	ALTH AND HUMAN SERVICES RUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER	DAYE(E) OF INEFECTION	
10 Waterview Blvd., 3rd Floor	05/02/2005 - 07/01/2005*	
Parsippany, NJ 07054	FEI NUMBER	
(973) 526-6000 Fax: (973) 526-6069	3004106764	
NUME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
TO: Garth (NMI) Boehm, Ph.D., Senior Vi	ce President, Chief Scientific Officer	
FIRM NAME	STREET ADDRESS	
Able Laboratories, Inc.	One Able Drive	
CITY, STATE, 2P COOE, 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 6/12/05 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.

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 reinjection 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

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10 Waterview Blvd., 3rd Floor	05/02/2005 - 07/01/2005*
Parsippany, NJ 07054	FEI NUMBER
(973) 526-6000 Fax: (973) 526-6069	3004106764
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	or Vice President, Chief Scientific Officer
FIRM NAME	ETREET ADDRESS
Able Laboratories, Inc.	One Able Drive
CITY, STATE, ZP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cranbury, NJ 08512	Generic Pharmaceutical Manufacturer

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 &	In-Process	Codeine Phosphate	Codeine Phosphate
Codeine Phosphate	Blend	% RSD: 5.4 %	% RSD: 3.8 %
Tablet, 300/30 mg	Uniformity		
Batch 502022	Testing	Spec:(-)	Spec: RSD ≤= a
Acetaminophen &	Finished	Codeine Phosphate	Codeine Phosphate
Codeine Phosphate	Product	Content Uniformity	Content Uniformity
Tablet, 300/30 mg	Testing	% RSD: 8.3 %	% RSD: 5.5 %
Batch 407148		Spec: RSD (a)	Spec: RSD ≤
Atenolol 25 mg Tablet	Stability	Dissolution, Tablet	Dissolution, Tablet
Validation Batch	Sample	D5 = 83.7%	D5 = 98.9%
408107A	3 mo RT	D6 = 83.8%	D6 = 98.7%
		Spec: NLT A	Spec: NLT
Atenolol 25 mg Tablet	Stability	Dissolution Testing	Dissolution Testing
Validation Batch	Sample	Tablet D6 = 30.9%	Tablet D6 = 102.8%
408107B	3 mo RT	Spec: NLT	Spec: NLT
Atenolol 25 mg Tablet	Stability	Dissolution, Tablet	Dissolution, Tablet
Test Batch	Sample	D5 = 83.7%	D5 = 98.9%
TB-203E	3 mo RT	D6 = 83.8%	D6 = 98.7%
		Spec: NLT	Spec: NLT
Bethanechol Chloride	Stability	Assay	Assay
10 mg Tablet	Sample	A1 = 89.6%	A1 = 99.5%
Validation Batch	9 mo RT	·	
404042A		Spec: 6	Spec: A
Diphenoxylate HCl	In-Process	Blender Location:	Blender Location:
and Atropine Sulfate	Blend	BR1 = 128.5%	BR1 = 99.5%
Tablets	Uniformity	ML2 = 158.3%	ML2 = 101.6%
Batch 404006	Testing	TL2 = 117.6%	TL2 = 108.3%
		Spec. Augustia	Spec. A
Diphenoxylate HCl	In-Process	Blender Location:	Blender Location:
and Atropine Sulfate	Blend	TR1= 145.9%	TR1 = 96.9 %
Tablets	Uniformity	<u></u>	'li
Batch 403203	Testing	Spec: 6	Spec: A

Daich 403.	203 Lesuing	Spec: (6) Spec: (a)	
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Parsippany, NJ 07054	FEINLAGEN
(973) 526-6000 Fax: (973) 526-6069	9 3004106764
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Garth (NMI) Boehm, Ph.D., Ser	nior Vice President, Chief Scientific Officer
FIRM NAME	STREET ADDRESS
Able Laboratories, Inc.	One Able Drive
City, STATE, EP COOK, COUNTRY	TYPE ESTABLISHMENT WEPECTED
Cranbury, NJ 08512	Generic Pharmaceutical Manufacturer

