DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax:(973) 526-6069	05/02/2005 - 07/01/2005* FEI NUMBER 3004106764

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Garth (NMI) Boehm, Ph.D., Senior Vice President, Chief Scientific Officer

FIRM NAME	STREET ADDRESS
Able Laboratories, Inc.	One Able Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cranbury, NJ 08512	Generic Pharmaceutical 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 quality control unit lacks authority to fully investigate errors that have occurred.

The Quality Unit and Senior Management failed to assure all drug products distributed have the safety, identity, quality, and purity that they are represented to possess. The Quality Unit failed to: review electronic data as part of batch release, review computer audit trails in the Waters Empower Data Acquisition System and provide adequate training to analytical chemists. These practices led to the Quality Unit releasing batches of drug products which failed to meet in-process, finished product and stability specifications. These practices also led to the submission of erroneous data in Annual Reports and Prior Approval Supplement # 004, for ANDA 75-838, which requested discontinuance of Blend Uniformity testing for Propoxyphene Napsylate and Acetaminophen 100mg/650 mg Tablets. The lack of Quality oversight resulted in: the ceasing of manufacturing on ~~5/13/05~~ 5/19/05, the ceasing of distribution of all drug products on ~~5/26/05~~ 5/13/05, the recall of all batches (3,184) of drug products and the withdrawal of at least five Abbreviated New Drug Applications.

OBSERVATION 2

Drug products failing to meet established standards, specifications, and quality control criteria are not rejected.

Samples of drug products were routinely resampled, and re-injected or reprocessed in the [redacted] System during testing in the QC Laboratory when out of specification (OOS) results were obtained. There were no Laboratory Investigations into OOS results or notebook documentation available to explain the re-injection or retesting of in-process, finished product and stability samples which did not meet specifications. The OOS results were not reported and within specification results from reprocessed or re-injected samples were reported on: In-Process Specification, Product Specification and Stability Study Specification Release Reports

SEE REVERSE OF THIS PAGE	AMENDED	Nancy Lobi Maria L. Harmon 7-6-05 David Saks	DATE ISSUED 07/06/2005

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and Stability Summary Reports. Examples of drug products which were released with OOS values are listed below.

Product/Batch #	Sample	Original OOS Result	Reported Results
Acetaminophen & Codeine Phosphate Tablet, 300/30 mg Batch 502022	In-Process Blend Uniformity Testing	Codeine Phosphate % RSD: 5.4 % Spec: [redacted]	Codeine Phosphate % RSD: 3.8 % Spec: RSD ≤ [redacted]
Acetaminophen & Codeine Phosphate Tablet, 300/30 mg Batch 407148	Finished Product Testing	Codeine Phosphate Content Uniformity % RSD: 8.3 % Spec: RSD [redacted]	Codeine Phosphate Content Uniformity % RSD: 5.5 % Spec: RSD ≤ [redacted]
Atenolol 25 mg Tablet Validation Batch 408107A	Stability Sample 3 mo RT	Dissolution , Tablet D5 = 83.7% D6 = 83.8% Spec: NLT [redacted]	Dissolution , Tablet D5 = 98.9% D6 = 98.7% Spec: NLT [redacted]
Atenolol 25 mg Tablet Validation Batch 408107B	Stability Sample 3 mo RT	Dissolution Testing Tablet D6 = 30.9% Spec: NLT [redacted]	Dissolution Testing Tablet D6 = 102.8% Spec: NLT [redacted]
Atenolol 25 mg Tablet Test Batch TB-203E	Stability Sample 3 mo RT	Dissolution , Tablet D5 = 83.7% D6 = 83.8% Spec: NLT [redacted]	Dissolution , Tablet D5 = 98.9% D6 = 98.7% Spec: NLT [redacted]
Bethanechol Chloride 10 mg Tablet Validation Batch 404042A	Stability Sample 9 mo RT	Assay A1 = 89.6% Spec: [redacted]	Assay A1 = 99.5% Spec: [redacted]
Diphenoxylate HCl and Atropine Sulfate Tablets Batch 404006	In-Process Blend Uniformity Testing	Blender Location: BR1 = 128.5% ML2 = 158.3% TL2 = 117.6% Spec. [redacted]	Blender Location: BR1 = 99.5% ML2 = 101.6% TL2 = 108.3% Spec. [redacted]
Diphenoxylate HCl and Atropine Sulfate Tablets Batch 403203	In-Process Blend Uniformity Testing	Blender Location: TR1 = 145.9% Spec: [redacted]	Blender Location: TR1 = 96.9 % Spec: [redacted]

