Validity Testing Information Part I

Laboratory Name: PharmChem, Inc
Address: 1505A O'Brien Drive, Menlo Park, CA 94025

Responsible Person: Neil Fortner (Printed Name)

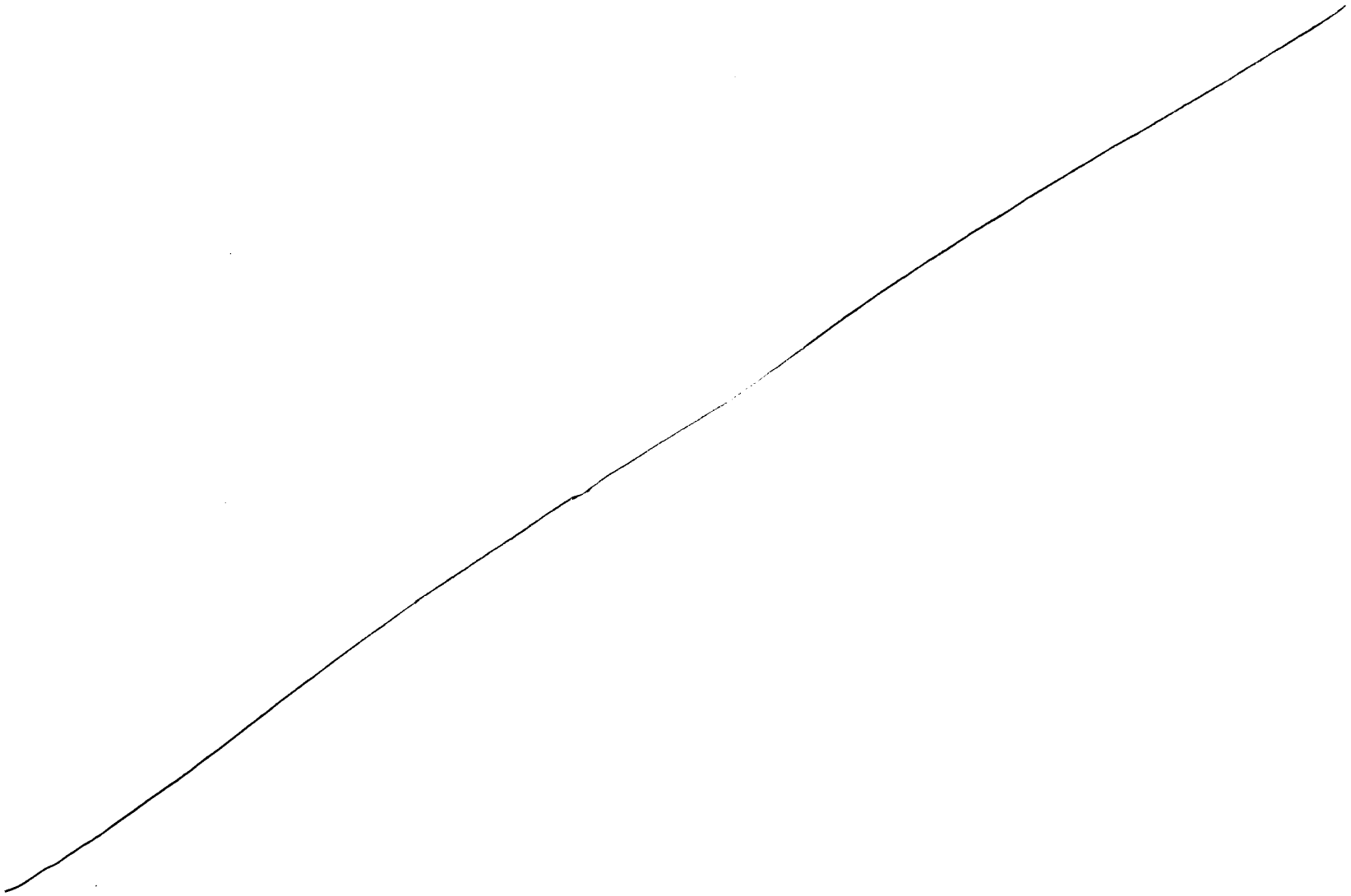
I certify that the answers and information provided are true and correct as of this date. Any false, fictitious, or fraudulent answers or information provided may violate Federal Law and could subject me to prosecution, monetary penalties, or both (Sec 18 U.S.C. 1001; 31 U.S.C. 3801-812).

