

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
202270Orig1s000

CHEMISTRY REVIEW(S)

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Application: NDA 202270/000

Action Goal:

Submission Date: 23-SEP-2010

District Goal: 24-MAY-2011

Reception Date: 03-FEB-2012

Applicant: MERCK SHARP DOHME
UG2CD 48
NORTH WALES, PA 19454

Brand Name: Sitagliptin + Metformin Extended Release

Estab. Name:

Generic Name:

Priority: 3

Product Number; Dosage Form; Ingredient; Strengths

Org. Code: 510

001; TABLET; SITAGLIPTIN; 50MG
001; TABLET; METFORMIN HYDROCHLORIDE; 500MG
002; TABLET; SITAGLIPTIN; 50MG
002; TABLET; METFORMIN HYDROCHLORIDE; 1000MG

Application Comment: SEE ESTABLISHMENT COMMENTS FOR THIS NEW NDA (on 01-OCT-2010 by K. SHARMA ())

FDA Contacts: K. SHARMA

Project Manager

S. TRAN

Team Leader

301-796-1764

Overall Recommendation:	ACCEPTABLE	on 25-JAN-2012	by S. HERTZ	(HFD-320)	301-796-3203
	PENDING	on 05-JAN-2012	by EES_PROD		
	WITHHOLD	on 05-JAN-2012	by EES_PROD		
	WITHHOLD	on 04-DEC-2011	by EES_PROD		
	WITHHOLD	on 10-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 03-AUG-2011	by EES_PROD		
	WITHHOLD	on 03-AUG-2011	by EES_PROD		
	WITHHOLD	on 21-JUL-2011	by EES_PROD		
	WITHHOLD	on 25-MAY-2011	by EES_PROD		

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Establishment: CFN: (b) (4) (b) (4)
(b) (4)
(b) (4)

DMF No: **AADA:**

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

Establishment Comment: DRUG SUBSTANCE (SITAGLIPTIN PHOSPHATE) MANUFACTURING, PACKAGING, AND RELEASE/STABILITY TESTING (on 01-OCT-2010 by K. SHARMA ())
Profile: NON-STERILE API BY CHEMICAL SYNTHESIS **OAI Status:** NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
OC RECOMMENDATION	05-OCT-2010			ACCEPTABLE BASED ON PROFILE	STOCKM
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Establishment: CFN: (b) (4) FEI: (b) (4)

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

Establishment Comment: DRUG SUBSTANCE (METFORMIN HYDROCHLORIDE) MANUFACTURING, TESTING AND RELEASE (on 01-OCT-2010 by K. SHARMA ())

Profile: NON-STERILE API BY CHEMICAL SYNTHESIS OAI Status: NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
OC RECOMMENDATION	05-OCT-2010			ACCEPTABLE BASED ON PROFILE	STOCKM
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

FDA CDER EES ESTABLISHMENT EVALUATION REQUEST DETAIL REPORT

Establishment: CFN: 2650235 FEI: 1000131917
 MERCK & CO., INC.
 RD 2, KM 60.3
 ARECIBO, PR 00688

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE MANUFACTURER
 FINISHED DOSAGE RELEASE TESTER

Establishment Comment: DRUG PRODUCT MANUFACTURING AND RELEASE TESTING (on 01-OCT-2010 by K. SHARMA ())

Profile: TABLETS, EXTENDED RELEASE **OAI Status:** NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
SUBMITTED TO DO	05-OCT-2010	Product Specific			STOCKM
ASSIGNED INSPECTION TO IB	14-OCT-2010	Product Specific			RHERNAND
INSPECTION SCHEDULED	15-OCT-2010		05-NOV-2010		RHERNAND
INSPECTION PERFORMED	14-APR-2011		14-APR-2011		JOSE.MELENDEZ

The FDA-483 Observation reads as follows:



(b) (4)

DO RECOMMENDATION 06-MAY-2011 WITHHOLD RHERNAND
 FIRM NOT READY



(b) (4)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.