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Product/Batch #	Sample	Original OOS Result	Reported Results
Diphenoxylate HCl and Atropine Sulfate Tablet, Batch 301068A	Stability Sample 21 mo RT	Assay A1 = 78.4% A2 = 78.7% Spec: [redacted]	Assay A1 = 90.4% A2 = 90.8% Spec: [redacted]
Diphenoxylate HCl and Atropine Sulfate Tablet, Batch 301068B	Stability Sample 21 mo RT	Assay A1 = 77.5% A2 = 77.5% Spec. [redacted]	Assay A1 = 90.11% A2 = 89.8% Spec: [redacted]
Diphenoxylate HCl and Atropine Sulfate Tablet, Batch 301068C	Stability Sample 21 mo RT	Assay A1 = 75.8% A2 = 78.4% Spec: [redacted]	Assay A1 = 89.41% A2 = 90.7% Spec: [redacted]
Dytan Suspension 25mg/5ml Batch L409001	Finished Product Testing	Assay - Beginning A2 = 89.2% Spec: [redacted]	Assay - Beginning A2 = 97.9% Spec: [redacted]
Methylphenidate HCl Tablets, 20 mg Extended Release Batch 303087	Finished Product Testing	Dissolution (1 Hour) Tablet: D1: 48.9% D2: 49.0% D3: 48.2% Spec: [redacted] (1 hour)	Dissolution (1 Hour) Tablet: D1: 43.4% D2: 43.3% D3: 42.4% Spec: [redacted] (1 hour)
Methylphenidate HCl Tablets, 5 mg Batch 412184	Finished Product Testing	Assay A1 = 90.0% A2 = 90.0% Spec. [redacted]	Assay A1 = 98.4% A2 = 98.5% Spec. [redacted]
Nitroglycerin 0.4 mg Sublingual Tablets Batch 502038	Finished Product Testing	Assay A1 = 75.8% Spec. [redacted]	Assay A1 = 101.5% Spec: [redacted]
Prochlorperazine Suppositories, 2.5 mg Batch 308029A	Stability Sample 12 mo RT	Unknown Impurities 0.52% 0.73% Spec: NMT [redacted]	Highest Unknown Impurities 0.04% Spec: NMT [redacted]
Prochlorperazine Suppositories, 5 mg Batch 308030A	Stability Sample 12 mo RT	Unknown Impurities 0.44 % 0.56 % Spec: NMT [redacted]	Highest Unknown Impurities 0.14% Spec: NMT [redacted]

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Product/Batch #	Sample	Original OOS Result	Reported Results
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 303110A	Stability Sample 12 mo RT	Dissolution D1 = 72.8% D5 = 73.2% Spec: NLT [redacted]	Dissolution D1 = 98.5% D5 = 96.9% Spec: NLT [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	Stability Sample 6 mo RT	Assay - Propoxyphene A2 = 89.9% Spec: [redacted]	Assay - Propoxyphene A2 = 95.9% Spec: [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 201016C	Stability Sample 24 mo RT	Assay - Propoxyphene A1 = 89.9 % Assay - APAP A1 = 88.7 % Spec: [redacted]	Assay - Propoxyphene A1 = 100.5% Assay - APAP A1 = 98.9 % Spec: [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 312015	Finished Product Testing	Content Uniformity Propoxyphene CU5 = 117.8 % Spec: [redacted]	Content Uniformity Propoxyphene CU5 = 104.2% Spec: [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 310158	In-Process Blend Uniformity Testing	Propoxyphene TL1 = 238.5 % TR1 = 80.5 % APAP TL1 = 218.9% Spec: [redacted]	Propoxyphene TL1 = 103.2 % TR1 = 104.0 % APAP TL1 = 105.6 % Spec: [redacted]