Neil Fortner
Signature, Responsible Person

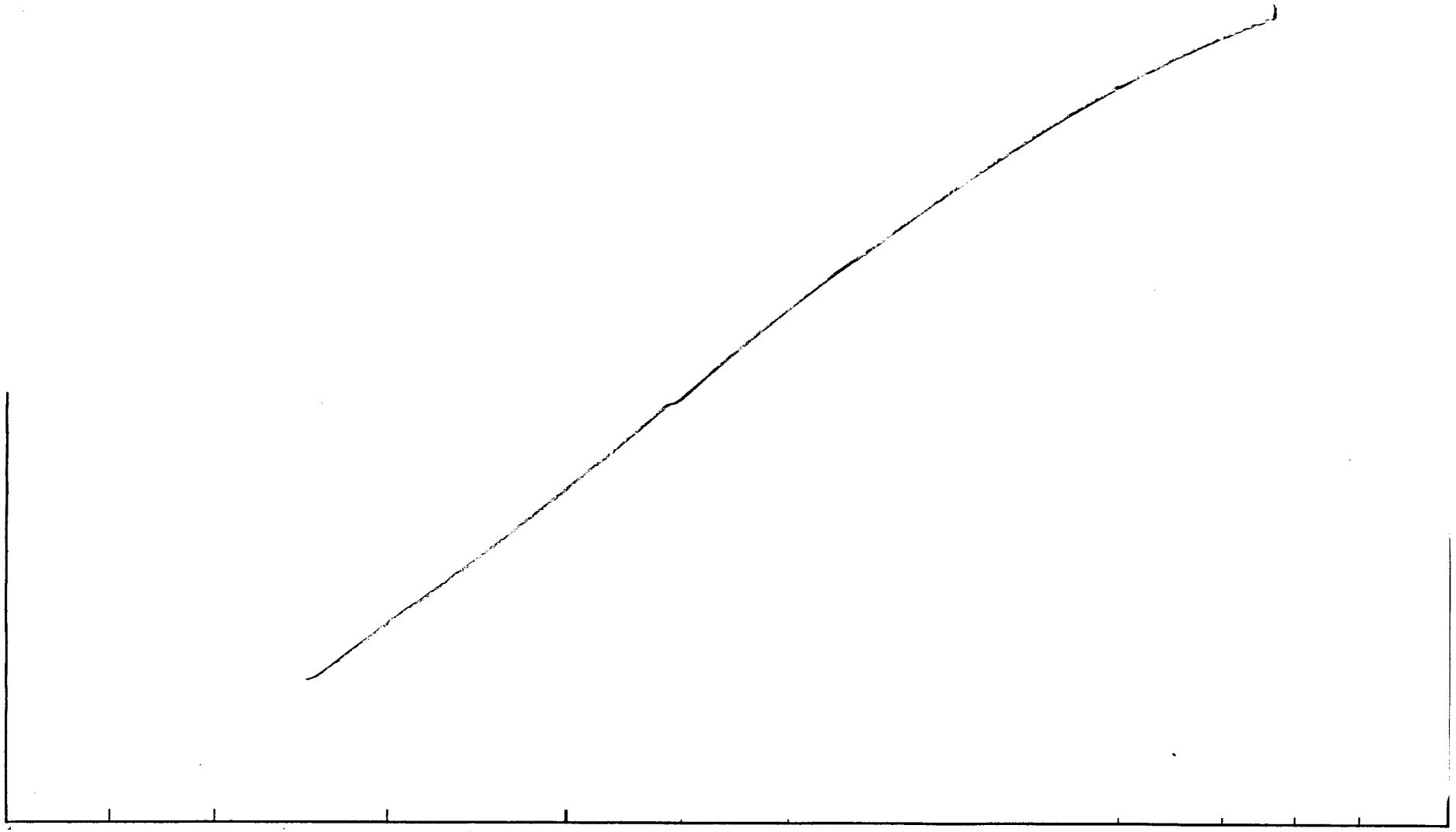
10-4-00
Date

Neil Fortner
Printed Name, Responsible Person

