

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FBI NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Your Quality system is deficient and lacks an overall oversight of drug products manufactured at your site to ensure they have validated processes before release for commercial distribution. Specifically, your Quality approved and released products that were compressed on (b) (4) tablet press but only validated on (b) (4) tablet press during process validation. A few examples of products compressed on (b) (4) but only validated on (b) (4) tablet presses are: Benazapril 5mg, Benazapril 10mg, Labetalol 200mg, Labetalol 300mg, Lovastatin 20mg, and Methimazole 10mg.

PRODUCTION SYSTEM

OBSERVATION 2

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Your firm released finished drug products for commercial distribution without a validated process. Specifically, you did not perform process validation for drug products using (b) (4) series tablet press. Examples of a few products compressed on (b) (4) series tablet press without process validation is listed in the table below from August 2010-current:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Hai Lien T Phung, Investigator Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	06/22/2011

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011* FBI NUMBER 3000210731
---	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc CITY, STATE ZIP CODE, COUNTRY Wilson, NC 27893-8143	STREET ADDRESS 4700 Sandoz Dr TYPE ESTABLISHMENT INSPECTED Drug Manufacturer
---	---

	Benazapril 5mg (Lot#)	Benazapril 10mg (Lot#)	Labetalol 200mg (Lot#)	Labetalol 300mg (Lot#)	Lovastatin 20mg (Lot#)	Methimazole 10mg (Lot#)
(b) (4) Series Tablet Press (b) (4) (b) (4)						
Asset#13053		193523 193524 193522 193530 BL1339 BL1340 BL3732			197682 197687 197684 197686 197685 197683 197688 197689 197690 197691 203505 202964 202963 203507 202965 202966 202967 203506 202968 202969 BH0569 BH0570 BH0571 BH0572 BH0573 BH0575 BH0574 BH0576 BH0577 BN0990 BN0991 BN0992 BN0993 BN0996	

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
-------------------------------------	---	---------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	RETNUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE OF ESTABLISHMENT INSPECTED Drug Manufacturer

					BN0997 BN0998 BN0999 BN1000 BN1001 BP5743 BP5744 BP5745	
Asset# 13320			188042 188043 188044 190658 190659 193940 193939 194021 194022 194023 196443 197761 196444 196445 196447 196446 197762 197763 197764 197765 198666 198665 198667 206096 206097 206099	188050 188052 188051 188053 188054 198096 198097 198098 205085 205086 206095 BR4476 BR4477 BR4479 BR4480	205945	
Asset# 15009			190533 192790 192791 192792	190606 190608 190609 190610		

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HVP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FBI NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE OF FACILITY/PRODUCT INSPECTED Drug Manufacturer

		190660	190607		
		190661	195850		
		192791	195851		
		199740	195852		
		199781	195853		
		199782	195854		
		199783	198099		
		199784	198661		
		BJ0799	198662		
		BJ0798	198100		
		BJ0800	198620		
		BJ0802	198620		
		BJ0801	200435		
			201436		
			201435		
			BN3475		
Asset# 15588	BH4733	188238		188352	BH4699
	BH4734	188239		188353	BH4700
	BH4735	188240		188354	BH4701
	BH4736	188241		188355	BH4702
	BH4737	188242		188356	BH4703
	BH4738	188243		188357	BH4704
	BH4739	188244		188358	BH4705
	BH4740	188245		188359	BS5217
	BH4745	188246		188361	BS5218
	BH4743	188247		188362	BS5219
	BH4742	190948		188363	BS5220
	BH4744	190952		188364	
		190949		190517	
		190950		190518	
		190951		190519	
		190953		190520	
		190954		190521	
		190955		190522	
		190956		190589	
		190957		190590	
		203904		190523	
		203905		190588	
		203906		190591	
		203907		190592	

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FSI NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Jon Rushford, VP Technical Operations	
FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

	204829		190593
	204830		190594
	204831		190595
	204832		190596
	204833		190597
	204834		191478
	BH4746		191479
	BH4747		191480
	BH4748		191481
	BJ7537		191482
	BJ7538		191483
	BJ7534		
	BJ7533		
	BJ7539		

OBSERVATION 3

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

A. The written procedure (SOP v-029) for your Statistical Process Control (SPC) system is deficient because incorrect application of statistical process control is being used.

For example:

- i. The σ (8.1.4) estimation used for the control charts is incorrect. This erroneous estimation could lead to inappropriate control limits on the respective statistical process control charts. Inappropriate control limits could lead to either an over controlled or under controlled process.
- ii. Step 9.1.4 is incorrect due to the fact that the constant A can only be used if both σ and μ are known and not estimated. According to section 8.1.3, your firm will be "estimating σ and μ on no less than (b) (4) data points." This contradicts the usage of constant A.
- iii. The calculation of the control limits for tablets greater than (b) (4) mg is incorrect as stated in 9.2.2. The value of A for a sample size of (b) (4) cannot be determined by dividing the value of A for a sample size of (b) (4). Not only is the calculation of control limits incorrect, the usage of constant A is inappropriate.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FBI NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

iv. Section 9.2 discusses how control limits are derived for (b) (4) weight control limits. These limits are based upon using an X-bar chart, which is an erroneous application of statistical process control, since only 1 reportable value is being plotted.

