Annual Report

SUBMITTED TO:

Dr. Mahmoud A. ElSohly
Research Institute of Pharmaceutical Sciences
School of Pharmacy
135 Coy Waller Complex
University of Mississippi
University, Mississippi 38677

PERFORMED BY:

Science and Engineering Bioanalytical Chemistry RTI International 3040 Cornwallis Road P.O. Box 12194 Research Triangle Park, NC 27709-2194

Period Performance:

November 9, 2002 - November 8, 2003

RTI No.:

RTI / 07753 / Annual-04

Subcontract No.:

UM SUB #00-12-028

NIDA Contract No.:

N01DA-0-7707

Production, Analysis and Distribution of Cannabis and Marijuana Cigarettes

November 17, 2003

Prepared by:

Surinder Sabharwal Research Chemist Approved by:

Kenneth H. Davis, Jr. Principal Investigator

Table of Contents

	Page
RODUCTION	1
DDUCTION OF HAND-ROLLED HIGH POTENCY MARIJUANA CIGARETTES	2
erial	2
1 Hand-rolled Marijuana Cigarettes Batch No. 10604-1202-54A	2
2 Hand-rolled Marijuana Cigarettes Batch No. 10747-1003-180A	2
3 Cigarette Tubes (70 mm without filter)	2
ipment	2
duction of Hand-Rolled High Potency Marijuana Cigarettes	2
2 Batch No. 10747-1003-180A	2
illary Gas Chromatography for Cannabis and Cannabinoids	3
NUFACTURE OF HIGH POTENCY MARIJUANA CIGARETTES	3
erials	3
Bulk Marijuana for High Potency Cigarettes	3
Paper	4
3 Glue	4
Packaging	4
pment	4
luction of Cigarettes	4
llary Gas Chromatography for Cannabis and Cannabinoids	6
ORATORY ANALYSIS OF MARIJUANA CIGARETTES	6
terly Quality Control Analysis of Marijuana Cigarettes	6
-Term Stability Studies of Marijuana Cigarettes	7
lation of Polytron Method Used for Extraction of Marijuana Plant Material	7
ysis of Bulk Placebo and Active Marijuana Plant Material for Shipment	8
NTORY AND STORAGE	16
MENTS	16
JECT ADMINISTRATION	16
	Hand-rolled Marijuana Cigarettes Batch No. 10747-1003-180A. Cigarette Tubes (70 mm without filter) Ipment

Page

List of Tables

		Page
Table 1.	Bulk Marijuana Plant Material for High Potency Cigarettes	3
Table 2.	Quarterly Quality Control Analyses for Marijuana Cigarettes	
Table 3.	Stability Study for Marijuana Cigarettes	
Table 4.	Marijuana Cigarette Balances	
Table 5.	Shipments of Marijuana Cigarettes	19

List of Figures

ure 1. Flowchart for Manufacture of Marijuana Cigarettes, Batch No. 10604-0203-955
ure 2. Stability Study of Low Potency Marijuana Cigarettes Batch No. 9223-0199-4711
ure 3. Stability Study of Mid Potency Marijuana Cigarettes Batch No. 9497-0499-103
ure 4. Stability Study of Mid Potency Marijuana Cigarettes Batch No. 9497-0499-99
ure 5. Stability Study of Mid Potency Marijuana Cigarettes Batch No. 10074-0301-97
ure 6. Stability Study of High Potency Marijuana Cigarettes RTI Batch # 10604-0203-95

List of Appendices

Appendix A Data Sheets

Appendix B Analytical Method: Capillary GC Assay of Major Cannabinoid Compounds (5854-010)

Production, Analysis and Distribution of Cannabis and Marijuana Cigarettes

Annual Report

November 9, 2002 - November 8, 2003

1.0 INTRODUCTION

This Annual report summarizes work performed at RTI International¹ (hereafter referred to as "RTI") during the period November 9, 2002 – November 8, 2003 under NIDA Contract N01DA-0-7707 entitled "Production, Analysis and Distribution of Cannabis and Marijuana Cigarettes." This work was performed by RTI under a subcontract to the University of Mississippi (UM SUB #00-12-028), which holds the prime contract to NIDA. During this report period, RTI provided the University of Mississippi and NIDA with analytical services, the manufacture of marijuana cigarettes, and secure facilities for drug storage, packaging and shipment. A complete description of these efforts is provided in the following sections:

