MICROGRAM

BUREAU OF NARCOTICS AND DANGEROUS DRUGS / U.S. DEPARTMENT OF JUSTICE

Washington, D. C. 20537
Office of Science and Education
Vol.II, No.2 Division of Laboratory Operations June, 1969

BNDD REGIONAL LABORATORIES ARE NOW OPEN and will become fully operational when equipment is installed and all personnel have reported. Table A, attached, gives addresses and telephone numbers of the five laboratories and shows the area served by each.

Laboratory spaces are being remodeled, and are being equipped with the latest model infra-red, and ultra-violet spectroscopes, gas chromatographs and other instruments necessary to meet the needs of modern investigation.

In addition to the five regional laboratories, there is a Special Testing and Research Laboratory in Washington, D. C. This laboratory is being equipped to identify and characterize "new" drugs obtained by BNDD agents and other law enforcement officers. In addition to the instruments used by the regional laboratories, this laboratory also has X-ray diffraction equipment and special microscopes needed for crystal identification. A Neutron Mass Spectrometer is being ordered. This laboratory also contains the authentic drug library, vital for the identification of tablets and capsules as to their source.

The BNDD laboratory system was designed to best serve BNDD's needs, within the limits of available resources. The laboratories will supplement, not replace, State and local laboratories, and have already been active assisting local laboratories with analytical problems, by furnishing analytical standards, by holding training seminars, and by publishing Microgram.

The BNDD laboratories will analyze narcotics, depressant, stimulant and hallucinogenic drugs for duly constituted State and local law enforcement agencies, as well as for federal agencies not having a laboratory. This service, of necessity, is secondary to the Bureau's own requirements. Instructions for requesting analyses can be obtained from any BNDD Regional or District Office, from the Regional Laboratories or from the Bureau of Narcotics and Dangerous Drugs, Washington, D. C. 20537, Attention: DRSL.

Chief Chemist in New York, Anthony Romano, Jr., was born and raised in New York, and is a graduate of City College of New York. Following service in the U. S. Army, Mr. Romano was appointed as a chemist in the U. S. Food and Drug Administration, where he worked in the Minneapolis and New York District laboratories. While with FDA, he attended several

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courses in modern analytical methods and in management. He has published several papers on various analytical problems, and has recently prepared a paper for publication on Automated Data Processing and Publications Procurement. Before transferring to the Department of Justice, Mr. Romano directed the Pharmaceutical Chemistry Section of FDA's New York District Science Branch.

Chief Chemist in the Washington, D. C., Regional Laboratory, Jack Rosenstein, was born and raised in New York, graduated from City College of New York and served in the U. S. Army. After graduate studies at Brooklyn College, he was employed as a chemist by New York State, until he received an appointment with the U. S. Food and Drug Administration as a chemist in the New York District, where he eventually become a Supervisory Chemist. Prior to coming to BNDD, Mr. Rosentein was Scientific Coordinator (Chemistry) with the Office of Field Scientific Coordination, Associate Commissioner for Science, U. S. Food and Drug Administration, Washington, D. C. He is a member of the ACS and the AOAC and has had a paper published in the Journal of the latter organization.

Chief Chemist of the Dallas Regional Laboratory is James H. Kluckhohn. His hometown is Cleveland, Ohio. After obtaining his degree at Kent State University, Kent, Ohio he served in the U. S. Army. After which he was appointed analytical chemist with the Internal Revenue Service's Alcohol and Tobacco Tax Laboratory, Washington, D. C. He remained with IRS, obtaining extensive analytical and administrative experience as Chief Chemist in the St. Paul, Omaha, and Dallas Laboratories, until his transfer to the Department of Justice. Mr. Kluckhohn is a Fellow in the American Academy of Forensic Sciences.

Chief Chemist in San Francisco, Robert K. Sager, was born and raised in Noble, Illinois, and graduated from Eastern Illinois University, Carleston, Illinois. He took graduate work in administration and in law at the University of Chicago, the U. S. Department of Agriculture Graduate School and George Washington School of Law, both in Washington, D. C. He has taken several short courses on analytical methods and management. Mr. Sager served with the U. S. Food and Drug Administration for twelve years. He served as a chemist in the St. Louis and Chicago Districts, and later became supervisory Chemist in the Minneapolis District Laboratory. He was transferred to FDA Headquarters, Washington, D. C., as a Chemist/Auditor, traveling to the various FDA Districts auditing management methods and procedures. He received broad administrative experience in FDA Headquarters, serving as a Food and Drug Officer and as a Program Analyst. His last position with FDA was that of Chief Chemist, Minneapolis District.

Chief Chemist, Chicago Regional Laboratory, Jerry D. Nelson, comes from Fairfield, Iowa. After attending Parsons College, Fairfield, he obtained his degree at Northeast Missouri State Teacher's College, Kirksville, Mo. Mr. Nelson was appointed as a chemist with the U. S. Food and Drug Admin-

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istration, where, after serving in the Kansas and Buffalo District laboratories, he was transferred to the New York District laboratory as Supervisory Chemist. He left a position as Assistant Chief Chemist in FDA's Chicago laboratory to open BNDD's first Regional Laboratory in Chicago.

BNDD's Regional Laboratories, as well as the Special Testing and Research Laboratory, come under the technical direction of Mr. John W. Gunn, Chief, Division of Laboratory Operations. Mr. Gunn also heads a small staff at Headquarters which publishes Microgram, and acts as technical advisors to the Bureau.

Mr. Gunn was born in Lynn, Massachusetts, and, after attending parochial schools there, served in the U. S. Navy. After service, he earned a degree in Chemistry at Boston College. Later, Mr. Gunn did graduate work at Georgetown University in Biochemistry, then attended American University, Washington, D. C., where he took graduate courses in management.