Post -Approval Reporting

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OBSERVATION 3

An annual report did not include reports of investigations involving chemical or physical properties which, as new information, might affect FDA's previous conclusions about the safety or effectiveness of the drug.

a. Annual Reports for ANDA's that were submitted to FDA did not include out of specification (OOS) results. Only passing data points were submitted. Due to the submission of erroneous data the following ANDA's were withdrawn.

Annual Report submitted 8/24/04, for reporting period 7/12/03 through 7/11/04

Product/Batch #	ANDA	Sample Type	OOS Results	Reported Result
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 303110A	75-838	Stability Sample 12 mo RT	Dissolution Tablet D1 = 72.8% D5 = 73.2% Spec: NLT [redacted]	Dissolution Tablet D1 = 98.5% D5 = 96.9% Spec: NLT [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 201016C	75-838	Stability Sample 24 mo RT	Assay - Propoxyphene A1 = 89.9 % Assay - APAP A1 = 88.7 % Spec: [redacted]	Assay - Propoxyphene A1 = 100.5% Assay - APAP A1 = 98.9 % Spec: [redacted]

Annual Report submitted 11/6/02, for reporting period 7/11/01 through 7/11/02

Product/Batch #	ANDA	Sample Type	OOS Results	Reported Result
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	75-838	Stability Sample 6 mo RT	Assay - Propoxyphene A2 = 89.9% Spec: [redacted] %	Assay - Propoxyphene A2 = 95.9% Spec: [redacted]

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(-) [redacted]

Annual Report submitted 8/11/04, for reporting period 7/12/03 through 7/11/04

Product/Batch #	ANDA	Sample Type	OOS Results	Reported Result
Prochlorperazine Suppositories, 2.5 mg Batch 308029A	40-407	Stability Sample Initial, 6 and 9 month RT	Unknown Impurities Initial: 0.41% & 0.37% 6M: 0.28, 0.29 & 0.23% 9M: 0.32 & 0.33% Spec: NMT [redacted]	Highest Unknown Impurities Initial: < 0.01% 6M: 0.14% 9M: 0.05% Spec: NMT [redacted]
Prochlorperazine Suppositories, 5 mg Batch 308030A	40-407	Stability Sample 3 & 6 month RT	Unknown Impurities 3M: 0.32% 6M: 0.30% Spec: NMT [redacted]	Highest Unknown Impurities 3M: 0.05% 6M: 0.15% Spec: NMT [redacted]

Annual Report submitted 6/9/04, for reporting period 5/10/03 through 4/10/04

Product/Batch #	ANDA	Sample Type	OOS Result	Reported Result
Methylphenidate HCl Tablets, 20 mg Extended Release Batch 303087A&B	76-032	Finished Product Testing	Dissolution (1 Hour) D1: 48.9 % D2: 49.0 % D3: 48.2 % Spec: [redacted]	Dissolution (1 Hour) D1: 43.4 % D2: 43.3 % D3: 42.4 % Spec: [redacted]

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Annual Report submitted 5/26/05, for reporting period 3/30/04 through 3/29/05

Product/Batch #	ANDA	Sample Type	OOS Result	Reported Result
Methylphenidate HCl Tablets, 5 mg Batch 202005A	40-404	18 mo RT Stability Testing	Pooled Dissolution 84.5% Spec: NLT [redacted]	Pooled Dissolution 92.2% Spec: NLT [redacted]

b. Prior Approval Supplement #004 for ANDA 75-838, Propoxyphene Napsylate and APAP Tablets, 100/650mg, was submitted on 3/16/04 to provide for the discontinuance of Blend Uniformity Testing. This supplement was approved 9/23/04. The test data submitted for Blend Uniformity and Content Uniformity did not contain initial OOS results for a number of batches, only passing results were submitted. Due to the submission of erroneous data the ANDA was withdrawn. OOS results for these batches are listed below.