Section 2.0 describes the manufacture of two batches of hand-rolled high potency marijuana cigarettes;

Section 3.0 describes the manufacture of a batch of high potency marijuana cigarettes;

Section 4.0 describes analytical activities, including quarterly reanalysis of marijuana cigarette and bulk plant material batches in storage at RTI, analyses associated with stability studies and validation of method used for extraction of marijuana plant material;

Section 5.0 provides a complete inventory of marijuana cigarettes that are being maintained under this contract;

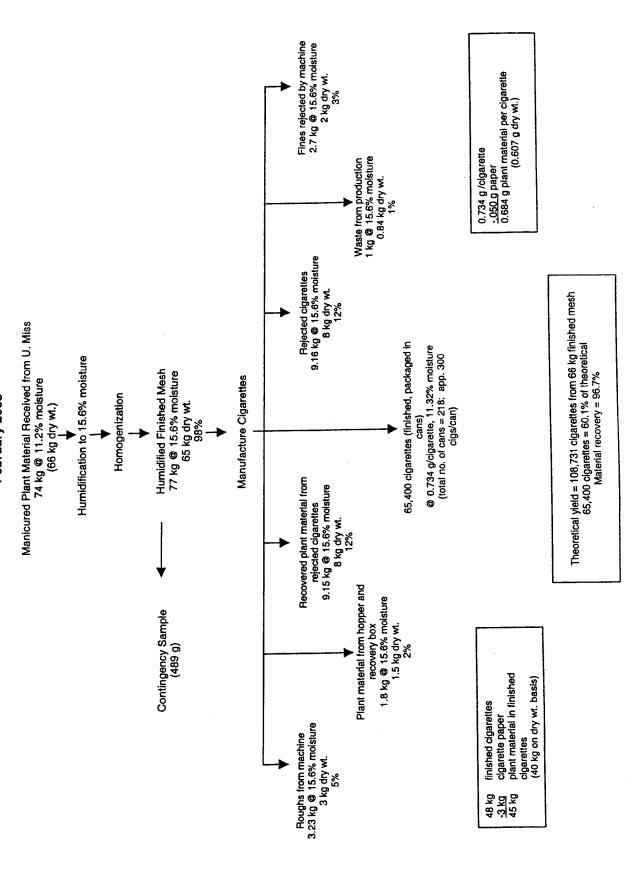
Section 6.0 describes the shipments that have been made from RTI as part of this project; and Section 7.0 provides a brief description of the administrative aspects particular to this project.

¹ RTI International is a trade name of Research Triangle Institute.

4 pages withheld in their entirety –

Proprietary Information

Figure 1. Flowchart for Manufacture of Marijuana Cigarettes, Batch No. 10604-0203-95 February 2003



3.4 Capillary Gas Chromatography for Cannabis and Cannabinoids

The analysis of marijuana cigarettes and *cannabis* preparations was performed by capillary GC (see Analytical Method No. 5854-010 in Appendix B). Briefly, solutions of *Cannabis* extracts were chromatographed on a 30 M DB-17 capillary column at 232 °C after the addition of the androst-4-ene-3, 17-dione internal standard. Samples were analyzed in duplicate using 7-point calibration curves with mean square regression.

In order to separately determine cannabidiol from cannabidiolic acid, and Δ^9 -THC from Δ^9 -THC acids A and B, it was necessary to derivatize the mixture with an agent such as bis (trimethylsily) trifluoroacetamide prior to chromatography to provide the TMS esters and ethers of the subject compounds. The TMS derivatives of cannabidiolic acid and Δ^9 -THC acids A and B can be separated on the 30 M DB-17 capillary column. Underivatized, the acids of Δ^9 -THC and other cannabinoids decarboxylate instantaneously in the injection port and chromatograph as the parent compound, while the TMS derivatives of the acids do not decarboxylate and can be chromatographically separated from the parent compounds.

