Validity Testing Information Part I

Laboratory Name: PharmChem, Inc - Texas
Address: Ft Worth, Texas 76118

Responsible Person: Robert D. Bost, PhD. (Printed Name)

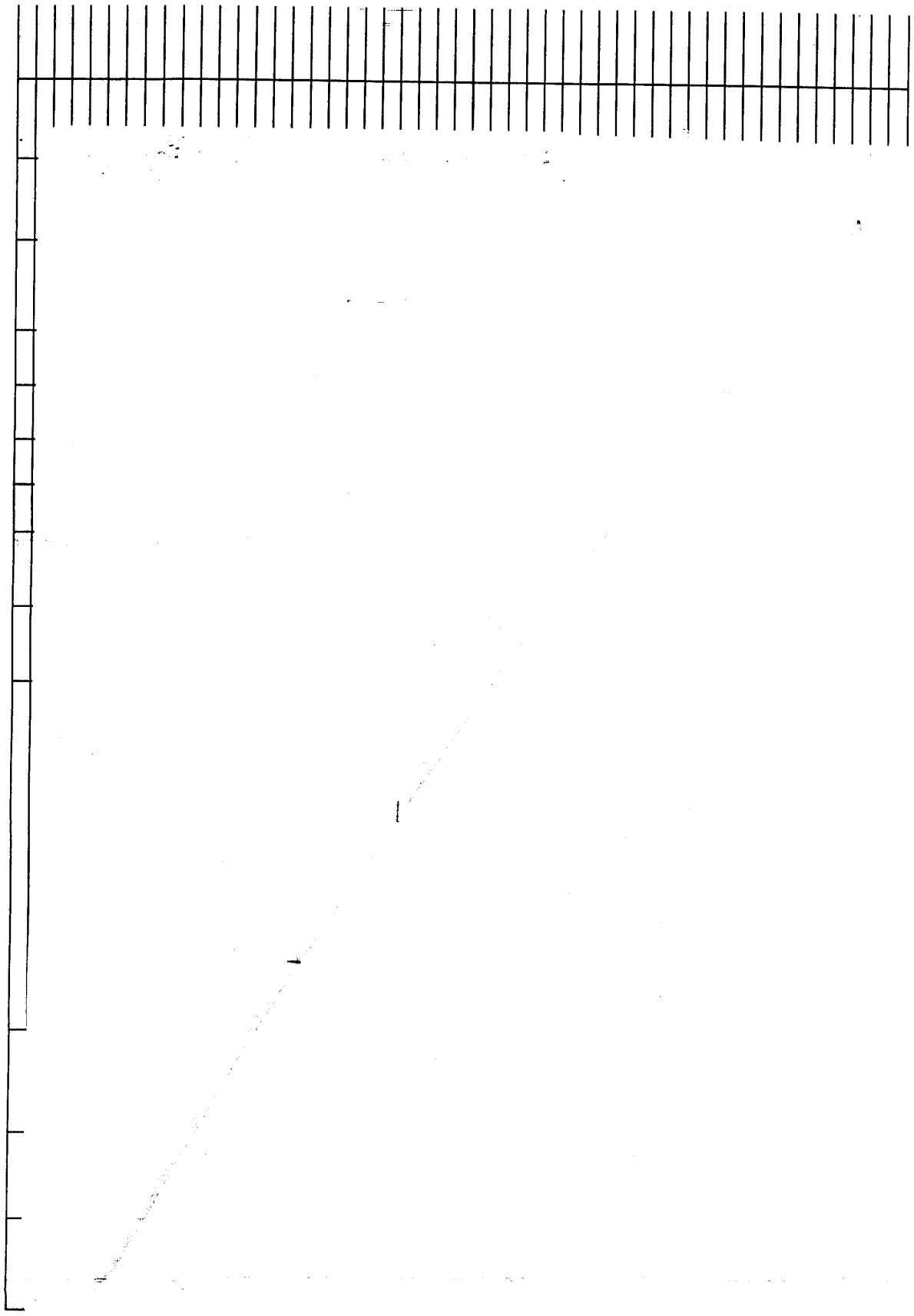
I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Robert O. Bost, PhD
Signature, Responsible Person

10/5/2000
Date

Robert O. Bost, PhD.
Printed Name, Responsible Person

Batch Number	Specimen ID	Specimen ID	Report Adulterated/Substituted	Creatinine mg/dL	Creatinine mg/dL	SpGr	SpGr	Nitrite ug/mL	Nitrite ug/mL	pH	pH	Other	Remarks
Batch No	Barcode	Accession No.	Comments										



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

November 6, 2000

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

The enclosed critique was developed from the inspection report associated with the October 25-27, 2000, specimen validity testing inspection of your laboratory under the National Laboratory Certification Program (NLCP). The laboratory's procedures were not in full compliance with program guidance issued in Program Document 035 (September 28, 1998) and Program Document 037 (July 28, 1999). The laboratory must submit information to correct/clarify the following issues raised:

3040 Cornwallis Road • Post Office Box 12194 • Research Triangle Park, North Carolina 27709-2194 USA
Telephone 919 541-6709 • Fax 919 541-7042

The laboratory must submit, within 30 calendar days of receipt of this letter, documentation to demonstrate that corrective actions have been implemented to address the issues raised. In responding to these issues, please organize the material in your document in accordance with the sections and item numbers as listed in this correspondence. The laboratory must also review the enclosed critique and take all necessary corrective actions. All corrective actions must be implemented within 30 days receipt of this correspondence and will be reviewed at the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

Enclosure

cc: Project Files/svt108

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0108
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Fort Worth, TX

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 25 October 2000

A review of the National Laboratory Certification Program (NLCP) consensus inspection report has been completed. Issues identified during the inspection are described on the following pages. Evidence that appropriate remedial action has been taken is required for continued certification.

