CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205874Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 8 August 2013

TO: NDA 205874

FROM: Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS

THROUGH: John Metcalfe, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS

cc: Russell Fortney
Regulatory Project Manager
OMPT/CDER/OND/ODEI/DCRP

SUBJECT: Product Quality Microbiology assessment of Microbial Limits for KRX-0502 (ferric citrate coordination complex) [Submission Date: 6 August 2013]

The Microbial Limits specification for KRX-0502 (ferric citrate coordination complex) is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.

KRX-0502 (ferric citrate coordination complex) is a tablet for oral administration.

The drug product is tested for Microbial Limits at release using a method consistent with USP Chapter <61> (Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests) and <62> (Microbiological Examination of Non-sterile Products: Tests for Specified Microorganisms). The Microbial Limits acceptance criteria are consistent with USP Chapter <1111> (Microbiological Examination of Non-sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use) and are provided in Table 1 below:

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Table 1 – Microbial Limits Specification

Test	Acceptance Criteria	Method
Total Aerobic Microbial Count	NMT (b) (4) CFU/g	USP <61>
Total Yeast and Mold Count	NMT (b) (4) CFU/g	USP <61>
Staphylococcus aureus	Absent in (b) (4) g	USP <62>
Pseudomonas aeruginosa	Absent in (b) (4) g	USP <62>
E. coli	Absent in (b) (4) g	USP <62>
S, aureus	Absent in (b) (4) g	USP <62>

The Microbial Limits test methods were verified to be appropriate for use with the drug product following procedures consistent with those in USP Chapter <61>and <62>.

The drug product will also be tested for Microbial Limits annually as part of the post-approval stability protocol.

ADEQUATE

Reviewer Comments – The microbiological quality of the drug product is controlled via a suitable testing protocol.

END

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/s/

STEPHEN E LANGILLE
08/08/2013

JOHN W METCALFE
08/09/2013
I concur.