

4-1 FACTS SAMPLE COLLECTION SCREEN

Action Edit Options Related Info Navigate Tracing Help Window

Maintain Sample Collection

Page 1 2

Sample Collection

Sample Number: 786776 **Sample Class:** Normal Everyday Sam **Sampling District:** CIN-DO **Status:** In Progress **Modif Count #:**

Collector: Cartwright, Guy W **Collection Date:** 12/12/2012 **Lot Size:** 125 cases, 12/100 tablet bottles

Sample Origin: Domestic **Sample Basis:** Compliance **Sample Type:** Documentary

FIS Sample Number: 13 208647 **Episode Number:** **Related Sample:** **Compliance Number:**

Sample Description: No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce.

Collection Reason: Collected during EI of Dealer dated 12/10-12/12 to document cGMP deviations. No analysis necessary.

Collection Remarks: "Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper la

Associated Firms

Resp Firm Type: Dealer **FEI Number:** **Firm Type:** **Firm Name:**

<input type="checkbox"/> Dealer is Consumer	3007888982	Dealer	ARO Pharmaceuticals, 356 Nc	Add
	1021745	Ingredient Supplier	Master Supply, 123879 Prige S	Delete
	1021745	Shipper	Master Supply, 123879 Prige S	

Product

Product Code: 60 L B A 05 B **Brand Name:** Wlilaprin Arthritis Formula

Product Name: Aspirin (Analgesic); Human - Non/Rx Combination I **Product Description:** Aspirin tablets packaged in a clear, non-flexib

Product Label: Finished product. Label on bottle reads in part, ""*VWLAPRIN ARTHRITIS FORMULA 100 Tablets""Active ingredients: Acetylsal

Documents Obtained Manufacturing Codes Sample Flags

Action Edit Options Related Info Navigate Tracing Help Window

Maintain Sample Collection

Page 1 2

Sample Collection

Sample Number: 786776 **Sample Class:** Normal Everyday Sam **Sampling District:** CIN-DO **Status:** In Progress **Modif Count #:**

Collection Method: Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/1

State: **County:** **Country of Origin:**

Estimated Value: \$4,500.00 **Sample Cost:** **Payment Method:** **Receipt Issued:** None

Carrier Name: Roadway Inc. **Date Shipped:** 06/16/2012 **Consumer Complaint Number:** **Recall Number:**

How Prepared: Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photographs made using

Collector's ID On Package/Document: "DOC 786776 12/12/2012 SHR" **Collector's ID On Seal:** "DOC 786776 12/12/2012 Sylvia H. Rogers"

Sample Delivered To: **Sample Delivered Date:**

CR & Records Sent To FACTS Org: CIN-DO **Storage Requirement:**

CR & Records Sent To Non FACTS Org: **Food Canning Establishment:** 704 (d) Sample

Dairy Permit Number: **National Drug Code:** **CRx/DEA Schedule:** 702 (b) Portion Collected

Collection PACs

PAC Code	Description	FACTS Org?	Physical Sample Sent To
56002	DRUG PROCESS INSPECTIONS(DPI)	<input checked="" type="checkbox"/>	
		<input type="checkbox"/>	
		<input type="checkbox"/>	

Add Delete

Sample Flags

Sample Flags

Sample Flag	Remarks
301(k) Sample	

OK
Add
Delete

Documents Obtained

Document Type	Document Number	Document Date	Remarks
Affidavit	1.	12/12/2012	Signed by Nicholas I. Herkimer, President
Invoice	2.	06/06/2012	Invoice no. 2346 documenting Master Supp
Bill of Lading	3.	06/16/2012	Bill of lading no. 124679 documenting inter

OK
Add
Delete

Manufacturing Codes

Manufacturing Codes

Manufacturing Code	Exp Date
"Lot 25C83" (finished product)	8/13
"Batch 5564" (active ingredient)	8/14

OK
Add
Delete

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 786776

This is an accurate reproduction of the original electronic record as of 01/30/2015