Product/Batch #	Sample	Original OOS Result	Reported Results
Diphenoxylate HCl	Stability	Assay	Assay
and Atropine Sulfate	Sample	A1 = 78.4%	A1 = 90.4%
Tablet, Batch	21 mo RT	A2 = 78.7%	A2 = 90.8%
301068A		Spec:	Spec:
Diphenoxylate HCl	Stability	Assay	Assay
and Atropine Sulfate	Sample	A1 = 77.5%	A1 = 90.11%
Tablet, Batch	21 mo RT	A2 = 77.5%	A2 = 89.8%
301068B		Spec. Attacked	Spec: (a)
Diphenoxylate HCl	Stability	Assay	Assay
and Atropine Sulfate	Sample	A1 = 75.8%	A1 = 89.41%
Tablet, Batch	21 mo RT	A2 = 78.4%	A2 = 90.7%
301068C		Spec: A	Spec: (a)
Dytan Suspension	Finished	Assay - Beginning	Assay - Beginning
25mg/5ml	Product	A2 = 89.2%	A2 = 97.9%
Batch L409001	Testing	Spec: (a)	Spec:
Methylphenidate HCl	Finished	Dissolution (1 Hour)	Dissolution (1 Hour)
Tablets, 20 mg	Product	Tablet: D1: 48.9%	Tablet: D1: 43.4%
Extended Release	Testing	D2: 49.0%	D2: 43.3%
Batch 303087	_	D3: 48.2%	D3: 42.4%
		Spec: (1 hour)	Spec: (1 hour)
Methylphenidate HCl	Finished	Assay	Assay
Tablets, 5 mg	Product	A1 = 90.0%	A1 = 98.4%
Batch 412184	Testing	A2 = 90.0%	A2 = 98.5%
		Spec.	Spec. 6
Nitroglycerin 0.4 mg	Finished	Assay	Assay
Sublingual Tablets	Product	A1 = <u>75.8%</u>	A1 = 101.5%
Batch 502038	Testing	Spec./Statement	Spec: 6
Prochlorperazine	Stability	Unknown Impurities	Highest Unknown
Suppositories, 2.5 mg	Sample	0.52%	Impurities
Batch 308029A	12 mo RT	0.73%	0.04%
		Spec: NMT	Spec: NMT (-)
Prochlorperazine	Stability	Unknown Impurities	Highest Unknown
Suppositories, 5 mg	Sample	0.44 %	Impurities
Batch 308030A	12 mo RT	0.56 %	0.14%
	,	Spec: NMT	Spec: NMT

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10 Waterview Blvd., 3rd Floor	05/02/2005 - 07/01/2005*
Parsippany, NJ 07054	PE NAMES
(973) 526-6000 Fax: (973) 526-6069	3004106764
MANIE AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	1
TO: Garth (NMI) Boehm, Ph.D., Senj	or Vice President, Chief Scientific Officer
FIRM NAME	STREET ADDRESS
Able Laboratories, Inc.	One Able Drive
CITY, STATE, 21P CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cranbury, NJ 08512	Generic Pharmaceutical Manufacturer

Product/Batch #	Sample	Original OOS Result	Reported Results
Propoxyphene		Dissolution	Dissolution
Napsylate and APAP	Stability	D1 = 72.8%	D1 = 98.5%
Tablets, 100/650mg	Sample	D5 = 73.2%	D5 = 96.9%
Batch 303110A	12 mo RT		
		Spec: NLT 6	Spec: NLT
Propoxyphene	Stability	Assay - Propoxyphene	Assay - Propoxyphene
Napsylate and APAP	Sample		
Tablets, 100/650mg	6 mo RT	A2 = 89.9%	A2 = 95.9%
Batch 104026B			
Validation Batch		Spec:	Spec:⊕
Propoxyphene	Stability	Assay - Propoxyphene	Assay - Propoxyphene
Napsylate and APAP	Sample	A1 = 89.9 %	A1 = 100.5%
Tablets, 100/650mg	24 mo RT	Assay - APAP	Assay - APAP
Batch 201016C		A1 = 88.7 %	A1 = 98.9 %
		Spec://	Spec: (a)
Propoxyphene	Finished	Content Uniformity	Content Uniformity
Napsylate and APAP	Product	Propoxyphene	Propoxyphene
Tablets, 100/650mg	Testing	CU5 = 117.8 %	CU5 = 104.2%
Batch 312015		Spec: A	Spec: (a)
Propoxyphene	In-Process	Propoxyphene	Propoxyphene
Napsylate and APAP	Blend	TL1 = 238.5 %	TL1 = 103.2 %
Tablets, 100/650mg	Uniformity	TR1 = 80.5 %	TR1 = 104.0 %
Batch 310158	Testing	·	
		APAP	APAP
		TL1 = 218.9%	TL1 = 105.6 %
]	Spec:/9	Spec:

Post -Approval Reporting

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10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054	05/02/2005 - 07/01/2005*
(973) 526-6000 Fax: (973) 526-6069 NAME OF HOMOGRAPH TO WHICH REPORT BEING TO: Garth (NMI) Boehm, Ph.D., Senior V:	3004106764
Able Laboratories, Inc.	STREET ADDRESS One Able Drive
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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%	Dissolution Tablet D1 = 98.5% D5 = 96.9%
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 201016C	75-838	Stability Sample 24 mo RT	Spec: NLT Assay - Propoxyphene A1 = 89.9 % Assay - APAP A1 = 88.7 % Spec: A	Assay - Propoxyphene A1 = 100.5% Assay - APAP A1 = 98.9 % Spec: A

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: 6	Assay - Propoxyphene A2 = 95.9% Spec:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069 NAME AND THILD OF HOMODIAL TO WHOM REPORT SILVED TO: Garth (NMI) Boehm, Ph.D., Senior Vice President, Chief Scientific Officer FRANCHE Able Laboratories, Inc. One Able Drive CIT. STATE, 2P COOE, COUNTRY Cranbury, NJ 09512 Generic Pharmaceutical Manufacturer

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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	Highest Unknown Impurities Initial: < 0.01% 6M: 0.14% 9M: 0.05%
Prochlorperazine Suppositories, 5 mg Batch 308030A	40-407	Stability Sample 3 & 6 month RT	Unknown Impurities 3M: 0.32% 6M: 0.30% Spec: NMT	Spec: NMTA Highest Unknown Impurities 3M: 0.05% 6M: 0.15% Spec: NMT()

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:	Dissolution (1 Hour) D1: 43.4 % D2: 43.3 % D3: 42.4 % Spec:

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10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054	05/02/2005 - 07/01/2005*
(973) 526-6000 Fax: (973) 526-6069	3004106764
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Able Laboratories, Inc.	One Able Drive
Cranbury, NJ 08512	Generic Pharmaceutical Manufacturer

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	40-404	18 mo RT	Pooled Dissolution	Pooled Dissolution
Tablets, 5 mg		Stability	84.5%	92.2%
Batch 202005A		Testing	Spec: NLT	Spec: NLT

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	Propoxyphene: CU8 = 84.1%	102.3% - 108.1%
	Content Uniformity	Specification:	102.376 - 108.176
309014	Finished Product	Propoxyphene: CU8 = 84.1%	101.6% - 107.5%
	Content Uniformity	Specification: 6	101.076 - 107.376
309016	In-process Blend	Propoxyphene: BL1 = 110.3%	97.6% - 107.0%
	Uniformity	Specification:	77.070 - 107.076
312015	Finished product	Propoxyphene: CU5 = 117.8%	102.8% - 108.2%
	Content Uniformity	Specification:	102.070 - 100.276
312022	In-process Blend	Propoxyphene: TL2 = 110.5%	99.0% - 107.7%
	Uniformity	ML2 = 110.6%	107.776
		Specification:	
310052	In-process Blend	Propoxyphene: TR2 = 110.2%	99.0% - 106.6%
	Uniformity	Specification:	100:07
310158	In-process Blend	Propoxyphene: TR1 = 80.5%	94.7% - 105.2%
	Uniformity	TL1 = 238.5%	
		Acetaminophen: TL1 = 218.9%	98.5% - 107.7%
210160		Specification:	
310150	Finished product	Propoxyphene: CU10 = 80.6%	99.8% - 106.5%
	Content Uniformity	Acetaminophen: CU10 = 80.1%	97.8% - 99.9%
		Specification: 6	

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10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6060	05/02/2005 - 07/01/2005* FEINAMER 3004106764
YO: Garth (NMI) Boehm, Ph.D., Senio	or Vice President, Chief Scientific Officer
Able Laboratories, Inc. OTY. STATE AP CODE, COUNTRY Cranbury, NJ 08512	One Able Drive ***********************************

Batch #	Sample Type	OOS Result	Reported Range
312005	In-process Blend Uniformity	Propoxyphene: BR1 = 110.4% Specification:	96.2% - 107.8%
312007	In-process Blend Uniformity	Propoxyphene: TL1 = 113.4% Specification:	97.6% - 106.9%
312044	In-process Blend Uniformity	Propoxyphene: TL2 = 83.7% : ML2 = 84.0% Specification: 6	93.3% - 100.5%
312079	In-process Blend Uniformity	Propoxyphene: TL1 = 116.9% Specification:	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	Dissolution, Tablet D5 = 98.9% D6 = 98.7% Spec: NLT
Atenolol 25 mg Tablet Validation Batch 408107B	76-907	Stability Sample 3 mo RT	Dissolution Testing Tablet D6 = 30.9% Spec: NLT	Dissolution Testing Tablet D6 = 102.8% Spec: NLT
Diphenoxylate HCl and Atropine Sulfate Tablet, Batch 301068A	40-395	Stability Sample 21 mo RT	Assay - Atropine A1 = 78.4% A2 = 78.7% Spec:	Assay - Atropine A1 = 90.4% A2 = 90.8% Spec: 5