Batch #	Sample Type	OOS Result	Reported Range
309013	Finished Product Content Uniformity	Propoxyphene: CU8 = 84.1% Specification: [redacted]	102.3% - 108.1%
309014	Finished Product Content Uniformity	Propoxyphene: CU8 = 84.1% Specification: [redacted]	101.6% - 107.5%
309016	In-process Blend Uniformity	Propoxyphene: BL1 = 110.3% Specification: [redacted]	97.6% - 107.0%
312015	Finished product Content Uniformity	Propoxyphene: CU5 = 117.8% Specification: [redacted]	102.8% - 108.2%
312022	In-process Blend Uniformity	Propoxyphene: TL2 = 110.5% ML2 = 110.6% Specification: [redacted]	99.0% - 107.7%
310052	In-process Blend Uniformity	Propoxyphene: TR2 = 110.2% Specification: [redacted]	99.0% - 106.6%
310158	In-process Blend Uniformity	Propoxyphene: TR1 = 80.5% TL1 = 238.5% Acetaminophen: TL1 = 218.9% Specification: [redacted]	94.7% - 105.2% 98.5% - 107.7%
310150	Finished product Content Uniformity	Propoxyphene: CU10 = 80.6% Acetaminophen: CU10 = 80.1% Specification: [redacted]	99.8% - 106.5% 97.8% - 99.9%

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Batch #	Sample Type	OOS Result	Reported Range
312005	In-process Blend Uniformity	Propoxyphene: BR1 = 110.4% Specification: [redacted]	96.2% - 107.8%
312007	In-process Blend Uniformity	Propoxyphene: TL1 = 113.4% Specification: [redacted]	97.6% - 106.9%
312044	In-process Blend Uniformity	Propoxyphene: TL2 = 83.7% : ML2 = 84.0% Specification: [redacted]	93.3% - 100.5%
312079	In-process Blend Uniformity	Propoxyphene: TL1 = 116.9% Specification: [redacted]	95.9% - 106.5%

OBSERVATION 4

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Field Alerts were not routinely filed when drug products did not meet the specifications listed in the Abbreviated New Drug Application (ANDA). There is no SOP covering the issuance of Field Alerts. Field Alerts (FA) were not submitted when the following batches of drug products failed to meet stability specifications.

Product/Batch #	ANDA	Sample	Failing Result – No F/A Submitted	Reported Result
Atenolol 25 mg Tablet Validation Batch 408107A	76-907	Stability Sample 3 mo RT	Dissolution , Tablet D5 = 83.7% D6 = 83.8% Spec: NLT [redacted]	Dissolution , Tablet D5 = 98.9% D6 = 98.7% Spec: NLT [redacted]
Atenolol 25 mg Tablet Validation Batch 408107B	76-907	Stability Sample 3 mo RT	Dissolution Testing Tablet D6 = 30.9% Spec: NLT [redacted]	Dissolution Testing Tablet D6 = 102.8% Spec: NLT [redacted]
Diphenoxylate HCl and Atropine Sulfate Tablet, Batch 301068A	40-395	Stability Sample 21 mo RT	Assay - Atropine A1 = 78.4% A2 = 78.7% Spec: [redacted]	Assay - Atropine A1 = 90.4% A2 = 90.8% Spec: [redacted]