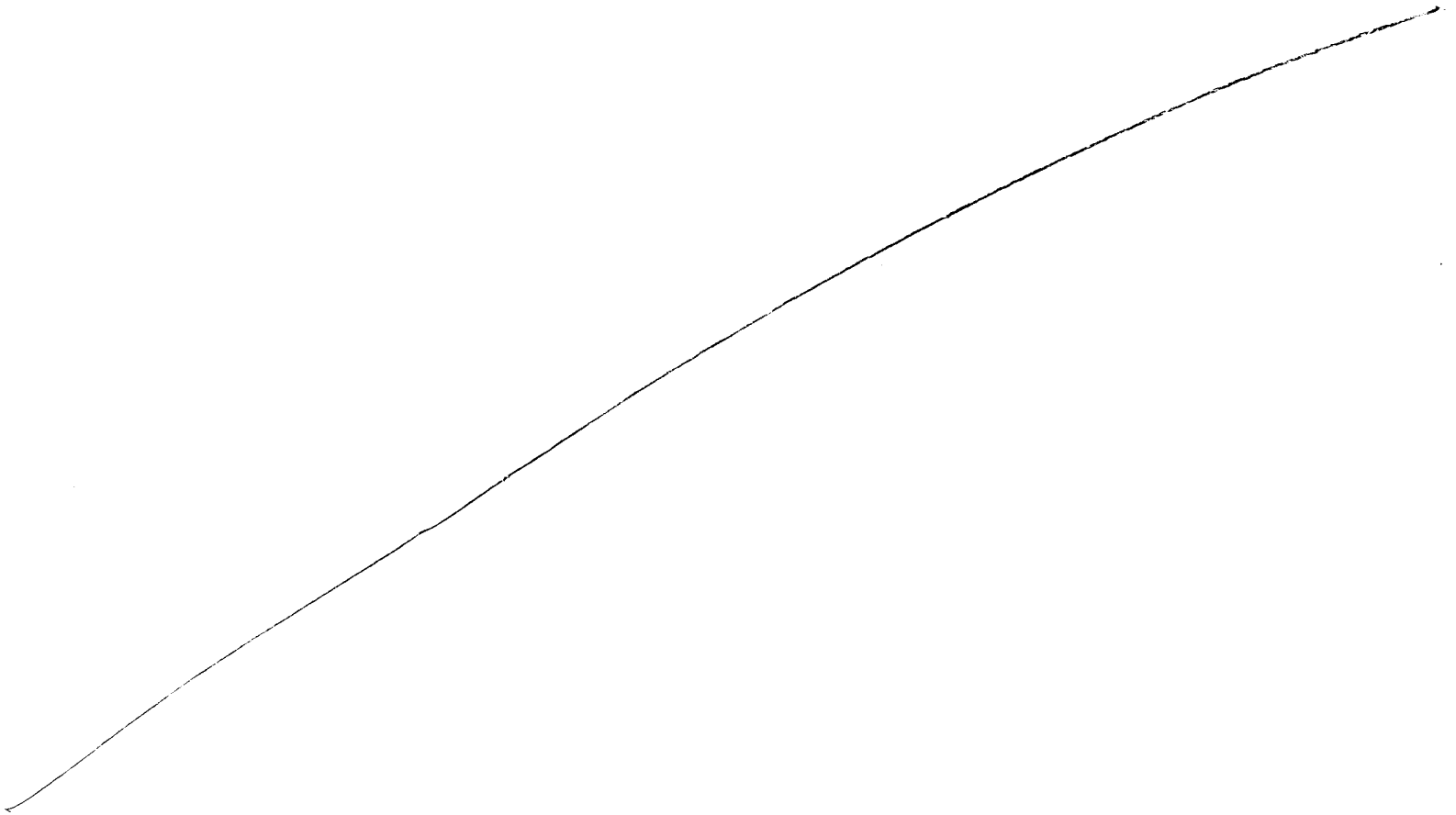
Barcode	Accession N	Receipt Date	Reported Date	Batch No	Account No	Results	Creatinine	pH	Nitrite	Spec Grav



