


Name of Policy:	Obtaining/Selling from or to other Hospitals and/or Pharmacies	 <p>Effective Date: July, 1993</p>
Policy Number:	3364-133-19	
Department:	Pharmacy	
Approving Officer:	Director of Pharmacy	
Responsible Agent:	Director of Pharmacy	
Scope:	University of Toledo Medical Center	
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Minor/technical revision of existing policy		
<input checked="" type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy		

(A) Policy Statement

Drugs may be obtained in when necessary (i.e., emergencies) from other hospitals and pharmacies. Drugs may also be sold to other hospitals, pharmacies, or institutions when requested (i.e., on an emergency basis).

(B) Purpose of Policy

To establish a procedure for obtaining/selling drugs from or to other hospitals and pharmacies when necessary and/or in emergencies.

(C) Procedure

Upon determining that a particular item is out of stock and/or not stocked in the pharmacy and that purchase through normal channels is contrary to good patient care, or an emergency exists:

1. The nearest community pharmacy or hospital pharmacy is called and the item requested.
2. Upon location of the needed item, a cab is dispatched for pick-up.
3. The packing slip and receipt for transportation charges is placed in our file.
4. As soon as possible, the item is obtained from our regular sources.
5. When an invoice is received, these slips are compared to the invoice and a requisition is issued for payment.

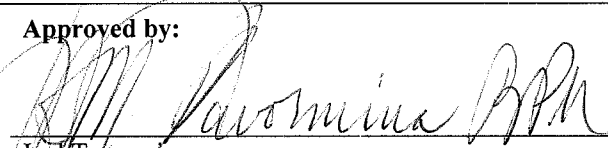

When a call is received from another pharmacy for an item in our stock:

1. Verify that the item is available.
2. If you have any doubt about the need for the requested product, verify that the individual calling is representing another pharmacy or hospital.
3. Fill out the "Sold To" form making sure to obtain the correct name and address of the purchasing facility if not familiar to The University of Toledo Medical Center (UTMC) Pharmacy.
4. Attach both copies of the "Sold To" form to the package.
5. Have the individual picking up the item sign the form. (this includes carriers, such as cab drivers). Keep the top white copy.
6. No Schedule II controlled substance may be sold unless a DEA Form 222 has been provided.

At the beginning of each month, these items are totaled and the purchasing is invoiced for items received in the previous month.

Obtaining compounded products that can not be produced at UTMC pharmacy.

- 1: On occasion products need to be purchased that UTMC pharmacy does not have the materials, equipment, or classification status to compound. Examples include compounding parenteral products from non-sterile materials and extended expiration parenterals.
- 2: UTMC pharmacy will verify credentialing and license verification including documentation of possessing a wholesaler licenses with compounding pharmacies. A list of approved pharmacies is maintained by the director of pharmacy.
- 3: The UTMC pharmacy will obtain the medication from the compounding pharmacy via the mechanism described above and provide additional documentation as required by the compounding pharmacy.
- 4: UTMC pharmacy will label and dispense the product to the patient.

<p>Approved by:</p> <div style="margin-bottom: 20px;">  <hr style="border: 0; border-top: 1px solid black; margin: 0;"/> Joel Tavormina Director of Pharmacy </div> <div style="margin-bottom: 20px;">  <hr style="border: 0; border-top: 1px solid black; margin: 0;"/> Norma Tomlinson, RN, MSN, CNA Associate Vice President/Associate Executive Director </div> <p><i>Review/Revision Completed By Pharmacy</i></p>	<p>Review/Revision Date:</p> <table style="width: 100%; border: none;"> <tr><td style="width: 50%;">5/83</td><td style="width: 50%;">02/08</td></tr> <tr><td>11/84</td><td>05/08</td></tr> <tr><td>10/87</td><td></td></tr> <tr><td>2/89</td><td></td></tr> <tr><td>7/90</td><td></td></tr> <tr><td>7/93</td><td></td></tr> <tr><td>5/94</td><td></td></tr> <tr><td>7/96</td><td></td></tr> <tr><td>3/99</td><td></td></tr> <tr><td>7/02</td><td></td></tr> <tr><td>7/04</td><td></td></tr> </table> <p>Next Review Date: 5/1/2011</p>	5/83	02/08	11/84	05/08	10/87		2/89		7/90		7/93		5/94		7/96		3/99		7/02		7/04	
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<p>Policies Superseded by This Policy:</p>																							

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.



171 Container Place ♦ Cincinnati, Ohio 45246
(513) 870-0293 ♦ Toll Free: 1 (800) 829-0293
www.agapeinstruments.com

CONTROLLED ENVIRONMENTAL TESTING REPORT
CERTIFICATE OF COMPLIANCE

Date: January 30, 2008
AIS CR-010605-1JO

Report 66741
Prior Report 63315
Retest Due July 2008

Project / Facility: Buderer Drug Corporation
26611 North Dixie Highway
Perrysburg, Ohio 43551

Contacts: Matt Buderer
419-873-2800

Performance Testing: Agape Instruments Service, Inc.
171 Container Place
Cincinnati, Ohio 45246

The data presented in this report is an exact record of Cleanroom and Cleanroom System Performance and was obtained in accordance with procedures as listed where applicable.