Mr. Gunn worked as a chemist with private industry, then was appointed as a Special Agent with the Federal Bureau of Investigation, where he served in the San Francisco and Detroit Field Offices, and later was Resident Agent in Marquette, Michigan. Mr. Gunn was then transferred to the FBI Laboratory, Washington, D. C., where he worked as a Special Agent in the Physics and Chemistry Section. He left the FBI to accept a post as laboratory supervisor for a large drug manufacturer, leaving that position to become a Senior Staff member at Johns-Hopkins Applied Physics Laboratory, Silver Springs, Maryland.

The Bureau of Drug Abuse Control was formed in the U. S. Food and Drug Administration, and Mr. Gunn became one of the first members of the staff, helping to form the new Bureau. He became Chief of the Investigative Services Branch in the former Bureau's Division of Investigations. With the President's Reorganization Plan No. 1, April 8, 1968, the new Bureau of Narcotics and Dangerous Drugs was formed, and Mr. Gunn went to the new Bureau, assisting in the development of its laboratory system and allied forensic science programs.

Mr. Gunn is a member of the American Chemical Society, the International Narcotic Enforcement Officers Association, the Association of Federal Investigators, American Academy of Forensic Sciences and the Society of Former Special Agents of the FBI. He is a General Referee on Narcotics and Dangerous Drugs for the Association of Analytical Chemists.

Frederick M. Garfield, Assistant Director for Science and Education, administors the laboratory system, and the BNDD science and education programs.

He is a veteran of thirty years service in the government as a chemist and as an administrator, all of the time being spent in the U. S. Food and

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Drug Administration until the formation of the new Bureau of Narcotics and Dangerous Drugs, April 8, 1969. At that time, Mr. Garfield was serving as the Deputy Director of FDA's Bureau of Drug Abuse Control, a bureau that he as a high official in FDA helped to design.

While in FDA, Mr. Garfield became well known both in regulatory agencies and in industry. Recognition for his work in FDA included the Department of Health, Education and Welfare's Superior Service Award and also that Department's Superior Service Group Award. Mr. Garfield has attended several courses for administrators, including the Management Course conducted by the American Management Association, and the Conference for Federal Executives on Business Operations, Brookings Institute.

Mr. Garfield is a native of St. Louis, Missouri, where he graduated with a degree in Chemical Engineering from Washington University. He also majored in chemistry, and did graduate work at the university.

He accepted a position with FDA, after working in private industry as a control chemist and as a research chemist.

Local and State Forensic Chemists' Seminar was held May 19-23, 1969, in BNDD's headquarter's Training Center. Sixteen chemists from eleven States, the District of Columbia, Puerto Rico, Ireland, Canada and The Netherlands attended seminars conducted by BNDD and U. S. Food and Drug Administration scientists. One day was spent in the BNDD laboratory discussing Color and Crystal Tests, Thin-Layer Chromatography, Column Chromatography and Infra-red and Ultra-violet Spectroscopy. Guest lecturer on the final day was Leo Goldbaum, Ph.D., Chief Research Toxicologist, Armed Forces Institute of Pathology, Walter Reed Army Medical Center, Washington, D. C., who discussed "Toxicology - Analysis for Narcotics and Dangerous Drugs."

After the final lecture, Mr. John E. Ingersoll, Director, addressed the group and handed out the diplomas.

Analytical methods published in Microgram do not have official status. There has been no attempt made to validate these procedures under all conditions. They should only serve as a guide in the analysis of new and controlled drugs.

MICROGRAM is not a periodical, therefore, it is published at irregular intervals. To determine whether or not you have missed an issue, use the issue numbers, rather than the month of publication. For example, this is the second issue published in 1969.

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TETRAHYDROCANNABINOL standards were generously supplied to us by Professor R. Mechoulam, The Hebrew University of Jerusalem, Israel. The Δ^1 and Δ^6 were analyzed with the gas chromatograph, which showed the Δ^1 tetrahydrocannabinol to have a purity of approximately 75%. Another component was noted at approximately 15% concentration, and six other components made up about 10% of the remainder of the material. The Δ^6 tetrahydrocannabinol is about 93% pure, and had about five components making up 7% of the material.

Infrared and ultraviolet spectrograms are attached.

ASTHMADOR

An item about "Asthmador" and similar stramonium preparations appeared in Microgram, Vol. I, No. 2. In that item we asked readers to send us information about instances of misuse or abuse of the preparations. A similar request was carried in the Bulletin.

As a result, sufficient instances of injury and abuse were reported to cause the U. S. Food and Drug Administration to issue a Statement of General Policy or Interpretation. This, in effect, requires that stramonium preparations, such as "Asthmador", bear the prescription legend. The order became effective on October 24, 1968. (See attached Federal Register reprint.)

PUBLICATION OF INTEREST

Handbook of Federal Narcotic and Dangerous Drug Laws, Bureau of Narcotics and Dangerous Drugs, U. S. Department of Justice. For sale by the Superintendent of Documents, U. S. Government Printing Office, Washington, D.C., 20402. Price: $0.50