The following comments were noted, and appear in the same order as the corresponding questions in the Laboratory Inspection Report:

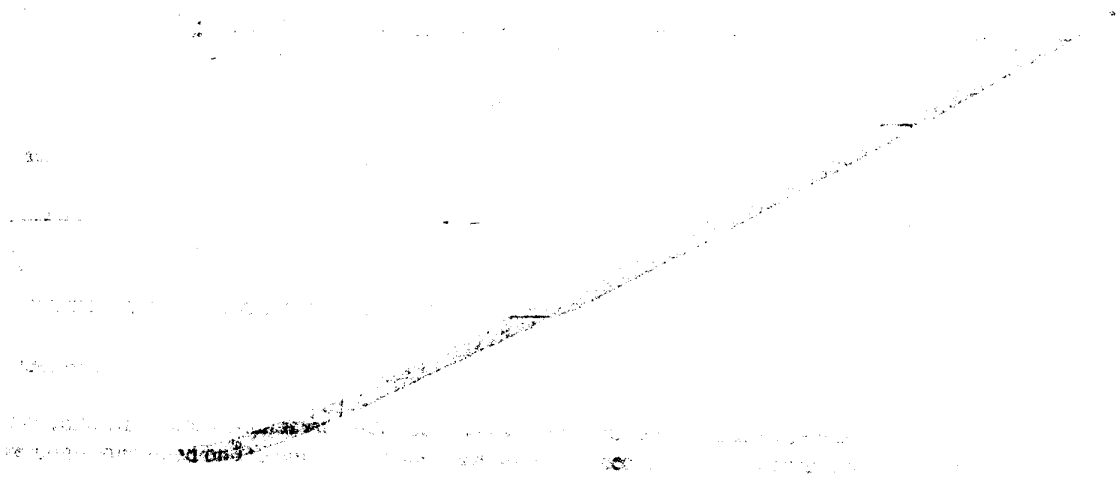
Section E. Standard Operating Procedures - Procedures Manual

Section F. Chain-of-Custody, Accessioning, and Security

Section G. Quality Control and Quality Assurance

Section I. Specimen Validity Tests

Section K. Records Audit



Section L. Certification and Reporting

PHARMCHEM
LABORATORIES, INC.

TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 ☐ (817)215-8800 ☐ (800)967-8378 ☐ Fax (817)215-8863
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park,Caliornia 94025 ☐ (800)446-5177 ☐ Fax (650)688-1122

December 11, 2000

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Crumpton:

The following information is provided in response to the issues raised in the critique submitted following the specimen validity inspection of PharmChem, Inc. – Texas Division.

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

December 21, 2000

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of December 11, 2000, submitted in response to issues raised during the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of November 6, 2000. The information submitted by the laboratory appears to demonstrate that corrective actions have been taken to address some of the issues raised. **However, the following issues require additional clarification and corrective action:**

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The laboratory must submit information from the MRO inquiries as noted in item K11 above ***no later than five working days after receipt of this correspondence. Failure to comply may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.*** All corrective actions will be reviewed at the next inspection.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0108

PHARMCHEM
LABORATORIES, INC.

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CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park,Caliornia 94025 ☐ (800)446-5177 ☐ Fax (650)688-1122

December 28, 1988

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Crumpton:

The following information is submitted in response to your letter Dated December 21, 2000 regarding the specimen validity inspection of our laboratory.

If there are further questions, please contact us.

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director

PHARMCHEM
LABORATORIES, INC.

TEXAS DIVISION ☐ 7606 Pebble Drive ☐ Fort Worth, Texas 76118 ☐ (817)215-8600 ☐ (800)867-8378 ☐ Fax (817)215-8863
CORPORATE HEADQUARTERS ☐ 1505A O'Brien Drive ☐ Menlo Park,California 94025 ☐ (800)446-5177 ☐ Fax (650)688-1122

January 5, 2001

Ms. Susan Crumpton
NLCP Technical Analyst
Research Triangle Institute
3040 Cornwallis Road
P. O. Box 12194
Research Triangle Park, North Carolina 27709-2194

Dear Ms. Crumpton:

The following information is submitted as a follow-up to your letter dated December 21, 2000 and our response submitted on December 28, 2000, regarding the specimen validity inspection of our laboratory.

I am sending this letter to you to show the efforts we have been making to obtain the requested information on the specimen identified above. We will continue working to make contact and provide the information needed.

Sincerely,

Robert O. Bost, PhD.

Robert O. Bost, Ph.D.
Laboratory Director

RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

January 10, 2001

0108
Dr. Robert Bost
PharmChem Labs, Inc., Texas Division
7606 Pebble Drive
Fort Worth, TX 76118

Dear Dr. Bost:

We have reviewed the material provided in your correspondence of December 28, 2000, and your faxed correspondence of January 5 and 8, 2001, submitted in response to issues remaining from the October 25-27, 2000, specimen validity testing inspection of your laboratory as outlined in our correspondence of December 21, 2000.

It appears that the laboratory's specimen validity testing procedures are in compliance with program guidance. All corrective actions will be reviewed during the next inspection. Failure to comply with program guidance may result in the laboratory's suspension to perform specimen validity testing on federally regulated specimens.

If you have any questions or if we can be of further assistance, please call me at (919) 541-6176 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Susan Crumpton
NLCP Technical Analyst

cc: Project Files/SVT0108

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