

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206995Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)



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

DATE: 04 November 2014

TO: NDA 206995

FROM: Robert J. Mello, Ph.D.
 Senior Review Microbiologist
 CDER/ONDQA/OPS/NDMS

THROUGH: Neal J. Sweeney, Ph.D.
 Senior Review Microbiologist
 CDER/ONDQA/OPS/NDMS

cc: Sharon Sickafuse
 Senior Regulatory Health Project Manager
 CDER/OND/OHOP/DOPII

SUBJECT: Filing Review and Product Quality Microbiology assessment of
 Microbial Limits for Iressa (Gefitinib) Tablets, 250mg [Submission
 Date: 17 September 2014].

Description: The drug product is a round, biconvex, brown film-coated tablets containing 250 mg of gefitinib. It will be produced at AstraZeneca's Macclesfield, Cheshire, UK facility.

Composition: The composition is shown in Table 1, below (copied from submission section 3.2.P.1, page 2/2; highlighted portion added by reviewer). (b) (4)

Table 1 Composition of IRESSA 250 mg film-coated tablets

Ingredient	Quantity (mg/tablet)	Function	Reference to standards
Tablet core			
Gefitinib	250.0	Drug substance	AstraZeneca standard
Lactose monohydrate	(b) (4)		USNF
Microcrystalline cellulose	(b) (4)		USNF
Croscarmellose sodium	(b) (4)		USNF
Povidone	(b) (4)		USP
Sodium lauryl sulphate	(b) (4)		USNF
Magnesium stearate	(b) (4)		USNF
Nominal core tablet weight			
Tablet coating			
Hypromellose ^a	(b) (4)		USP
Polyethylene glycol 300	(b) (4)		USNF
Red ferric oxide ^a	(b) (4)		USNF 21 CFR 73.1200
Yellow ferric oxide ^a	(b) (4)		USNF 21 CFR 73.1200
Titanium dioxide ^a	(b) (4)		USP 21 CFR 73.575, 21 CFR 73.1575

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- Acceptable -

Reviewer Comments – The applicant's proposal to waive all microbial enumeration testing (release and stability) is acceptable since the applicant has demonstrated adequate control over the manufacturing processes and has batch data supporting this control.

Conclusion: NDA 206995 is fileable from a microbiology product quality perspective. In addition, this review memo also serves as the final microbiology product quality review for this NDA with a recommendation for APPROVAL.

END

Robert J.
Mello -A

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Mello -A
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Reviewer's Signature

Robert J. Mello, Ph.D.
Senior Microbiology Reviewer

Neal J.
Sweeney -A

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Endorsement Block

Neal J. Sweeney, Ph.D.
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