Standards and Procedures:
IES-RP-CC006.3 Testing Cleanrooms
ISO-14644 Standard
National Sanitation Foundation (NSF STD. #49)
IEST-RP-CC-002.2 Laminar Flow Clean Air Devices

Work performed in the following areas:

- Pharmacy Clean Room

Certification Performed by:


James R. Sargent

Chapter 3

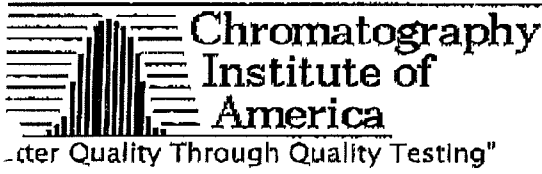
Facilities and Cleaning Procedures

- 3.010 Sterile Compounding Area Requirements
- 3.020 Cleaning and Maintenance of the Clean Room Facility
- 3.030 Environmental Monitoring of the Clean Room Facility
- 3.040 Non-Sterile Compounding Area Requirements
- 3.050 Cleaning and Maintenance of the Non-Sterile Compounding Area

Chapter 9

Quality Assurance/Quality Control

- 9.010 The Quality Assurance Program
- 9.020 Good Documentation Practices (GDP)
- 9.030 Corrective and Preventative Action (CAPA) Management
- 9.040 Formula Worksheet
- 9.050 Beyond-Use Dating (BUD) of Compounded Preparations
- 9.060 Product Quarantine, Storage and Release
- 9.070 Destruction of Expired Product and Reagents
- 9.080 Recall of Compounded Product
- 9.090 Proper Hand Washing Procedure
- 9.100 Required Garb for Clean Room Facility Access
- 9.110 Sterile Compounding Process Validation (Media Fills)
- 9.120 Sterile Compounding Finished Preparation Testing
- 9.130 Required Garb for Non-Sterile Compounding Area
- 9.140 Non-Sterile Compounding Process Validation
- 9.150 Non-Sterile Compounding Finished Preparation Testing
- 9.160 Safety Procedures



**LAB REPORT
CERTIFICATE OF ANALYSIS**

Buderer Drug Company
 26611 N. Dixie Hwy
 Perrysburg, OH 43542
 Contact: Lisa Pawliski
 Phone: (419) 873-2800
 Fax: (419) 873-04940
 E Mail: info@BudererDrug.com

Date Received: 5/16/07
Condition of Sample: Good
Sample Lot#: T700150AS
**Description / Concentration(s) Morphine Sulfate
 50MG/ML**

Tracking Designation	Active(s) / Concentration(s)	Concentration Found	% Potency	Date of Test	Comments
Bb 04	Morphine Sulfate 50MG/ML	56.57MG/ML	113.1%	5/22/07	Reported as morphine sulfate anhydrous, not as the pentahydrate

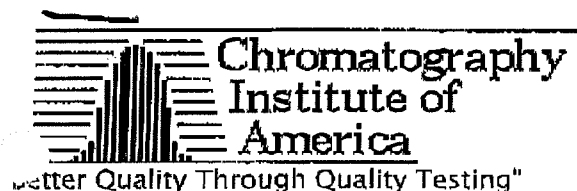
Endotoxin Report	Date Test Began	Date Test Ended	Media Info	USP Limits	Incub. Temp	Results	Comments
Bb 04	5/17/07	5/17/07	08707K 5/23/09	17.0USPEU	36°	Negative	No clot formed in assay vial Meets USP requirements

Preliminary Sterility Report	Date Test Began	Date of Prelim. Report	Dates Checked	Incub. Temp	Results	Comments
Bb 04	5/17/07	5/24/07	5/18, 5/21, 5/23	24°	Negative	No growth observed after one week Test will continue for one more week

Final Sterility Report	Date Test Began	Date Test Ended	Media Info	Dates Checked Cont. from Prelim.	Incub. Temp	Results	Comments
Bb 04	5/17/07	5/31/07	07507H 2/7/09	5/25, 5/29, 5/31	24°	Negative	No growth observed after two weeks Meets USP requirements

Final Fungi Report	Date Test Began	Date Test Ended	Media Info	Dates Checked	Incub. Temp	Results	Comments

Reported By *Nancy Sutton*
 Date *5/31/07*



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Buderer Drug Company
 26611 N. Dixie Hwy
 Perrysburg, OH 43542
 Contact: Lisa Pawliski
 Phone: (419) 873-2800
 Fax: (419) 873-049490
 E Mail: info@BudererDrug.com

Date Received: 4/30/07
Condition of Sample: Good
Sample Lot#: T7062400S
Description / Concentration(s): Hydromorphone HCL 50MG/ML

Tracking Designation	Active(s) / Concentration(s)	Concentration Found	% Potency	Date of Test	Comments
Bb 03	Hydromorphone HCL 50MG/ML	49.74MG/ML	99.5%	5/1/07	

Endotoxin Report	Date Test Began	Date Test Ended	Media Info	USP Limits	Incub Temp	Results	Comments
Bb 03	4/30/07	4/30/07	0B707K 5/23/09	88.0USPEU	36°	Negative	No clot formed in assay vial Meets USP requirements

Preliminary Sterility Report	Date Test Began	Date of Prelim Report	Dates Checked	Incub Temp	Results	Comments
Bb 03	4/30/07	5/7/07	5/1, 5/3, 5/7	24°	Negative	No growth observed after one week Test will continue one more week

Final Sterility Report	Date Test Began	Date Test Ended	Media Info	Dates Checked Cont. from Prelim	Incub Temp	Results	Comments
Bb 03	4/30/07	5/14/07	03607H 1/7/09	5/9, 5/11, 5/14	24°	Negative	No growth observed after two weeks Meets USP requirements

Final Fung Report	Date Test Began	Date Test Ended	Media Info	Dates Checked	Incub Temp	Results	Comments

Reported By

Date