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RESEARCH**

*APPLICATION NUMBER:*

**207768Orig1s000**

**MICROBIOLOGY / VIROLOGY REVIEW(S)**

# Product Quality Microbiology Review

13 February 2014

**NDA:** 207-768

**Drug Product Name**

**Proprietary:** Tuzistra XR

**Non-proprietary:** Codeine Polistirex and Chlorpheniramine  
Polistirex ER Oral Suspension

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
27 JUN 2014	30 JUN 2014	19 JUL 2014	24 JUL 2014

**Applicant/Sponsor**

**Name:** Tris Pharma Inc.

**Address:** 2033 Route 130 Suite D  
Monmouth Junction, NJ 08852

**Representative:** W. Scott Groner

**Telephone:** 732-940-0358

**Name of Reviewer:** Jessica G. Cole, PhD

**Conclusion:** Recommended for Approval

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## Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** 505(b)(2) application
  - 2. SUBMISSION PROVIDES FOR:** A new drug product
  - 3. MANUFACTURING SITE:**  
Tris Pharma, Inc.  
2033 Route 130  
Monmouth Junction, NJ 08852  
FEI No.: 3004712471  
DUNS No.: 947472119
  - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - (b) (4) suspension for oral administration
    - 20 mg codeine phosphate/4 mg chlorpheniramine per 5 mL
  - 5. METHOD(S) OF STERILIZATION:** This product is non-sterile
  - 6. PHARMACOLOGICAL CATEGORY:** (b) (4)  
(b) (4) of symptoms associated with upper respiratory allergies
- B. SUPPORTING/RELATED DOCUMENTS:** Microbiology review of DMF 27314 dated 13 February 2014.
- C. REMARKS:** This submission is in the eCTD format. This reviewer was not informed of the filing meeting and no microbiology filing review was conducted for this submission.

**filename:** N207768R1.doc

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability** - Recommended for Approval.
- 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** – This is a non-sterile, (b) (4), oral suspension.
- B. Brief Description of Microbiology Deficiencies** – Not applicable.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.
- D. Contains Potential Precedent Decision(s)-**  Yes  No

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Jessica G. Cole, PhD
- B. Endorsement Block** \_\_\_\_\_  
Bryan Riley, PhD  
Microbiology Branch Chief
- C. CC Block**  
In DARRTS

**Product Quality Microbiology Assessment**

The 13 February 2015 microbiology review of DMF 27314 found the DMF adequate to support approval of this NDA.

**LIST OF MICROBIOLOGY DEFICIENCIES AND COMMENTS:**

None.

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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.**  
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/s/  
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JESSICA COLE  
02/13/2015

BRYAN S RILEY  
02/13/2015  
I concur.