USE OF FUNDS FOR PRINTING THIS PUBLICATION APPROVED BY THE BUREAU OF THE BUDGET APRIL 8, 1969

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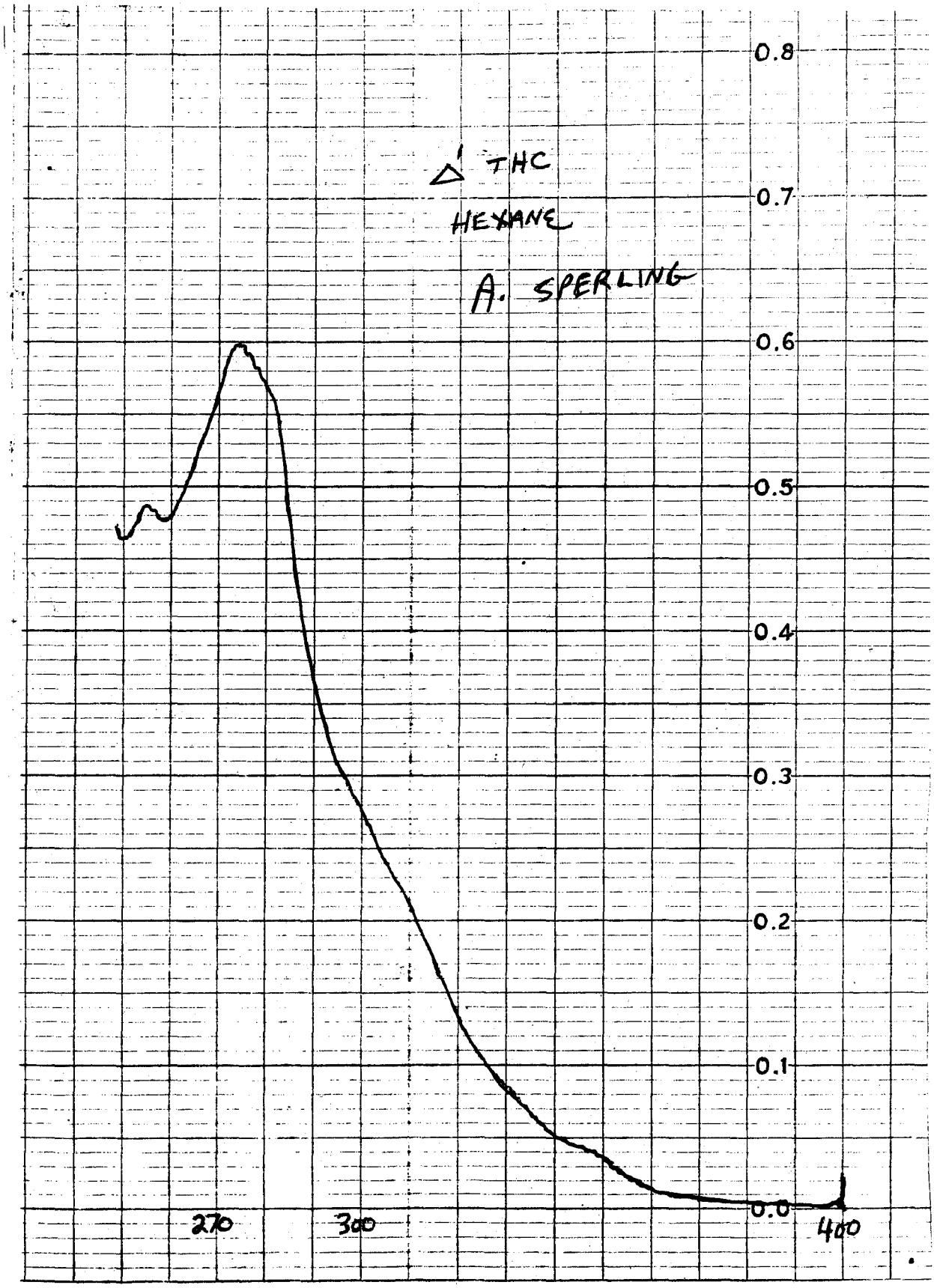

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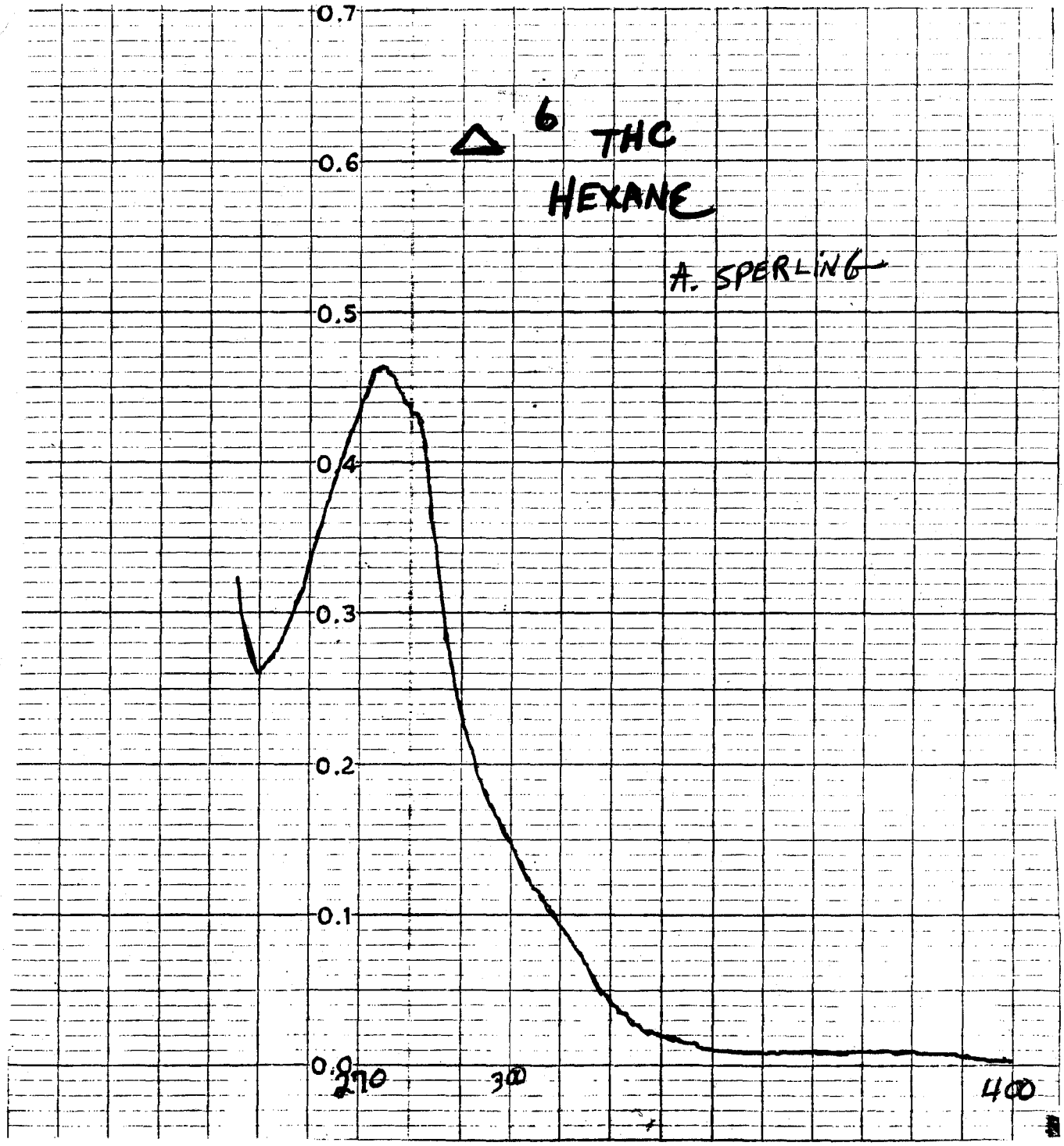