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Product/Batch #	ANDA	Sample	Failing Result – No F/A Submitted	Reported Result
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 303110A	75-838	Stability Sample 12 mo RT	Dissolution Tablet D1 = 72.8% D5 = 73.2% Spec: NLT [redacted]	Dissolution Tablet D1 = 98.5% D5 = 96.9% Spec: NLT [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	75-838	Stability Sample 6 mo RT	Assay - Propoxyphene A2 = 89.9% Spec: [redacted]	Assay- Propoxyphene A2 = 95.9% Spec: [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 201016C	75-838	Stability Sample 24 mo RT	Assay - Propoxyphene A1 = 89.9 % Assay - APAP A1 = 88.7 % Spec: [redacted]	Assay - Propoxyphene A1 = 100.5% Assay - APAP A1 = 98.9 % Spec: [redacted]
Prochlorperazine Suppositories, 2.5 mg Batch 308029A	40-407	Stability Sample Initial, 6, 9 and 12 mo RT	Unknown Impurities Initial:0.41% & 0.37%, 6M: 0.28, 0.29 & 0.23% 9M: 0.32 & 0.33% 12M: 0.52, 0.73% Spec: NMT [redacted]	Highest Unknown Impurities Initial:< 0.01%, 6M: 0.14% 9M: 0.05% 12M: 0.04% Spec: NMT [redacted]
Prochlorperazine Suppositories, 5 mg Batch 308030A	40-407	Stability Sample 3, 6, & 12 mo RT	Unknown Impurities 3M: 0.32% 6M: 0.30% 12M: 0.44% & 0.56% Spec: NMT [redacted]	Highest Unknown Impurities Spec: NMT 0.2% 3M: .05% 6M: 0.15% 12M: 0.14% Spec: NMT [redacted]

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Laboratory Control System

OBSERVATION 5

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

The QC Laboratory notebooks and binders lacked data from all analytical testing conducted in the QC Laboratory. Laboratory records did not include all data such as out of specification (OOS) results, chromatograms, sample weights, and processing methods. OOS results were substituted with passing results by Analysts and Supervisors. The substitution of data was performed by cutting and pasting of chromatograms, substituting vials, changing sample weights and changing processing methods. For Example:

Product /Batch Number	Lack of Complete Data
Products and batches listed in FDA-483, point # 2	OOS results not documented in laboratory records. Unreported OOS results found in electronic data files.
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 303110A	Changed chromatogram headers by cutting and pasting, so during review all sample injections would appear to be in sequence, for Dissolution Testing of Tablets D1 and D5.
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	Original Sample Weights not recorded in notebook. Sample weights were changed by the analyst until a passing result was obtained for Assay (A2)
Acetaminophen & Codeine Phosphate Tablets, 300/30mg Batch 407148	Processing methods changed by analyst until the processing method resulted in a passing result. Original processing method not recorded in laboratory notebook.

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OBSERVATION 6

Input to and output from the computer and records or data are not checked for accuracy.

Audits were not conducted of the (-) [redacted] System used to run the HPLC instruments during analysis of drug products. Sample injections, processing methods, and sample weights were not reviewed or verified for the accuracy of reported sample results during testing of in-process, finished product and stability samples.

OBSERVATION 7

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Laboratory investigations were not conducted when out of specification (OOS) results were generated during in-process, finished product and stability testing of drug products. Examples of batches where OOS results were generated and not investigated are included in FDA-483, point # 2. Quality Control Procedure, SOP # QC-021-06, Acceptance/Rejection Criteria for OOS Analytical Test Results, requires an investigation be conducted when OOS results are generated.

OBSERVATION 8

Employees are not given training in current good manufacturing practices and written procedures required by current good manufacturing practice regulations.

QC Laboratory analysts were not routinely trained in Quality Control procedures such as SOP # QC-011-03, Laboratory Deviation Investigations and SOP # QC-021-06, Acceptance/Rejection Criteria for OOS Analytical Test Results. This lack of training and oversight by management contributed to the non-reporting of OOS results in the QC Laboratory.