Flag	Flag Remarks				
301(k) Sample					
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	13208647	In Progress
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3007888982	12/12/2012	60LBA05	Dealer	56002	.5
Compliance Num	Country of Origin				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	CIN-DO			
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Wilaprin Arthritis Formula	
Product Description					
Aspirin tablets packaged in a clear, non-flexible plastic bottle (See "Remarks")					
Product Label					
See continuation.					
Reason for Collection		MFG Codes		Expiration Date	
Collected during EI of Dealer dated 12/10-12/12 to document		"Lot 25C83" (finished product)		8/13	
cGMP deviations. No analysis necessary.		"Batch 5564" (active ingredient)		8/14	
Firm Legal Name	Address	Type of Firm	Firm FEI	FCE	
ARO Pharmaceuticals	356 Northview Dr Powell, OH 43065-9479	Dealer	3007888982		
	US				
Master Supply	123879 Prige Street Henderson, KY 42420	Ingredient	1021745		
	US	Supplier			
Master Supply	123879 Prige Street Henderson, KY 42420	Shipper	1021745		
	US				
Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped	
125 cases, 12/100 tablet bottles	\$ 4,500.00	None	Roadway Inc.	06/16/2012	
Description of Sample					
See continuation.					
Method of Collection					
Copies of records collected during EI at the Dealer dated 12/10-12/2012. Photograph taken on 12/11/2012. Affidavit obtained on 12/12/2012.					
How Prepared					
See continuation.					
Collector's Identification on Package and/or Label			Collector's Identification on Seal		
"DOC 786776 12/12/2012 SHR"			"DOC 786776 12/12/2012 Sylvia H. Rogers"		
Sample Delivered To		Date Delivered	Orig C/R & Records To		
			CIN-DO		
		Lab w/Split Sample	Lab		
Document Number	Document Date	Document Type	Document Remarks		
1.	12/12/2012	Affidavit	Signed by Nicholas I. Herkimer, President. (1 page.)		
2.	06/06/2012	Invoice	Invoice no. 2346 documenting Master Supply's sale		

Date: 01/30/2015

Page: 1 of 3

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 786776

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3.	06/16/2012	Bill of Lading	of 1 - 250 lb. drum of acetylsalicylic acid batch no. 5564 to the Dealer. (1 page.) Bill of lading no. 124679 documenting interstate shipment of 1 - 250 lb. drum of acetylsalicylic acid from Master Supply, Henderson, KY to the Dealer via Roadway Inc. (2 pages.)
4.	06/16/2012	Other	"Raw Material Inventory Record" documenting the receipt of acetylsalicylic acid batch no. 5564. (1 page.)
5.	11/21/2012	Other	"ARO Pharmaceuticals Batch Record" for Wilaprin Arthritis Formula lot 25C83 documenting the manufacturing, packaging and labeling of the finished product and the related quality records. (20 pages.)

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
Sylvia H. Rogers	Sylvia H. Rogers	No	No	Sylvia H. Rogers
		Date & Time of Signature		Meaning
		12/12/2012 12:40 PM ET		Collector

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 786776**

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Continuation:**Product Label**

Finished product: Label on bottle reads in part, "****WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Paperboard carton reads in part, "WILAPRIN ARTHRITIS FORMULA 100 Tablets***Active ingredients: Acetylsalicylic acid 500 mg.***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." Printing on cardboard box reads in part, "****WILAPRIN ARTHRITIS FORMULA***12/100 Tablet Bottles***Lot 25C83***EXP 8/2013***ARO Pharmaceuticals***Powell, OH 43065***." (Labeling attached as part of the "Master Pharmaceuticals Batch Record" on pages 13 - 15.)

Active ingredient: Label on drum reads in part, "****Acetylsalicylic Acid UPS***Batch No. 5564***Use by 8/14***Net Weight 250 lbs.***Master Supply Henderson, KY 42420***." (Photograph attached on page 26.)

Description of Sample

No physical sample collected. Documentation accompanying sample includes copies of records documenting interstate commerce and cGMP deviations, one photograph and an affidavit.

How Prepared

Records and mini CD-R identified as in the "Collector's ID on Package/Document" field. Original copy of digital photographs made using a mini CD-R, which was officially sealed in a FDA 525 envelope as in the "Collector's ID on Seal" field.

Remarks

"Product Description" (continued): with a white screw-on cap with a clear plastic seal. Bottle has yellow wrap around paper label with black printing. Bottle packaged in a white paperboard carton with black printing. Packed 12 cartons per box in a brown corrugated cardboard box with black printing.

Refer to EIR of Dealer dated 12/10-12/2012. FDA 483 dated 12/12/12 observation nos. 1 through 5 are cGMP observations related to this product.