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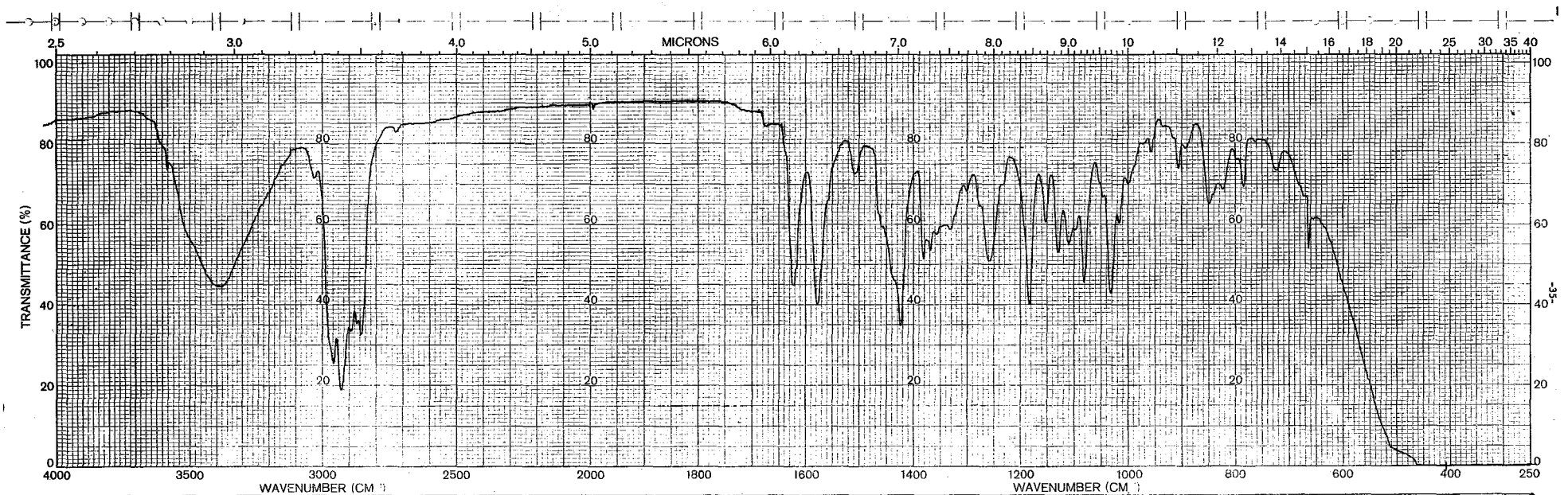

SAMPLE $\Delta^{1,6}$ THC	SOLVENT	REMARKS	SCAN SPEED M	OPERATOR A. R. Sperling, Ph.D.
ORIGIN	CONCENTRATION FILM BETWEEN		SLIT N	DATE 1-29-68
	CELL PATH NaCl SALT PLATES		PERKIN-ELMER	REF. No.
	REFERENCE		PART NO. 457 - 5001	

