DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111	08/19/2008 - 08/28/2008* FEI NUMBER 1931484

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jesse E. Rettig, CEO

FIRM NAME	STREET ADDRESS
Apotheca, Inc	313 Lowrey Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woodbine, IA 51579-1505	Homeopathic Drug Manufacturing

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:

OBSERVATION 1

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,

Your firm has no completed or documented process validation reports for any drug products produced by your firm.

(This is a repeat observation)

OBSERVATION 2

Each lot of components, drug product containers, and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically,

Your firm does not have documentation for the testing and approval or rejection of all components, drug product container, and closures received and used by your firm in the manufacture, processing, packing or holding of a drug product. Your firm uses the supplier's certificates of analysis to verify compliance with predetermined specifications for many of your components, drug product containers and closures, yet has never established the reliability of the supplier's analyses by validation of all of these test results.

(This is a repeat observation)

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OBSERVATION 3

Batch production and control records do not include the results of any investigation made into any unexplained discrepancy, whether or not the batch of drug product had already been distributed.

Specifically,

1. Batch production records for the manufacturing of [redacted], lot number [redacted], included an entry on the bottom of the [redacted] Tablet Press Weight and Hardness Chart, which is part of the batch production record, which indicated there was a "loud pop then on one of the top punches had metal shavings". Behind this entry were the initials "JKH" and the date "5-13-08". Below this entry, on the same page, was another entry, initialed with "DW", and the date "5-13-08", indicating "[redacted]kg of tablets & powder thrown away that was done around the time the metal shavings was found." In this same batch production record another entry was recorded on a record previously identified as the [redacted] Tablet Press Weight and Hardness Chart. The "[redacted]" section of the title of this report had been lined out, and "[redacted]", was written in its place. On the bottom of this form the entry "found a piece of duct tape in shoot" was written in, with the initials "JKH" and a date "5-15-08" behind this entry. Below this entry, on the same form of the batch production record, there is the entry "[redacted] grams of powder & tablets disposed of in strainer & container." The initials "DW" and a date "5-15-08" were written beside this entry. There was no evidence of any investigation being conducted related to these incidents found in the batch production records, and no evidence quality assurance personnel were notified to review these deviations when they occurred.

2. Batch Production Records for [redacted], lot number [redacted], indicates the product was incorrectly compounded during manufacturing and was disposed of. A report of this investigation was not found with the batch production and control record. There is no indication on the batch record which employee incorrectly compounded the product or on what date the compounding began.

3. Batch production records for [redacted], lot number [redacted], indicates the product was incorrectly compounded by adding one of the ingredients twice. The investigation never determined which ingredient was added twice, nor did it indicate whether or not any attempt was made to determine which ingredient was added twice. The investigation also indicates employees FV and TL compounded the product, but the batch production record only has the signature of employee FV as the employee who compounded the product.

4. During the encapsulating of [redacted], lot number [redacted], a small balance was reported to have been knocked off of a counter it was on, shattering glass near a container where product was being stored after encapsulation. The product was quarantined, and after an investigation, the product was eventually released. There was no documentation of this incident in the batch record for [redacted], lot number [redacted]

(This is a repeat observation)

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OBSERVATION 4

Investigations of an unexplained discrepancy did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

1. a. During the manufacturing of [redacted], lot number [redacted], manufacturing employees reported black specks had been found in tablets, and metal shaving were found on the upper gear shield of your [redacted] tablet press after the hopper was emptied. It was determined by the quality assurance team the completed product was contaminated, as was the remaining un-pressed powder which was removed from the hopper, and all pressed tablets and powder were disposed of. This investigation found an adjustment bolt for the feed plate was misaligned, and when tightened it pulled the upper gear shield against the turret, which allowed rubbing and caused the metal shavings. However, the investigation does not indicate whether or not any previous batches of product manufactured on this equipment may have been affected by this same mechanical problem.

   b. The same batch production record for [redacted], lot number [redacted], indicates [redacted] grams of powder had been thrown away from cleanup, but does not indicate any tables were manufactured. However, the investigation report for this incident, dated April 3, 2008, indicates "All pressed tables and remaining powder was disposed of."

   c. The investigation report for this same incident, dated April 3, 2008, indicates the incident occurred on March 27th, yet it was not reported to Quality Control until March 31, 2008. There is no documentation on the batch record indicating Quality Control was notified and made any decision about this product prior to March 31st.

2. During the manufacturing of [redacted], lot number [redacted], the batch production records indicated a "loud pop then on one of the top punches had metal shavings" and "[redacted]kg of tablets & powder thrown away that was done around the time the metal shavings was found." The batch production record also indicated employees "found a piece of duct tape in shoot" and "[redacted] grams of powder & tablets disposed of in strainer & container." There was no evidence of any investigation being conducted related to these incidents, and no evidence any investigation was conducted to determine whether or not any previous batches of product manufactured on this equipment may have been affected by this piece of equipment.

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OBSERVATION 5

Batch production and control records do not include the identity of individual major equipment used for each batch of drug product produced.

Specifically,

1. Batch production records for [redacted], lot number [redacted], indicates the [redacted] tablet Press was set up for use for the manufacturing of this product. Dates listed for the tableting of this product range from 5/7/08 to 5/16/08. A review of the firm's batch production records indicate both the [redacted] tablet press and [redacted] Tablet Press were used during the manufacture of this lot of product. The batch production records do not clearly identify on what dates these tablet presses were used, nor do the records indicate the [redacted] Tablet Press was ever set up correctly and approved for use. Batch production records indicate a "loud pop then on one of the top punches had metal shavings" and "[redacted]kg of tablets & powder thrown away that was done around the time the metal shavings was found." The batch production record also indicated employees "found a piece of duct tape in shoot" and "[redacted] grams of powder & tablets disposed of in strainer & container." Firm management was unable to determine by the batch production records which one of the tablet presses was in use when these incidents occurred.

2. The batch production records for [redacted], lot number [redacted], indicate the machine was torn down & cleaned. However, there was no entry on the firm's equipment maintenance logs indicating the [redacted] or the [redacted] Tablet Press was ever taken out of service for maintenance during the time period this lot of product was being manufactured.

3. A review of the firm's [redacted] and [redacted] Tablet Press Use and Cleaning Logs found both the [redacted] and [redacted] tablet press were logged in for use for the production of [redacted], Lot number [redacted], on 5/7/08 by employee JKH. However, there is no documentation in the batch production records of when these machines were actually used and/or when either one of these machines were taken out of use.

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*** DATES OF INSPECTION:**
08/19/2008(Tue), 08/20/2008(Wed), 08/21/2008(Thu), 08/22/2008(Fri), 08/25/2008(Mon), 08/26/2008(Tue), 08/28/2008(Thu)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

David L Miser, Investigator

Brent T. Hall, Investigator

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