SEE REVERSE OF THIS PAGE

AMENDED

MKH 7-6-05
DC MR

DATE ISSUED
07/06/2005

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax:(973) 526-6069	05/02/2005 - 07/01/2005*
	FEI NUMBER 3004106764

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Garth (NMI) Boehm, Ph.D., Senior Vice President, Chief Scientific Officer

FIRM NAME	STREET ADDRESS
Able Laboratories, Inc.	One Able Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cranbury, NJ 08512	Generic Pharmaceutical Manufacturer

OBSERVATION 9

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and followup.

OOS Investigation # 04-00S-031, for Methylphenidate HCl ER Tablets 20 mg 18 month stability lot 303087A was initiated due to dissolution failing results. The specification required the average of 24 tablets to be within the range of [redacted] at the L3, 1 hour dissolution time point. The average of the 24 tablets was reported to be 48.4% with a minimum result of 45.8% and a maximum of 50.2%. The investigation was found to be incomplete. The investigation concluded that the original failing results were invalid due to an analyst technique issue. There was no documentation provided within the investigation or within the analyst notebook to justify invalidating the failing dissolution results. Although corrective measures were identified in the investigation, there was no documentation to show that the corrective measures had been completed. Additionally, there was no review of data acquired by the same analysts for the same tests for other lots of the same product.

OBSERVATION 10

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

a. The Laboratory Records SOP # QC-022-04 effective 6/25/04, specified numerically ordered notebooks will be issued and a log maintained. Notebook issuance logs showed large gaps in numbering of notebooks issued, which were not accounted for in the log. Additionally, the procedure for issuance of notebooks, as described by management, which indicated a notebook request form was to be used, was not described in the procedure available.

b. SOP Method Number I-037, approved 10/18/00, General Guidelines for sample Logging for Analytical Laboratory using [redacted] software did not include procedures and responsibilities to be followed by personnel authorized to enter samples into the [redacted] database. According to management, authorized personnel included floor inspectors and incoming inspectors. The SOP required the use of forms to authorize addition or deletion of groups, items, samples, and users to the [redacted] system. Forms to be used to authorize the addition or deletion of groups, items, samples, and users to the [redacted] system as specified by the SOP were not used.

c. There was no SOP describing the use of (SP) special samples tested in the Analytical Laboratory. Additionally, special samples were not listed as a group in the [redacted] procedure. Special samples in the testing of Methylphenidate HCl ER Tablets 20mg Lot # 303087A 9MRT SP 04-101 dated 4/24/04(6 tablets) and SP04-101

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(6 tablets) dated 4/26/04 were used to report L3 Dissolution results for the stability sample #ST04-407 for the same lot. Dissolution testing for L2 and L3 were not labeled L2 and L3 in the notebook.

OBSERVATION 11

Established laboratory control mechanisms are not followed.

a. An Investigation was not issued prior to any retesting for Lot 303087B, Methylphenidate HCl ER 18M stability lot, as required by procedure SOP # QC-011-03, Laboratory Deviation Investigation. Lot 303087B, Methylphenidate HCl ER Tablets 20 mg, 18M Dissolution stability analysis found that the original L3 testing results were within specification. Two months after the analysis of 24 tablets for Lot 303087B for 18M stability, 6 more tablets were tested. The results from the final analysis of the 6 tablets were reported as 18 M Dissolution results.

b. SOP # QC-006-01 Retesting and Resampling Analytical Control Laboratory, effective 8/27/03 was not followed for Methylphenidate HCl ER18M stability lot 303087A:

1. There was no documentation of the number of retests to be performed as required by the SOP. The SOP required the number of retest to be documented prior to initiating testing to establish a definite limit beyond which no additional testing would be permitted.

2. The procedure required retests to be conducted by the original chemist and a second chemist, where the second chemist conducts at least 60% of the tests, or by two chemists, neither of which being the chemist producing the original result. Retests were not carried out by the original chemist and a second chemist. Additionally, the test was not carried out by two chemists other than the original chemist.

