CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 202270Orig1s000

CHEMISTRY REVIEW(S)



Application:

NDA 202270/000

Action Goal:

S' 7 Date:

23-SEP-2010

District Goal:

24-MAY-2011

N. atory:

03-FEB-2012

Applicant:

MERCK SHARP DOHME

Brand Name:

Sitagliptin + Metformin Extended Release

UG2CD 48

Estab. Name:

NORTH WALES, PA 19454

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

	by S. HERTZ	(HFD-320)	204 706 2202
5-JAN-2012		•	301-796-3203
	by EES_PROD		
5-JAN-2012	by EES_PROD		
4-DEC-2011	by EES_PROD		
0-AUG-2011	by EES_PROD		
4-AUG-2011	by EES_PROD		
3-AUG-2011	by EES_PROD		
3-AUG-2011	by EES_PROD		
1-JUL-2011	by EES PROD		
'	-,		
	4-AUG-2011 4-AUG-2011 4-AUG-2011 3-AUG-2011 3-AUG-2011	4-AUG-2011 by EES_PROD 4-AUG-2011 by EES_PROD 4-AUG-2011 by EES_PROD 3-AUG-2011 by EES_PROD 3-AUG-2011 by EES_PROD	4-AUG-2011 by EES_PROD 4-AUG-2011 by EES_PROD 4-AUG-2011 by EES_PROD 3-AUG-2011 by EES_PROD 3-AUG-2011 by EES_PROD

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Page 1 of 9



Establishment: CFN: (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:

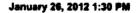
DRUG SUBSTANCE (SITAGLIPTIN PHOSPHATE) MANUFACTURING, PACKAGING, AND RELEASE/STABILITY TESTING (on

01-OCT-2010 by K. SHARMA ())

Profile: NON-STERILE API BY CHEMICAL SYNTHESIS

OAI Status: NONE

Milestone Name Comment	Milestone Date	Request Type	Planned Completion	Decision Reason	Creator
SUBMITTED TO OC	05-OCT-2010	, , , , , , , , , , , , , , , , , , , ,			SHARMAKH
OC RECOMMENDATION	05-OCT-2010			ACCEPTABLE BASED ON PRO	STOCKM FILE
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PRO	STOCKM FILE



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Page 2 of 9



Establishment:	CFN:	(b) (4)	(6) (4)	FEI:	(b) (4)
OME No:				AADA	

Responsibilities:

DRUG SUBSTANCE MANUFACTURER

DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

Establishment Comment:

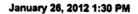
DRUG SUBSTANCE (METFORMIN HYDROCHLORIDE) MANUFACTURING, TESTING AND RELEASE (on 01-OCT-2010 by K.

SHARMA())

Profile: NON-STERILE API BY CHEMICAL SYNTHESIS OAI St

OAI Status: NONE

Milestone Name Comment	Milestone Date	Request Type	Planned Completion	Decision Reason	Creator
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
OC RECOMMENDATION	05-OCT-2010		•	ACCEPTABLE BASED ON PRO	STOCKM
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PRO	STOCKM



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Page 3 of 9



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

Milestone Name Comment	Milestone Date	Request Type	Planned Completion	Decision Reason	Creator
SUBMITTED TO OC	05-OCT-2010	landa da d	e gere et en disployation de la Prince Institut de la Prince pe la grandia	Reason	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 The FDA-483 Observation reads	14-APR-2011 as follows:		14-APR-2011		JOSE.MELENDEZ
				(b) (4)	

DO RECOMMENDATION 06-MAY-2011

WITHHOLD

RHERNAND

(b) (4) FIRM NOT READY

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Page 4 of 9



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