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	Or Vice President, Chief Scientific Officer STREET ADDRESS One Able Drive
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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%	Dissolution Tablet D1 = 98.5% D5 = 96.9%
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	75-838	Stability Sample 6 mo RT	Assay - Propoxyphene A2 = 89.9% Spec: 5	Assay- Propoxyphene A2 = 95.9%
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: A	Spec: 6 Assay - Propoxyphene A1 = 100.5% Assay - APAP A1 = 98.9 %
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	Highest Unknown Impurities Initial:<0.01%, 6M: 0.14% 9M: 0.05% 12M: 0.04%
Prochlorperazine Suppositories, 5 mg Satch 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	Spec: NMT Highest Unknown Impurities Spec: NMT 0.2% 3M: 05% 6M: 0.15% 12M: 0.14%

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10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	DIS/02/2005 - 07/01/2005* FRANKSK 3004106764
TO: Garth (NMI) Boehm, Ph.D., Senior V FROM NAME Able Laboratories, Inc. City, STATE 2P CODE, COLUMNY Cranbury, NJ 08512	One Able Drive
	Generic Pharmaceutical Manufacturer

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, solduring 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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	DEPARTMENT OF F	BEALTH AND HUMAN SI		
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Parsippant	7. NJ 07054	H	05/02/2005 - 07/	01/2005*
(973) 526-	6000 Fax: (973) 526-6069		3004106764	
	(NMI) Boehm, Ph.D., Senior	Vice President,		
Able Labor	atories Tem	1		Officer
CHY, STATE, ZIP COOE,	COUNTRY	One Able Dri	ve	
Cranbury,	NJ 08512	Generic Phar	maceutical Manuf	ecturer
OBSERVATK				
Audits were no during analysis	ot conducted of the (a) s of drug products. Sample injections, if the accuracy of reported sample results	Syste	on used to run the HP	LC instruments ere not reviewed
samples.	the accuracy of reported sample results	during testing of m-	process, finished produ	uct and stability
			1	
OBSERVATIO	N 7		•	
Written records a components to m	are not made of investigations into unexplained specifications.	ined discrepancies and	the failure of a batch or s	any of its
Laboratory invo process, finishe generated and n	estigations were not conducted when ou d product and stability testing of drug p not investigated are included in FDA-48 Rejection Criteria for OOS Applytical	at of specification (Oproducts. Examples of	OS) results were gener of batches where OOS	rated during in- results were
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10 Waterview Blvd., 3rd Floor	74.4	BATE(S) CIT	MERICINEN	
Parsippany, NJ 07054		05/02	/2005 - 07/0	1/2005*
(973) 526-6000 Fax: (973) 526-6069		1	06764	
TO: Garth (NMI) Boehm, Ph.D. Seni	or Vice Pres			
Able Laboratories, Inc.	SINCE! ADD	PLESS	SCIENCILIC	Officer
CITY, STATE, ZIP COOR, COUNTRY		ble Drive		
Cranbury, NJ 08512		ic Pharmaceu	tical Manufa	cturer
			<u></u>	
OBSERVATION 9				
Written records of investigations into unexplained dis	crepancies and the	e failure of a batcl	o or any of its con	monents to meet
specifications do not always include the conclusions a	nd followup.		•	
OOS Investigation # 04-00S-031, for Methylpher	nidate HCl ER T	`ablate 20 mg 18		1 - 2020074
was unusied due to missolution ishing lesinis	he specification i	required the av-		4-4-1
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1 TO TO WILL A HUMINIMIN I CSUIT OF 43.6% and a mar	X11110m of 50 7%	a The investion	HOW WHAT CALLED	An Lasters 4 .
THE DESCRIPTION OF THE PROPERTY OF THE PROPERTY IN THE PROPERT	itio regnite were s	mazalid disa éa an		•
failing dissolution results. Although corrective m	igation or within	i the analyst note	cbook to justify	invalidating the
documentation to show that the corrective measur	res had been com	nnleied Additio	walls than see	e was no
data acquired by the same analysts for the same te	ests for other lot	ipieceu. Auuquo cof the same pro	mally, there was	no review of
	/bm eve) UL MAN SERVE P	Ruci.	
OBSERVATION 10			• · · · · · · · · · · · · · · · · · · ·	
The responsibilities and procedures applicable to the qu	sality control unit	are not in writing	and fully followe	ed
a. The Laboratory Records SOP # QC-022-04 effe				
reserve and a toli institianico. Notebook issuance in	DVS showed large	t dans in number	ring of natabool	المنافح الاستنجارية
were not accounted for in the log. Additionally, the	te procedure for:	issuance of note	aboole on dead	M-11-
management, which indicated a notebook request	form was to be r	sed, was not de	scribed in the pr	weithe
available.		. !		COCCER O
h COD Mathed Number 1.027 amounted 10/10/00		<u>-</u> .	-	
b. SOP Method Number I-037, approved 10/18/00 Laboratory using A software did not include	, General Guider	ines for sample	Logging for An	alytical
authorized to enter samples into the A data	de procedures an Mase. Accordina	id responsibilitie	s to be followed	i by personnel
microded from mapectors and incoming inspectors.	. The SOP recruit	g to management	t, authorized per	rsonnel
deterior of groups, items, samples, and users to the	System 5	m. Forms to be	mis to authorize	addition or
or deletion of groups, items, samples, and users to		stem as specifie	d hy the SOP w	ere not used.
•	, —			
c. There was no SOP describing the use of (SP) special samples were not listed as a group in the	cial samples tes	ited in the Analy	tical Laboratory	y. Additionally,
special samples were not hated as a proup in the A	procedin	nt Special samo	ales in the testine	~ -£
Methylphenidate HCl ER Tablets 20mg Lot #3030	8/A MKI SF	04-101 dated 4/	24/04(6 tablets)	and \$204-101
		41+47-	r .nt	DATE BARRO
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INSPECTIONAL OBSERVATIONS