B. Individual tablet weights of in-process samples taken during a compression run (collect (b) (4) tablets every (b) (4) minutes) are not recorded to determine weight variation. Instead, your firm recorded total weight of the (b) (4) tablets and apply this practice for many drug products including Lisinopril tablets manufactured at your facility.

C. Individual Other Related Compound (IORC) for 3-month accelerated and CRT stability samples of (b) (4) and (b) (4) were outside of specification of NMT (b) (4) as shown below:

Sample	Individual Other Related Compound (IORC), NMT (b) (4)
200767 (b) (4)	0.6%
200767 (b) (4)	0.8%
200768 (b) (4)	0.6%

The impurity was identified as (b) (4) which came from food-grade bag used for intermediate packaging for delivery of the lozenges with dosing stick to the laboratory and the third party packager. (b) (4) is pending FDA approval.

D. No investigation and/or assessment was performed for low % yield during granulation of (b) (4) drug-layered pellets for lots (b) (4) (93.0%) (b) (4) (89.0%), and (b) (4) (88.2%) as required by your Computation of Yields and Material Reconciliation SOP, G-017 version 2.0 effective June 15, 2010. The specified range is NLT (b) (4) NMT (b) (4). These lots were used in process validation of (b) (4) capsules. (b) (4) is pending FDA approval.

E. During your process validation of (b) (4) Capsules (b) (4) you failed to achieve blend homogeneity for final blend of batches (b) (4) (b) (4) due to agglomeration of talc. This product is pending FDA approval.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FEI NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Jon Rushford, VP Technical Operations	
FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

F. During your process validation of (b) (4) Capsules (b) (4) you did not achieved acceptable % usable yield according to your specification (b) (4) for the following process validation lots during encapsulation process:

Lot#	% Yield (range: (b) (4))
(b) (4)	63.1
(b) (4)	65.9
(b) (4)	74.1
(b) (4)	63.0

Due to (b) (4) agglomeration and low % yield observed during your execution of process validation batches, your firm has recommended that (b) (4) Capsule is not to be considered validated. These batches will be designated for developmental/ clinical purposes only and further evaluation will be conducted.

G. Your manufacturing process during process validation drug product (b) (4) Capsules (b) (4) (pending FDA approval) is not the same as what was submitted to the FDA.

(b) (4) Pellets blend lot (b) (4) required mixing the following ingredients in the order listed below:

- i) (b) (4)
- ii) (b) (4) Pellets I
- iii) (b) (4) II
- iv) (b) (4) (screened)

This blend lot (b) (4) was used to make submission batches of (b) (4) Capsules (b) (4). However, during the execution of your process validation of (b) (4) the order of adding the above ingredients were changed as follow:

- i) (b) (4)
- ii) (b) (4) I
- iii) (b) (4)
- iv) (b) (4) Pellets II

Your Regulatory Affairs has determined this change to be annual reporting.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
	FIR NUMBER 3000210731

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

H. Your firm does not monitor if the filters in the air purification unit have been fully seated. This could result in some of the Hydrochlorothiazide dry granulation to pass through the filters with potential granulation lost resulting in potency loss of product Benazepril/Hydrochlorothiazide 20mg/25mg bulk tablets.

I. The spray rate specification during granulation for (b) (4) Pellets I and II was changed from (b) (4) /min to (b) (4) /min without adequate justification. Your firm submitted in submission batches (b) (4) and (b) (4) with specified spray rate of (b) (4) /min. However, during process validation for lot (b) (4) and (b) (4) your firm changed the specification to (b) (4) (b) (4) /min due to peristaltic pump not capable of being set below (b) (4) therefore, could not achieve lower g/min rate limit of (b) (4) min as specified in the Formulation Manufacturing Record (FMR) during pump set-up according to your Deviation investigation (WDEV-09-0472). However, contrary to your investigation finding, the submission FMR for batches (b) (4) and (b) (4) indicated your firm was able to achieve spray rate of (b) (4) /min.

OBSERVATION 4

Examination and testing of samples is not done to assure that in-process materials conform to specifications.

Specifically,

A. Your firm has not conducted a blend hold time study for all products manufactured at your site [(30+ products) to support your (b) (4) days blend completion. According to your current Batch Record Review and Reconciliation procedure, SOP USWY-SOP-00391 Version 3.0 effective date March 15, 2011, it stated: (b) (4)

(b) (4) This procedure applies for all manufactured intermediates, solutions, processed raw materials, in-process materials (bulk products), finished dosage forms, packaged product and labeled packages manufactured and/or packaged at the Wilson, NC facility. However, you have not conducted a blend hold time study for products manufactured at your facility.