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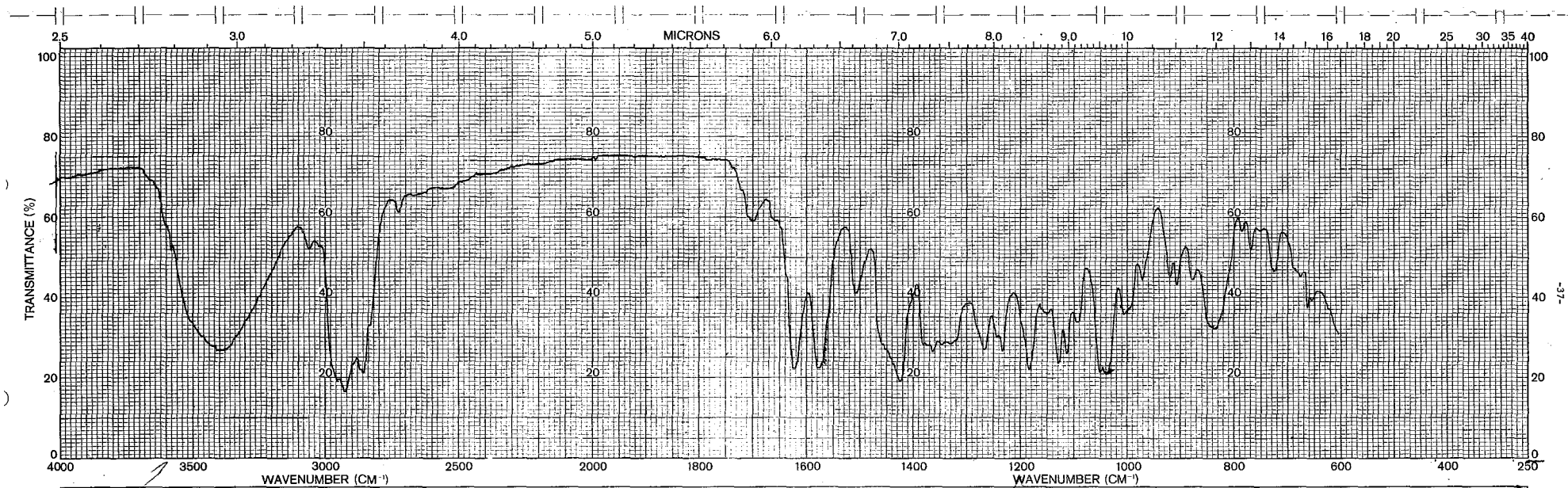

SAMPLE Δ' THC	SOLVENT NEAT	REMARKS	SCAN SPEED N	OPERATOR A. R. SPERLING, Ph.D.
ORIGIN	CONCENTRATION FILM BETWEEN		SLIT N	DATE 1-29-68
	CELL PATH NaCl PLATES		PERKIN-ELMER	REF. No.
	REFERENCE		PART NO. 457 – 5001	

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IDENTIFICATION OF METHYLBENZILATE

by Albert Sperling
Research Chemist
Special Testing and Research Laboratory

Recently our laboratories received a sample of an unknown material that was suspected of being a new benzilate derivative. It gave color tests characteristic of the benzilates - a red color when heated with sulfuric acid and an orange to green to blue color with Marquis reagent (see Microgram Vol. I, No. 9).

Thin layer chromatography revealed that the material was a mixture of two components, subsequently identified as JB-336 (N-Methyl-3-piperidyl-benzilate) and the methyl ester of benzilic acid. The methylbenzilate comprised about 80% of the sample, and was identified by a combination of ultraviolet and infrared spectroscopy and nuclear magnetic resonance.

ANALYSIS

The material was suspended in 1N sulfuric acid and extracted with chloroform. The neutral methyl benzilate was extracted into the chloroform layer while the basic JB-336 remained in the acidic aqueous phase.

Ultraviolet Spectrum:
Absorption maxima at
252, 258 and 264 mμ

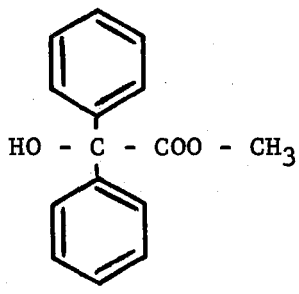
Infrared Spectrum:
a 200 mg. Potassium bromide pellet was obtained by evaporating the chloroform without heat. One mg. of the sample was used.

Physical Properties:

Pale yellow crystals, MP 75° C

$C_{15}H_{14}O_3$ MW 242

Structure:



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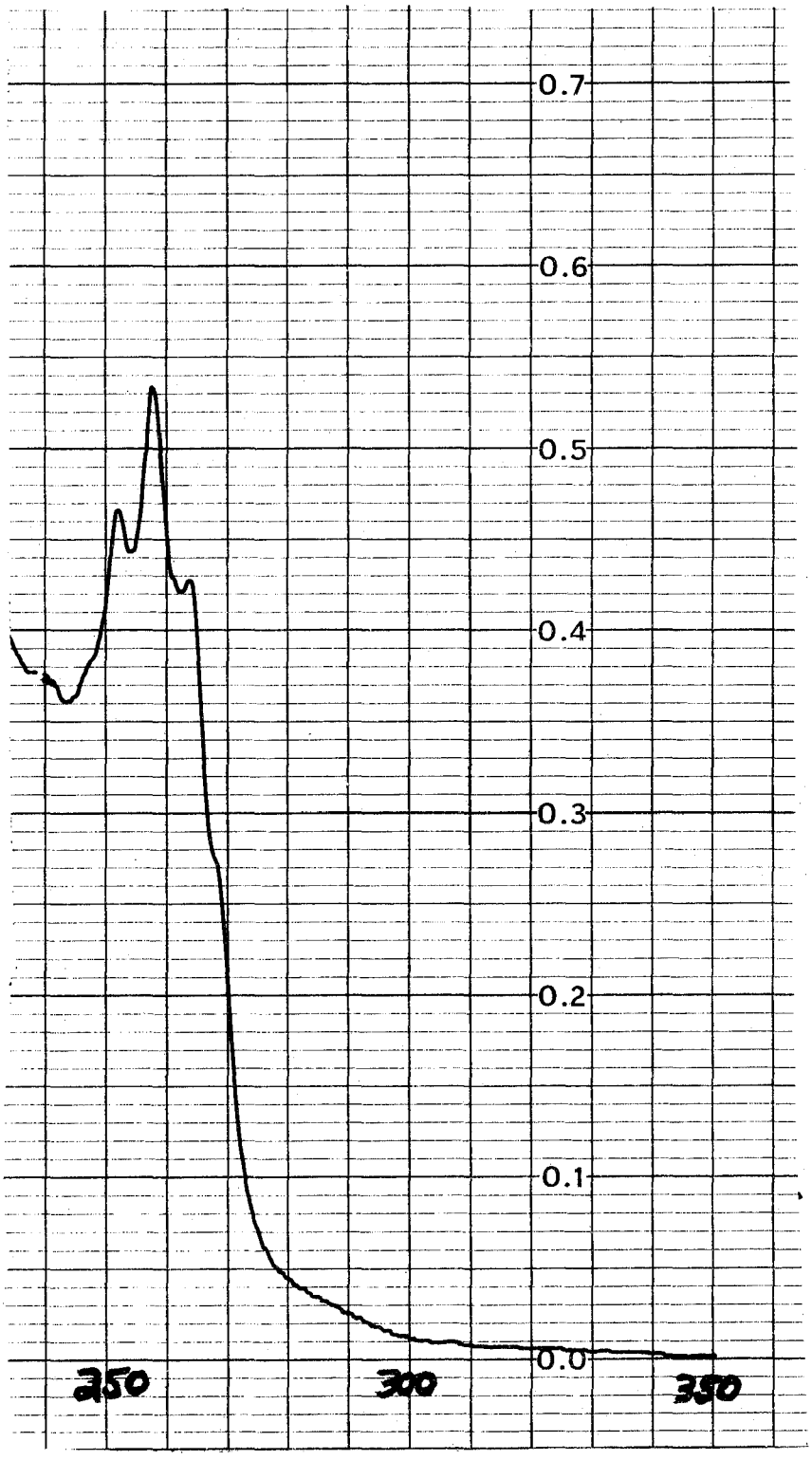