Barcode	Accession N	Receipt Date	Reported Date	Batch No	Account No	Results	Creatinine	pH	Nitrite	Spec Grav



Barcode	Accession N	Receipt Date	Reported Date	Batch No	Account No	Results	Creatinine	pH	Nitrite	Spec Grav



RESEARCH TRIANGLE INSTITUTE

National Laboratory Certification Program

October 27, 2000

0006
Mr. Neil Fortner
PharmChem Laboratories, Inc.
1505-A O'Brien Drive
Menlo Park, CA 94025

Dear Mr. Fortner:

The enclosed critique was developed from the inspection report associated with the October 11, 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 address 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) 541-7265 or Dr. Michael Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

Enclosure

cc: Project Files/svt006

NATIONAL LABORATORY CERTIFICATION PROGRAM

Document Review and Critique

Laboratory I.D. Number: 0006
Document No. Final

Laboratory: PharmChem Laboratories, Inc.

Location: Menlo Park, CA

Document Reviewed: [XX] Specimen Validity Testing Inspection Report

Date: 11 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:

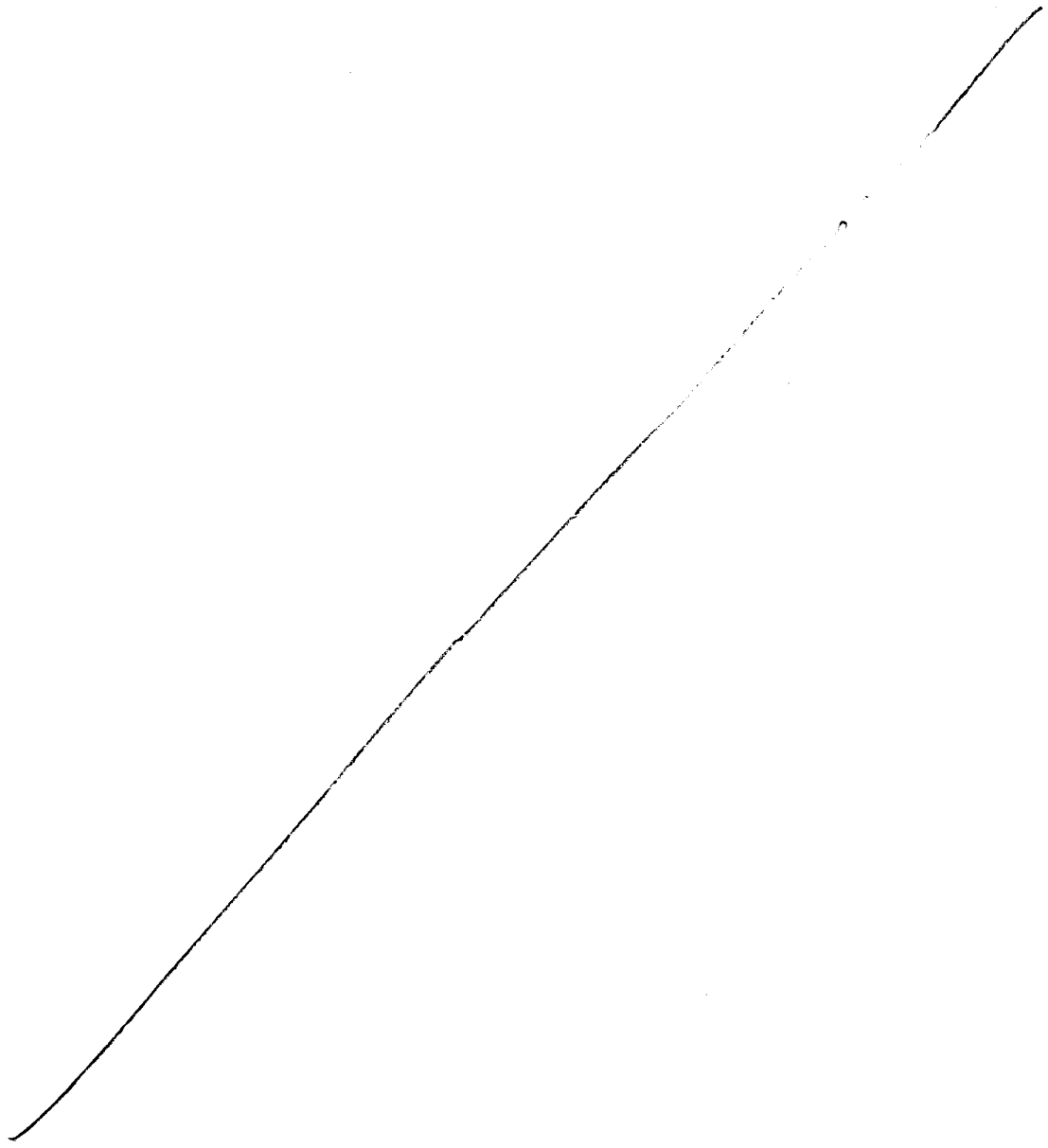
Section E. Standard Operating Procedures - Procedures Manual