B. Your firm is not using previous acceptable process variability estimates where possible and determined by application of suitable statistical procedures. For example:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
---------------------------------	--	----------------------------------

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Jon Rushford, VP Technical Operations		PIR NUMBER 3000210731
FROM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr	
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	
<p>i. For product Lisinopril 20mg, the σ (8.1.4) estimation used for the control charts is incorrect. The estimate of σ is not based on suitable statistical procedures. The in-process specifications are not based on previous process variability estimates and they are not determined by the application of suitable statistical procedures.</p> <p>ii. BM7189 (pp 33-36), your control limits are not based on suitable statistical procedures. The current control limits are final product specifications.</p>		
OBSERVATION 5		
<p>Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.</p> <p>Specifically, your multipoint content uniformity acceptance criteria is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The rationale for (b) (4) acceptance criteria (RSD NMT (b) (4) for multipoint content uniformity sampling states that for smaller data-sets, they are allowing a larger acceptable RSD. This rationale is not statistically based.</p>		
LABORATORY SYSTEM		
OBSERVATION 6		
<p>Established test procedures are not followed.</p> <p>Specifically, your firm does not follow your validated dissolution test method. During FDA personnel visit to the laboratory it was found that dissolution unit Number 17259, had bubbles on the paddles. The unit was been used for (b) (4) Stability studies. Also, it was observed that the filters installed in the auto analyzer's probes had been used in a previous unknown analysis. After reviewing the dissolution monograph G008 QC version 04, 10/15/10 page 17 of 52 it was observed that it specify that the dissolution medium has to be degassed. Sandoz personnel later indicated that the validation of the (b) (4) tablets was performed by degassing by two different techniques, (b) (4) (b) (4) However, your validated test method requires degassing using (b) (4) technique. Sandoz</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	06/22/2011
FORM FDA 483 (05/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS
		PAGE 9 OF 11 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 06/06/2011 - 06/22/2011*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Jon Rushford, VP Technical Operations		FIRM NUMBER 3000210731
FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr	
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	
<p>personnel alleged that degassing was important because the results were more accurate. However, the data submitted by Sandoz does not show any comparative result of both degassing techniques. Both techniques were indiscriminately used without been individually validated to show equivalency.</p> <p>(b) (4) product is pending FDA approval.</p>		
OBSERVATION 7		
<p>Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.</p> <p>Specifically,</p> <p>A. OOS investigation document USWY- SOP-00738 version 1 does not describe what specific actions should be taken if OOS cause is not found. OOS investigations are closed by rejecting the OOS based on re-test statistical analysis without finding the cause of the OOS.</p> <p>B. Your firm submitted to the FDA theoretical weight values for Metformin spike recovery instead of actual values. Specifically, the Metformin method validation, on section 5.6 of "Analytical method validation Report # MVR00093v2, Table 13 titled " Assay Accuracy/Recovery solution preparations" the theoretical weight values for the (b) (4) level were reported as (b) (4) (b) (4). However, the actual weight values are 56.9, 56.4, 56.7, 116.0, 116.2, 119.1, 231.1, 229.8, 230.1 mg according to Book 4681 page 053. These actual weight values were not reported as part of the method validation for this product. Also method validations do not include carryover analysis to preclude unknown impurities co-elution interferences.</p>		
EQUIPMENT SYSTEM		
OBSERVATION 8		
<p>There is a failure to supply potable water under continuous positive pressure.</p> <p>Specifically,</p> <p>A. The pressure limit for the microfiltration unit of the water system has not been evaluated. Specifically, there is no limit established for the pressure difference between input and output for the microfiltration unit. However, Sandoz maintenance personnel acknowledge that an inadequate pressure gradient could potentially create a backward flow that could damage the unit.</p>		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator <i>HLP</i> Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

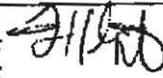
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry	DATES OF INSPECTION 06/06/2011 - 06/22/2011* FEI NUMBER 3000210731
--	---

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Jon Rushford, VP Technical Operations

FIRM NAME Sandoz Inc	STREET ADDRESS 4700 Sandoz Dr
CITY, STATE, ZIP CODE, COUNTRY Wilson, NC 27893-8143	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

B. There is no qualification performed for the ⁽⁴⁾ disinfection unit 107223 installed in the water purification system. Your firm has never validated this unit after installed to ensure that it is effectively killing potential microorganisms.

* DATES OF INSPECTION:
06/06/2011 (Mon), 06/07/2011 (Tue), 06/08/2011 (Wed), 06/09/2011 (Thu), 06/10/2011 (Fri), 06/13/2011 (Mon), 06/14/2011 (Tue), 06/15/2011 (Wed), 06/16/2011 (Thu), 06/17/2011 (Fri), 06/22/2011 (Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hai Lien T Phung, Investigator  Tonshina R. Hall, Investigator Luis M. Burgos Medero, Investigator	DATE ISSUED 06/22/2011
-------------------------------------	--	----------------------------------