METHYL BENZILATE
In Chloroform

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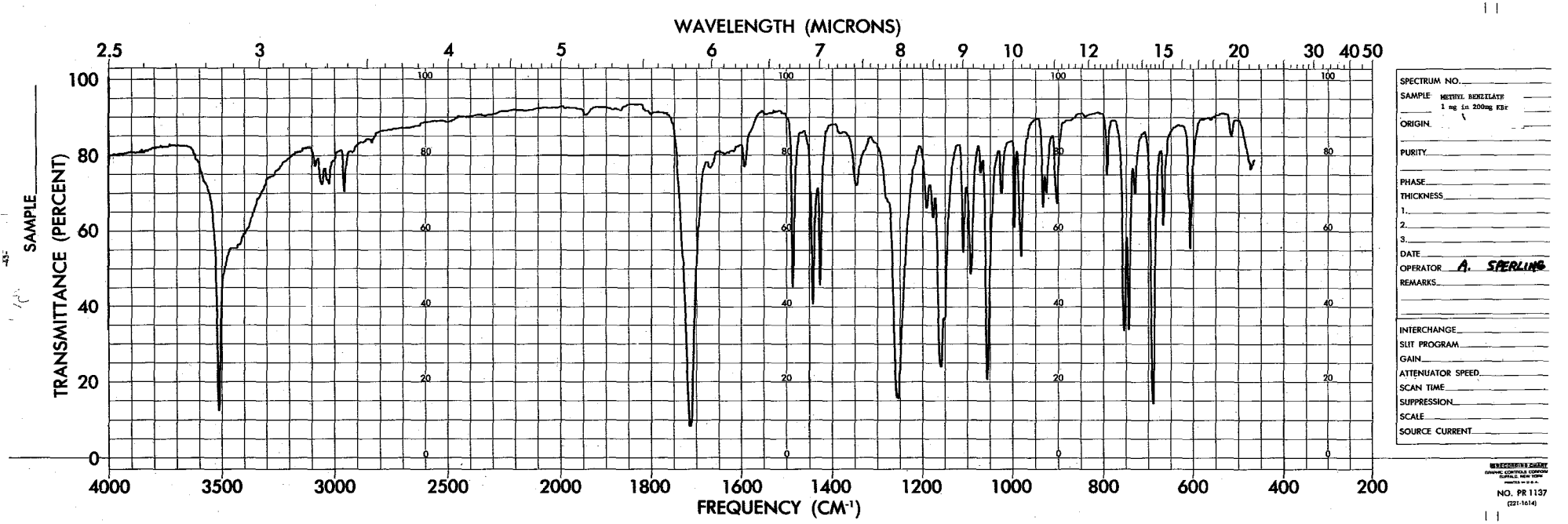

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ANALYSIS OF PHENCYCLIDINE HYDROCHLORIDE(PCP) BY GAS CHROMATOGRAPHY

By James P. Done, Chicago Regional Laboratory, BNDD

A quick qualitative and quantitative method of analysis of phencyclidine hydrochloride on BNDD Samples employing gas chromatography was devised. The method may also be used as a general screening method for the drug.

The advantages of this method over existing methods are: 1) a minimum of sample manipulation; 2) the loss of phencyclidine hydrochloride is kept at a minimum because the sample is not heated or solvent evaporated prior to the determination.

The injection port temperature is sufficiently high to cause dissociation of the amine salt. This is a condition which makes this method feasible.

Method:

Standard Solution: Weigh 5mg phencyclidine hydrochloride and transfer to a 10ml volumetric flask; dissolve amine salt in several mls. of methanol and then make to volume with methanol.

Sample Preparation: Transfer finely powdered tablet material equivalent to the weight of one tablet (usual dosage is 4-5mg phencyclidine hydrochloride per tablet) to a 25ml g.s. flask and add 10.0ml methanol. Shake the flask for several minutes and then filter solution through glass wool. The filtrate is used for the analysis.

Column for gas chromatography: 6 ft. x 4 mm i.d. glass column packed with 1% SE-30 on Gas Chrom Q 80/100.

Detector: Flame ionization detector.