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

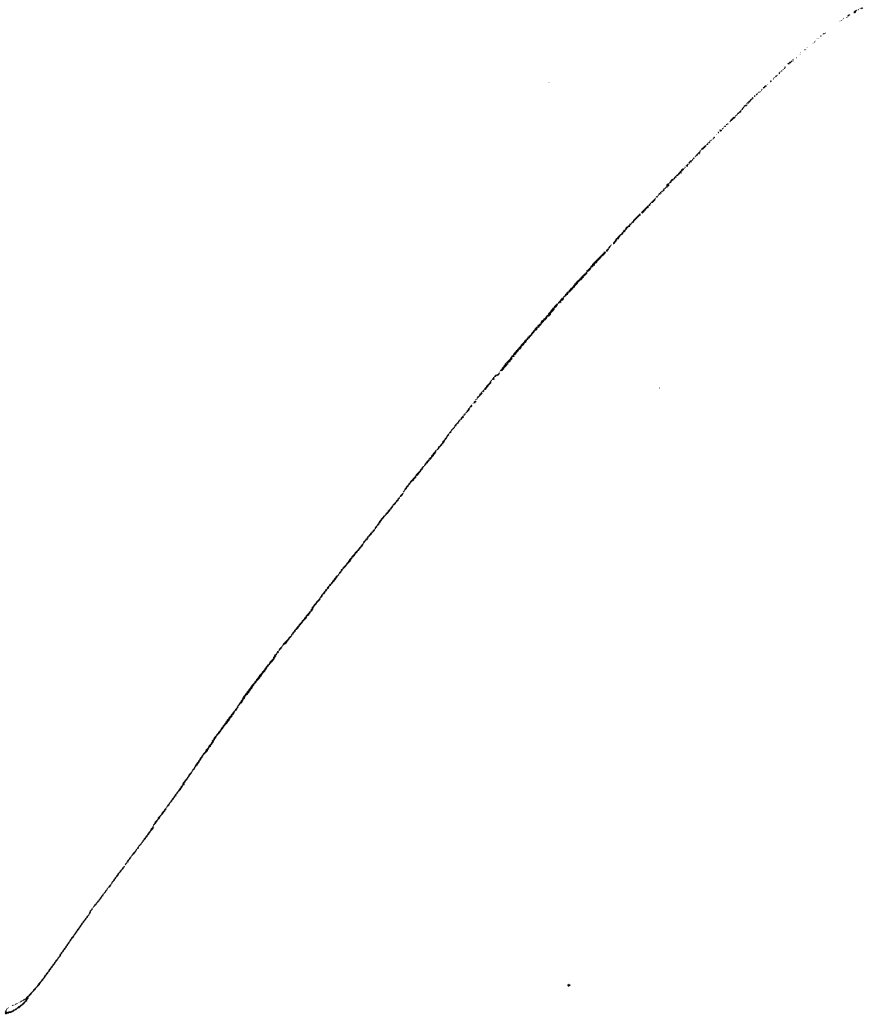
PHARMACHEM, INC.

1505A O'Brien Drive ☐ Menlo Park, California 94025-1435 ☐ (650) 328-6200 ☐ Fax: (650) 463-7500

December 3, 2000

Deborah J. Denson
NLCP Technical Analyst
National Laboratory Certification Program
3040 Cornwallis Road
Research Triangle Park, NC 27709

Dear Ms. Denson,



If I can be of further assistance, or should you have any questions, please call me at 1-800-446-5177, extension 217.

