205703Orig1s000

MICROBIOLOGY/VIROLOGY REVIEW(S)

Product Quality Microbiology Review

24 February 2014

NDA: **205-703/N000**

Drug Product Name
Proprietary: NA
Non-proprietary: Esmolol Hydrochloride Premixed Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
28 June 2013	28 June 2013	28 June 2013	3 July 2013
14 August 2013	14 August 2013	--	--
12 December 2013	12 December 2013	--	--
30 December 2013	30 December 2013	--	--
30 January 2014	30 January 2014	--	--

Submission History (for 2nd Reviews or higher) – NA

Applicant/Sponsor
Name: HQ Specialty Pharma Corporation
Address: 120 Route 17 North
Paramus NJ 07652
Representative: Joseph Pizza
President
Telephone: (201) 857-8290

Name of Reviewer: Denise A. Miller

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original new drug application

2. SUBMISSION PROVIDES FOR: Initial submission.

3. MANUFACTURING SITE:

(b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Dosage Form: Sterile solution in (b) (4) 100 mL bags
- Route of Administration: Intravenous
- Strength/Potency: 2500 mg/250 mL and 2000 mg/100 mL

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Supraventricular Tachycardia (SVT) and Intra-operative and Postoperative tachycardia and/or hypertension.

B. SUPPORTING/RELATED DOCUMENTS: NA

C. REMARKS:

1) The filing review included an information request for container closure integrity (CCI) studies. The CCI studies were provided by the sponsor on 14 August 2013.

2) Information request # 2 dated 22 November 2013 requested information on the endotoxin test, the sterility test and additional information on the CCI testing. A response was received on 12 December 2013.

3) Information request #3 dated 05 December 2013 requested data to support the hold time after a bolus is removed from the vial. The response on 30 December 2013 indicated that they are performing the microbial studies and that the completed report will be sent to the Agency by mid-February 2014. The report was sent on 30 January 2014. The study was not supportive of the hold time and another IR was sent. The sponsor requested a T-con which was held on 10 February 2014. Clarification was provided and the storage and handling portion of the label will be revised to state that the product is not to be stored after the bolus is removed.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for approval from a quality microbiology perspective.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – This product is (b) (4)

B. Brief Description of Microbiology Deficiencies – There were no deficiencies identified in the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies – NA

D. Contains Potential Precedent Decision(s)- ☐ **Yes** ☒ **No**

III. Administrative

A. Reviewer's Signature _____

Denise A. Miller
Microbiologist, OPS/NDMS

B. Endorsement Block _____

Bryan S. Riley, Ph.D.
Senior Microbiologist, OPS/NDMS

C. CC Block
N/A

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

/s/

DENISE A MILLER
02/26/2014

BRYAN S RILEY
02/26/2014
I concur.