Temperatures:

Column: 140°C
Injector: 265°C
Detector: 250°C

Carrier gas: Nitrogen. Flow rate: 80ml per minute
Sensitivity: 100/2

At the sensitivity selected a 5mcl injection (2.5mcg) of Pencyclidine Hydrochloride Standard Solution gave approximately one-half scale deflection (Peak area: 380.8mm^2). Retention time was 6.30 minutes.

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IDENTIFICATION OF COCAINE BY INFRA-RED SPECTROSCOPY

L. E. WENER, CHICAGO REGIONAL LABORATORY, BNDD

The spectrogram obtained from the infra-red spectroscopic examination of compounds isolated in a pure or nearby pure state is one of the most substantive methods of examination. It is a very important aid to the forensic chemist now that the courts and defense attorneys are beginning to challenge the identification of alkaloids, such as cocaine, by means of crystal and color tests alone.

Cocaine is ordinarily separated from most of its adulterants and/or diluents by extracting it as the hydrochloride salt with chloroform from a solution or suspension in 1+9 Hcl. The filtered chloroform extract is then evaporated on the steam bath to obtain the cocaine salt relatively pure. No difficulty was ordinarily encountered in obtaining the characteristic identifying crystals with the platinic chloride or gold chloride reagent solution. However, the cocaine hydrochloride crystals isolated this way were found not to give infra-red spectrograms which, for forensic purposes, sufficiently matched that given by the authentic.

It was theorized that the above difficulty was due to the acid hydrolysis, however much or slight, of the cocaine at steam bath temperatures due to the hydrochloric acid dissolved in the water solubilized in the chloroform. When the chloroform extract was first dried with excess anhydrous sodium sulfate, decanted, and then evaporated no such deterioration of the cocaine occurred and excellent infra-red spectrograms were obtained.

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BNDD LABORATORY NOTES
DALLAS REGIONAL LABORATORY
by John Wittwer

PROBLEM:

Dallas Regional BNDD Laboratory received an exhibit of purported Mescaline tablets. The tablets are deep red, round, biconvex compressed tablets weighing about 0.4120 gram. Presumptive test using Ehrlich reagent indicated an indole ring was present. Considerable U.V. specgral interference was encountered at about 275 mm in ethanol solvent. Analysis showed LSD and caffeine.

BACKGROUND:

Alexander's[1] alternate extraction procedure employing a chloroform shakeout from aqueous-bicarbonate solution was used, followed by chromatographing on an aluminum oxide column. The caffeine was carried along with the procedure. The basic deficiency is that Alexander's[1] alternate extraction procedure will extract all compounds of the following categories soluble in organic solvents: (a) bases, (b) phenolics, and (c) neutral compounds. A method combining Alexander's[1] 2% and 8% citric acid columns and a mini Al_2O_3 column was used. Alexander's[1] procedure was followed through extrusion of the 8% citric acid column and extraction of the alkaline ($NaHCO_3$) solution with $CHCl_3$. Instead of making to volume for U.V. scan, the combined $CHCl_3$ extract was evaporated to dryness and taken up in about 1 ml ethyl ether for transfer to Al_2O_3 column.

Al_2O_3 Column Chromatographic Step

Apparatus:

1. Disposable pipet having an I.D. of 5 mm and a total length of about 15 cm.
2. Portable U.V. light.

Reagents:

1. Chloroform - reagnet grade.
2. Ethyl Ether - reagent grade.
3. Aluminum Oxide - chromatographic (Mercke or Alcoa).
4. 95 % ethanol

1/ Alexander, T. G., Microgram, Volume 1, No. 2

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PROCEDURE:

A pledget of glass wool is placed in the constriction of the disposable pipet and alumina is added to a depth of about 5 cm. The column is pre-washed with about 5 cc of ethyl ether and the sample extract in 1 ml of ethyl ether is added to the column using an eye dropper. The column is washed with about 10-15 cc of ethyl ether. LSD reamins at the top of the column. LSD is then eluted with $CHCl_3$. The progress of the elution is then monitored using a portable ultra violet light. 15-20 cc $CHCl_3$ is sufficient to elute the LSD.

It has been found that spectro grade chloroform will not elute LSD from alumina. Apparently the small amount of ethanol present in reagent grade chloroform is responsible for eluting the LSD.

The addition of the Al_2O_3 column gives very clean extracts and it is possible to get good infra-red scans with nearly all samples.

Pioch[2] uses an aluminum oxide column on a preparative scale. LSD is eluted with Benzeneplus $CHCl_3$ (3 plus 1) and ISO-LSD is then eluted with $CHCl_3$.

2/ Pioch, R. P., Chemical Abstracts, Volume 50, 1956, page 10,803

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A RAPID ANALYSIS OF LSD

by

Albert R. Sperling, Ph. D.

The following is a method for rapidly analyzing preparations containing LSD. It will not separate LSD from iso-LSD or other lysergic acid containing moieties. These other substances, however, can easily be detected by thin-layer chromatography and will not interfere with the identification of LSD.

Analysis

The sample is mixed with 5 ml of 1% citric acid. If the sample consists of tablets or capsules, two or three should be used if available. The solution is transferred to a separatory funnel and made basic by small additions of powdered sodium carbonate. The solution is extracted with three 10 ml portions of Chloroform. The Chloroform is filtered and examined under long wave ultraviolet light. If there is no fluorescence there is no LSD present.

Quantitation

The chloroform solution is concentrated to a convenient volume (usually 10 ml) which will have an approximate concentration of 20 micrograms per ml. The solution is scanned on an ultraviolet spectrophotometer. LSD free base in chloroform exhibits a maximum at 308 mu. The absorbance of a standard solution is compared to that of the unknown.

