

FACTS Version 4.9.01 - [Create Assignment]

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Assignment

Requesting Organization: MIN-IB-SPV Requester Completion Date: 11/21/2005 Priority: High ORA Req: N/A Compliance Number: 145 - 0

Subject: Pharma-Mix Digitalis ORA Cnrc Num: Survey Num:

Remarks: Request for samples as follow-up to violative EI Reporting Method: Notify SI DoMore by phone when accomplish

Background Information: Firm's manufacturing practices may lead to low potency POC Name: James W. DoMore

Operations

Op Code: 31 Sample Collection Rqstr Prty: High

Subject: Pharma-Mix Digitalis Target Date: 11/21/2005

Requester Remarks: Collect 12/100 tab bottles of lot DC-01234 as follow-up to vi

Estmtd Hours: 4 Estmtd Smpl Cost: \$150.00 Reimbursable:

Organizations

Accomp Org	Num Of Ops	Perf Org (Adhoc Work)
NWJ-DO	1	

Buttons: Add, Delete, Prev Op, Next Op, Delete

PACS & Products

PAC	Description
56002	DRUG PROCESS INSPEC

Buttons: Add, Delete

Product Code	Description
63 F C E 04	Digitalis (Cardiotonic); Human - Rx/

Buttons: Add, Delete

Firms & Cross References

FEI B	Name
3000900992	Drug Distributors, I

Buttons: Add, Delete

Code	Value

Buttons: Add, Delete

Lab References

Sample Number: PAF: LID:

Buttons: Delete

FACTS Editor

Collect 12/100 tab bottles of lot DC-01234 as follow-up to violative EI of Pharma-Mix, Minneapolis, MN (FEI 3000901012), conducted on 9/31-10/05/2005. 30 cases were shipped to Drug Distributors Inc., 3910 Riverside St., Newark, NJ on 10/03/05 via Cross Country Express, Kansas City, MO. Invoice # 8328 10/05/05, B/L A-3026, 10-3-05.

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