



Sample Collection

Sample Number: 2340
 Sample Class: Normal Everyday Sam
 Sampling District: CHI-DO
 Status: In Progress
 Modif Count #:

Collector: Rogers, Sylvia H
 Collection Date: 09/25/2000
 Lot Size: 125CS/12BTL/100 TAB
Sample Origin:
 Sample Basis:
 Sample Type: Documentary
FIS Sample Number: 00
Episode Number:
Related Sample:
Compliance Number:

Sample Description: Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wluprin A

Collection Reason: Collected during EI of dealer, dated 9/20-25/2000 to document interstate commerce and cGMP deviations. No analysis needed.

Collection Remarks: See EIR of Dealer and FDA-483, dated 9/20-25/2000 for more information. Product description continued ***non-flexible plastic

Associated Firms

Resp Firm Type: Dealer Dealer is Consumer

FEI Number	Firm Type	Firm Name
3000901032	Dealer	Wluprin Pharmaceutical, 30
3000901032	IngredientSupplier	Woleske Chemical, 100 W. M

Product

Product Code: 60 L B A 05 B
 Brand Name: Wluprin Arthritis Formula
Product Name: Aspirin (Analgesic); Human - Non/Rx Combination Ir
Product Description: Aspirin tablets packed in clear*** see remarks
Product Label: Finished product labeled in part "***WLAPRIN ARTHRITIS FORMULA 500 Tablets*** Active ingredients: Acetylsalcylic Acid...



Sample Collection

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 Modif Count #:

Collection Method: Copies of records collected during EI of Dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.
State: L
County: COOK
Country of Origin: United States
Estimated Value: \$4,500.00
Sample Cost: \$0.00
Payment Method: No Charge
Receipt Issued: None
Carrier Name: Roadway Inc.
Date Shipped: 06/16/2000
Consumer Complaint Number:
Recall Number:

How Prepared: All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525

Collector's ID On Package/Document: "DOC 2340 9/25/00 SHR"
Collector's ID On Seal: "DOC 2340 9/25/00 Sylvia H. Rogers"
Sample Delivered To:
Sample Delivered Date:
CR & Records Sent To FACTS Org: CHI-DO
CR & Records Sent To Non FACTS Org:
Storage Requirement:
Food Canning Establishment:
 704 (d) Sample
Dairy Permit Number:
CRx/DEA Schedule:
 702 (b) Portion Collected
National Drug Code:

Collection PACs

PAC Code	Description
56002	DRUG PROCESS INSPECTIONS(DPI)

FACTS Org?
Physical Sample Sent To

Sample Flags

Sample Flag	Remarks
301(k) Sample	

OK
Add
Delete

Documents Obtained

Document

Document Type	Document Number	Document Date	Remarks
Affidavit	1	09/25/2000	Affidavit signed by Robert Wilson, Presid
Invoice	2	06/16/2000	Invoice no. 2346 dated 06/16/2000 from
Bill of Lading	3	06/16/2000	Bill of lading no. 124679 dated 06/16/2000

OK
Add
Delete

Manufacturing Codes

Manufacturing Code	Exp Date
"Lot 25C83" (Finished Product)	8/06
"Batch 5564" (Active Ingredient)	8/02

OK
Add
Delete

**United States Food and Drug Administration
Collection Report
For Sample Number: 2340**

This is an accurate reproduction of the original electronic record as of 11/07/2003

Flag	Flag Remarks				
301(k) Sample					
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Documentary	00908358	In Progress
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3000901032	09/25/2000	60LBA05	Dealer	56002	8
Compliance Num	Country of Origin				
Related Smpl Number	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt
	2	CHI-DO			
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Wilaprin Arthritis Formula	

Product Description
Aspirin Non-Rx Combination Tablet

Product Label
See continuation

Reason for Collection	MFG Codes	Expiration Date
Collected during EI of dealer, dated 9/20-25/2000 to document Interstate commerce and cGMP deviations. No analysis needed	"Lot 25C83" (Finished Product)	8/06
	"Batch 5564" (Active Ingredient)	8/02

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Wilson Pharmaceutical	300 Riverside Chicago, IL 60606 US	Dealer	3000901032	
Woleske Chemical	100 W. Main Kansas City, MO 64111 US	Ingredient Supplier	3000901033	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
125 CS/12 BTLS/100 TAB	\$4,500	None	Roadway	06/06/1999

Description of Sample
Sample consists of 3 photographs and copies of records documenting interstate commerce and cGMP deficiencies for Wilaprin Arthritis Formula

Method of Collection
Copies of records collected during EI of dealer, dated 09/20-25/2000. Photographs taken 09/23/2000.

How Prepared
See continuation.

Collector's Identification on Package and/or Label	Collector's Identification on Seal
"DOC 2340 9/25/00 SHR"	"DOC 2340 9/25/00 Sylvia H. Rogers"

Samples Delivered To	Date Delivered	Orig C/R & Records To
		CHI-DO

**United States Food and Drug Administration
Collection Report
For Sample Number: 2340**

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Lab w/Split Sample Lab

Document Number	Document Date	Document Type	Document Remarks
1.	09/25/2000	Affidavit	Affidavit signed by Robert Wilson, President
2.	06/16/2000	Invoice	Invoice no. 2346 dated 06/16/2000 from Woleske Chemical, Kansas, MO for 1-250 lb drum of Acetylsalicylic Acid, batch 5564
3.	06/16/2000	Bill of Lading	Bill of Lading no. 124679 dated 06/16/2000 from Roadway Inc. Smith Center Kansas for shipment of 250 lbs of Acetylsalicylic Acid from Woleske Chemical, Kansas City, MO to Wilson Pharmaceutical, Inc. Chicago, IL
4.		Other	Raw Material Inventory Card for Acetylsalicylic Acid Batch no. 5564
5.		Other	Photographs 1-3 of labeling for bulk 250 lb. Drum of Acetylsalicylic Acid, Batch 5564
6.		Other	Wilson Pharmaceuticals Batch Record for Wilaprin Arthritis Formula, lot 25C83 (25 pages) (Page 13, 14 and 15 contain copies of all labeling distributed with lot 25C83)

Remarks

See EIR of dealer and FDA-483, dated 9/20-25/2000 for more information. FDA-483 points 1-12 discuss deviations specific to this product.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Silvia H. Rogers

Name of Signer	Date & Time of Signature	Meaning

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Product Label

Finished product is labeled in part: “***WILAPRIN ARTHRITIS FORMULA 500 Tablets***Active Ingredients: Acetylsalicylic Acid...5000mg, Caffeine...32mg.***100 Tablets***Lot 25C83***EXP 8/06***Wilson Pharmaceuticals, Chicago, IL 60606”. Each bottle is placed in a white, paperboard box labeled in part, “*** WILAPRIN ARTHRITIS FORMULA *** 100 Tablets Active ingredients: Acetylsalicylic Acid...5000mg, Caffeine...32mg. ***Lot #25C83 Expires 8/06 *** Wilson Pharmaceuticals, ***”. White paperboard boxes are placed in brown cardboard cartons labeled in part, “*** WILAPRIN ARTHRITIS FORMULA ***Wilson Pharmaceuticals***Lot 25C83***EXP8/06***”

Active ingredient documented is Acetylsalicylic Acid packaged in 250 lb drum, labeled in part: “***Acetylsalicylic Acid, USP***Batch No 5564***Use by 8/02***Woleske Chemical, Kansas City, MO 64111***”

How Prepared

All records and photographs identified as below and submitted to Supervisory Investigator. Negatives and extra photos placed in 525, sealed as below and submitted to Supervisor.