3. Investigation 04-OOS-031, initiated 12/8/04 and completed 2/18/05, exceeded 30 working days. The procedure required investigations to be completed in a brief time frame not to exceed 30 working days from the start of the investigation.

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Production System

OBSERVATION 12

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.

a. There is no assurance that results for in-process physical testing are recorded accurately. For example, the Pre-Validation batch record (TB-110) for Hydrocodone Bitartrate and Acetaminophen Tablets, USP 5mg/325mg shows the specification for tablet thickness range as 0.308" to 0.358"; this range was crossed out and the correct range of ([redacted] was handwritten in the batch record. The in-process tablet thickness results show all tablets were within the corrected thickness specification of [redacted]" during compression on 10/15/01. The Research and Development (R&D) In-Process Data Sheet shows the thickness of 60 tablets to be within a thickness range of 0.330" and 0.334" which corresponds to the tablet thickness specification which was incorrectly written on the Master Batch Record. Retains from this batch were tested on 6/10/05, and the results show the thickness of the tablets were between [redacted] which was the correct specification that was handwritten on the Master Batch Record.

b. Manufacturing Investigations into rejected batches of drug products did not include an evaluation of the validated manufacturing process. For example, seven of nine batches (78%) of Methylphenidate ER 20 mg Tablets, manufactured between May 2003 and November 2004 were investigated in the laboratory, due to initial OOS results or out of trend results. Two of the seven lab investigations, resulted in the rejection of batches 411021 and 310004. Manufacturing Investigations, 04-008, for batch 310004, and Manufacturing Investigation 05-001, for batch, 411021 did not include an evaluation of the validated manufacturing process for Methylphenidate ER 20 mg Tablets.

c. There is no assurance that manufacturing processes for drug products are validated in that out of specification (OOS) results were generated, but not reported. Several examples are listed below.

Product Validation Batch #	Type Sample	Original OOS Result	Reported Results
Atenolol 25 mg Tablet Validation Batch 408107A	Stability Sample 3 mo RT	Dissolution , Tablet D5 = 83.7% D6 = 83.8% Spec: NLT [redacted]%	Dissolution , Tablet D5 = 98.9% D6 = 98.7% Spec: NLT [redacted]%

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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Product Validation Batch #	Type Sample	Original OOS Result	Reported Results
Atenolol 25 mg Tablet Validation Batch 408107B	Stability Sample 3 mo RT	Dissolution Testing Tablet D6 = 30.9% Spec: NLT (-)	Dissolution Testing Tablet D6 = 102.8% Spec: NLT [redacted]
Propoxyphene Napsylate and APAP Tablets, 100/650mg 104026B Validation Batch	Stability Sample 6 mo RT	Assay - Propoxyphene A2 = 89.9% Spec: (-) [redacted]	Assay A2 = 95.9% Spec: (-) [redacted]

*** DATES OF INSPECTION:**
05/02/2005(Mon), 05/03/2005(Tue), 05/04/2005(Wed), 05/05/2005(Thu), 05/09/2005(Mon), 05/10/2005(Tue), 05/11/2005(Wed), 05/12/2005(Thu), 05/16/2005(Mon), 05/17/2005(Tue), 05/18/2005(Wed), 05/19/2005(Thu), 05/20/2005(Fri), 05/23/2005(Mon), 05/24/2005(Tue), 05/25/2005(Wed), 05/26/2005(Thu), 05/27/2005(Fri), 05/31/2005(Tue), 06/01/2005(Wed), 06/02/2005(Thu), 06/06/2005(Mon), 06/09/2005(Thu), 06/10/2005(Fri), 06/15/2005(Wed), 06/23/2005(Thu), 06/29/2005(Wed), 06/30/2005(Thu), 07/01/2005(Fri)

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