CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209091Orig1s000

PRODUCT QUALITY REVIEW(S)

Recommendation:
APPROVAL
(including the Overall Manufacturing Inspection Recommendation)

NDA 209091
Review #1
Review Date (see last page)

Drug Name/Dosage Form	saxagliptin and dapagliflozin tablets
Strength	5/10 mg/mg
Route of Administration	oral
Rx/OTC Dispensed	Rx
Applicant	Astra Zeneca

SUBMISSION(S) REVIEWED	DOCUMENT DATE
0000	4/27/2016

Quality Review Team

DISCIPLINE	REVIEWER	DIVISION/OFFICE
Application Technical Lead	Suong (Su) Tran	New Drug Products II/ONDP
Regulatory Business Process Manager	Anika Lalmansingh	Regulatory Business Process Management I/OPRO
Drug Product	John Amartey	New Drug Products II/ONDP
Facility	Vipulchandra Dholakia	Inspectional Assessment/OPF

Quality Review Data Sheet

1. **RELATED/SUPPORTING DOCUMENTS:**

   A. **DMFs:** Adequate (see OPQ review of NDA (b) (4))

   B. **Other Documents:**

DOCUMENT	APPLICATION	DESCRIPTION
NDA	(b) (4)	saxagliptin and dapagliflozin tablets (same product, same applicant)

2. **CONSULTS:** not applicable

Executive Summary

I. Recommendation and Conclusion on Approvability

The recommendation from the Office of Pharmaceutical Quality (including the 11/21/16 Overall Manufacturing Inspection Recommendation) is for **APPROVAL**.

II. Summary of Quality Assessment

A. Product Overview

This is a 505(b)(1) application for a fixed dose combination of two approved drug substances, saxagliptin and dapagliflozin, 5 mg and 10 mg. This is not an NME application because the applicant has several approved NDAs for these drug substances.

The same product in this new NDA was previously submitted in NDA (b) (4) by the same applicant. NDA (b) (4) received a Complete Response on 10/15/2015 (b) (4) OPQ review recommended "approval" at the time of the action with no pending Quality issue.

B. Quality Assessment Overview

The CMC information in the new NDA and the previously reviewed NDA (b) (4) (b) (4)

(b) (4)

[redacted]

The OPQ review of NDA 209091 consists of the drug product review of the new and updated information listed above and a cross-reference to the OPQ review of NDA (b) (4) for the evaluation of all other Quality information. The Overall Manufacturing Inspection Recommendation is updated on 11/21/16 for "approval".

Application Technical Lead Signature:

Suong (Su) Tran, Ph.D.
electronic signature on the last page

CHAPTERS: Primary Quality Assessment

Chapter I: Drug Substance (see OPQ Review of NDA [redacted])
Chaper II: Drug Product
Chapter III: Environmental Assessment (see OPQ Review of NDA [redacted])
Chapter IV: Labeling
Chapter V: Process (see OPQ Review of NDA [redacted])
Chapter VI: Facilities (see OPQ Review of NDA [redacted])
Chapter VII: Biopharmaceutics (see OPQ Review of NDA [redacted])
Chapter VIII: Microbiology (see OPQ Review of NDA [redacted])
Attachment I: Final Risk Assessment (see OPQ Review of NDA [redacted])

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