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DEPARTMENT OF HE DISTRICT ADDRESS AND PHONE NAMED. FOOD AND D.	ALTH AND HUMAN SERVICES RUG ADMINISTRATION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax: (973) 526-6069	04TE(0) OF NEFFECTION 05/02/2005 - 07/01/2005* FEINMANN 3004106764
TO: Garth (NMI) Boehm, Ph.D., Senior V	ice President, Chief Scientific Officer
Able Laboratories, Inc. CHY. STATE, JP CODE COUNTRY Cranbury, NJ 08512	One Able Drive TYPE ESTABLISHENT RESPECTED Generic Pharmaceutical Manufacturer

(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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DEPARTMENT OF FOOD AN	HEALTH AND HUMAN SERVICES D DRUG ADMINISTRATION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax:(973) 526-6069	05/02/2005 - 07/01/2005+ FEI HUMBER 3004106764
TO: Garth (NMI) Boehm, Ph.D., Senior Able Laboratories, Inc. ANY STATE 2P COOK COUNTRY Cranbury, NJ 08512	Vice President, Chief Scientific Officer STREET ADDRESS

Pr	oduction	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 a was handwritten in the batch record. The in-process tablet thickness results show all tablets were within the corrected thickness specification of 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 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: NLTA	Dissolution, Tablet D5 = 98.9% D6 = 98.7% Spec: NLT

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	FOOD AND DRUG ADMINISTRATIO	N SERVICES
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73) 526-60/	59	TEI NUMBER
AUED		3004106764
, Ph.D., S	enior Vice President	Chief Scientific off:
	One Able D	rive
	Generic Ph	armaceutical Manufacturer
Type	Original OOS Posult	Daniel 12
	Jugaan OOD Result	Reported Results
	Dissolution Testing	Director: D
	2 issortation resuing	Dissolution Testing
	Tablet D6 = 20 00/	Tally De cook
	120101250 - 30.9%	Tablet D6 = 102.8%
1	Spec: NI TA	Smar Norm
Stability		Spec: NLT
	1 mony - x topoxyptiene	Assay
_	A2 = 80 0%	40 55 55
	J 134 - 07.770	A2 = 95.9%
1	1	· · · -
	d Floor 73) 526-606	73) 526-6069 Jeff Ph.D., Senior Vice President STREET ADDRESS One Able In Three STARCHMENT Generic Ph Type Sample Stability Dissolution Testing Sample 3 mo RT Tablet D6 = 30.9% Spec: NLT (-) Stability Sample Stability Assay - Propoxyphene

* 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(Thu), 05/01/2005(Wed), 06/02/2005(Mon), 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)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

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Nancy L. Rolli, Investigator

Dail Dei

Daniel J. Grabicki, Investigator

11 Area K. Narmon 7-6-05 Marca K. Harmon, Investigator

Joanne Heim, Investigator

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INSPECTIONAL OBSERVATIONS

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