Preparation of Standard Solution

Accurately weigh approximately 300 micrograms of LSD tartrate and dissolve in 3 ml of water. Transfer to a separatory funnel and make basic with sodium carbonate. Extract three times with 3 ml portions of chloroform and collect in a 10 ml volumetric flask. Bring to volume with chloroform.

Calculations

Convert the weight of LSD tartrate to the equivalent weight of LSD free base.

Wt. of LSD tartrate x .78 = wt. of LSD free base

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The amount of LSD in the sample is calculated by the formula

$$\frac{Au \times Cs}{As \times T} = \text{micrograms per ml of LSD free base (in the unknown solution)}$$

where Au is the absorbance of the unknown solution
A_s is the absorbance of the standard solution
C_s is the concentration of the LSD standard (free base) in micrograms per ml.
T is the number of tablets or capsules used.

Thin-Layer Chromatography

The chloroform solution is evaporated to about 1 ml and 10 microliters of standard and sample are spotted on silica gel G 250 micron plates. Two different plates are spotted each using a different solvent system.

System 1

chloroform	9	
methanol	2	

System 2

chloroform	18	(saturated with concentrated ammonium hydroxide)
methanol	2	

In these two systems LSD has an Rf of about 0.6. Iso-LSD spot. The plates are viewed under long wave ultraviolet light and LSD exhibits a blue-purple fluorescense. The plates are then sprayed with p-dimethylaminobenzaldehyde spray reagent. This is prepared as follows:

p-dimethylaminobenzaldehyde	2 grams
ethanol	50 ml.
concentrated hydrochloric acid	50 ml

LSD appears as a blue-purple spot.

Note
It is necessary that both of these systems be used in order to obtain a positive identification of LSD.

Discussion

This method is very rapid and can be used for many types of samples. However, some samples are more complex than others and may require a column chromatographic separation before analysis can be performed.

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TABLE A

ADDRESSES OF BNDD LABORATORIES	AREA SERVED
New York, New York Chief Chemist New York Regional Laboratory Bureau of Narcotics and Dangerous Drugs Room 1304 90 Church Street New York, New York 10007 Telephone: 212 264-6901	Maine, New Hampshire, Vermont, Rhode Island, New York, Massachusetts, Connecticut, New Jersey, Pennsylvania, Delaware
Washington, D.C. Chief Chemist Washington Regional Laboratory Bureau of Narcotics and Dangerous Drugs Washington, D.C. 20537 Telephone: 202 962-2556	Maryland, West Virginia, Virginia, North Carolina, South Carolina, Georgia, Florida, Puerto Rico
Chicago, Illinois Chief Chemist Chicago Regional Laboratory Bureau of Narcotics and Dangerous Drugs Room 725 New Post Office Building 433 West Van Buren Street Chicago, Illinois 60607 Telephone: 312 353-3640	North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Missouri, Wisconsin, Michigan, Illinois, Ohio, Indiana, Kentucky
Dallas, Texas Chief Chemist Dallas Regional Laboratory Bureau of Narcotics and Dangerous Drugs Room 1023 1114 Commerce Street Dallas, Texas 65202 Telephone: 214 749-3188	Oklahoma, Texas, Arkansas, Mississippi, Louisiana, Tennessee, Alabama
San Francisco, California Chief Chemist San Francisco Regional Laboratory Bureau of Narcotics and Dangerous Drugs 450 Golden Gate Avenue Box 36075, Room 8450 San Francisco, California 94102 Telephone: 415 556-0952	Washington, Oregon, Montana, Idaho, Wyoming, California, Nevada, Utah, Colorado, Arizona, New Mexico, Hawaii, Alaska

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PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Stramonium Preparations Labeled for Self-Medication

Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act) secs. 502 (a), (f), 503(b), 701(a); 52 Stat. 1050–51, 1052, as amended, 1055; 21 U.S.C. 352 (a), (f), 353(b), 371(a)) and delegated to the Commissioner of Food and Drugs (21 CFR 2.120), Part 3 is amended by adding thereto the following new section:

§ 3.64 Stramonium preparations labeled with directions for use in self-medication regarded as misbranded.

(a) Stramonium products for inhalation have been offered for use in the therapy of the acute attacks of bronchial asthma for many years although their reliability and effectiveness are questionable. Recently, a significantly increased number of reports have come to the attention of the Food and Drug Administration showing that such products have been subject to abuse and misuse on a fairly large scale, mostly by young people, through oral ingestion for the purpose of producing hallucinations. Reports of such use have been received from physicians and police and other law enforcement authorities. Reports have also appeared in the public press and in medical journals.

(b) Labeling these products with a warning that they are not for oral ingestion has not been effective in protecting the public. Misuse of stramonium preparations can cause serious toxic effects including toxic delirium, visual disturbances, fever, and coma. A number of serious reactions have already occurred from the oral ingestion of such products.

(c) On the basis of this information, the Commissioner of Food and Drugs has concluded that such articles have a potentiality for harmful effect through misuse and are not safe for use except under the supervision of a physician. In the interest of public health protection, therefore, the Food and Drug Administration adopts the following policy:

(1) Preparations containing stramonium supplied from the leaves, seeds, or any other part of the plant in the form of a powder, pipe mixture, cigarette, or any other form, with or without admixture of other ingredients, will be regarded as misbranded if they are labeled with directions for use in self-medication.

(2) The Food and Drug Administration will, on request, furnish comment on proposed labeling limiting any such preparation to prescription sale.

(d) The labeling or dispensing of stramonium preparations contrary to this statement after 60 days following the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

(Secs. 502 (a), (f), 503(b), 701(a); 52 Stat. 1050–51, 1052, as amended, 1055; 21 U.S.C. 352 (a), (f), 353(b), 371(a))

Dated: August 15, 1968.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

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