Sincerely,

Neil A. Fortner, M.S., T.C.-NRCC; FTS-ABFT
Vice President, Laboratory Operations
SAMHSA Responsible Person

Neils/inspections-00/SVT Menlo Park October 2000

RESEARCH TRIANGLE INSTITUTE

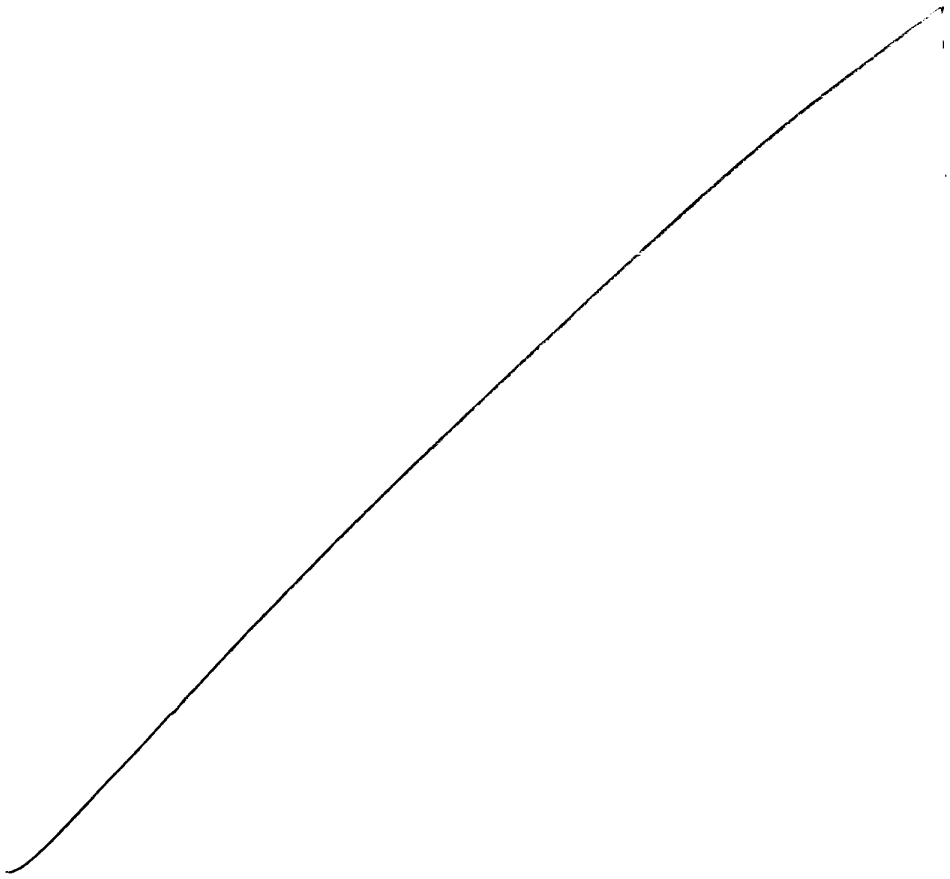
National Laboratory Certification Program

December 22, 2000

0006
Mr. Neil Fortner
PharmChem Laboratories, Inc.
1505-A O'Brien Drive
Menlo Park, CA 94025

Dear Mr. Fortner:

We have reviewed the material provided in your correspondence of December 3, 2000 submitted in response to issues raised during the October 11, 2000 specimen validity testing inspection of your laboratory as outlined in our correspondence of October 27, 2000. The information submitted by the laboratory appears to demonstrate that appropriate corrective actions have been taken to address the issues raised. The following is a review of the material submitted:



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

Based upon our review of the material submitted, it appears that the laboratory is taking steps to ensure that its specimen validity testing procedures are in compliance with program guidance. All corrective actions must be implemented within 30 days of the receipt of this correspondence and will be reviewed during the next inspection. Failure to comply 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) 541-7265 or Dr. Michael R. Baylor at (919) 541-7043.

Sincerely,

Deborah J. Denson

Deborah J. Denson
NLCP Technical Analyst

cc: Project Files/SVT006