Extracts obtained with three different extraction procedures are analyzed to provide an overall picture of the cannabinoid content of *Cannabis* samples. For individual *Cannabis* samples, two aliquots are extracted and analyzed by the ethanol-Soxhlet method, one by the modified Lerner method, and one by the Polytron method. This approach provides a quadruple analysis with a built-in method crosscheck, as well as an estimate of the cannabinoid acids after derivatization.

3.5 Analysis of High Potency Marijuana Cigarettes (Batch No. 10604-0203-95)

During the grading process described in Section 3.3, cigarettes were removed from each tray for inclusion in an on-going cigarette stability study. Cigarette samples in this stability study were stored under three different temperature conditions (room, refrigerator, and frozen). An additional five cigarettes were removed from each tray for moisture content determination and GC analysis (see SOP PDFA-400). The average weight per cigarette was determined from the weights of 20 cigarettes taken from each tray.

The results of our capillary GC analysis of the high potency cigarettes indicate that the average Δ^9 -THC content of the 29 trays was 6.34 \pm 0.21%. The average weight per cigarette was 0.734 \pm 0.05 g and the average moisture content was determined to be 11.32%.

4.0 LABORATORY ANALYSIS OF MARIJUANA CIGARETTES

4.1 Quarterly Quality Control Analysis of Marijuana Cigarettes

Quarterly quality control studies were performed on twelve batches of marijuana cigarettes in storage at RTI. The analytical method employed for the analysis of marijuana cigarettes at RTI utilizes the same method of analysis as described in Section 3.4. The representative samples for analysis were taken from contingency containers stored in freezers at –18 °C. Complete, up-to-date analytical information obtained through these quarterly quality control analyses is provided in Table 2. Cigarette data sheets were updated quarterly based on the results of these studies. The current versions of these data sheets are provided in Appendix A.

The hand-rolled high potency marijuana cigarettes (Batch No. 10747-1003-180A) prepared in October 2003 have been added to the quarterly quality control storage studies mentioned above.

4.2 Long-Term Stability Studies of Marijuana Cigarettes

Stability studies on marijuana cigarettes were begun under the previous RTI contract with NIDA, and continued under the current contract arrangement. Six batches of marijuana cigarettes have been analyzed for the stability study so far. All batches of cigarettes have been stored under three temperature conditions. The study temperatures were frozen (-18 °C), refrigerated (4 °C), and room temperature (18 °C). All samples were stored in the dark.

All batches of cigarettes stored under these three temperature conditions have been analyzed quarterly for up to 52 months for cigarette Batch No. 9223-0199-47 and 49 months for batches 9497-0499-99 and 9497-0499-103. Cigarette Batch No. 10074-0301-97 has been analyzed for 27 months so far. Batch No. 10604-0203-95 has been analyzed for 4 months and Batch No. 10747-1003-180A for time zero. The six study batches include a low potency batch (9223-0199-47), three medium potency batches (9497-0499-99, 9497-0499-103, and 10074-0301-97), one high potency batch (10604-0203-95) and one hand-rolled high potency batch (10747-1003-180A). The new hand-rolled high potency marijuana cigarettes, RTI Batch No. 10747-1003-180A, have been added to the stability storage studies in October 2003.

Cannabinoid content was determined as a measure of cigarette stability. The analytical methodology utilized, briefly described in Section 3.4, is detailed in Analytical Method 5854-010. The results to date show no observable decrease in Δ^9 -THC content when cigarettes are stored at -18 °C. Table 3 contains the data obtained to date in this study. Figures 2, 3, 4, 5, and 6 are graphic representations of the cannabinoid and cannabinoid acid content of cigarettes obtained on a quarterly basis when stored at the three temperatures.

Based on these stability studies, it appears that Δ^9 -THC content remained relatively constant with no significant decomposition when the cigarettes were stored in a freezer. The expected slow decomposition is observed when stored at refrigerated or room temperature.

4.3 Validation of Polytron Method Used for Extraction of Marijuana Plant Material

We have validated the Polytron method of extraction of marijuana plant material. We have been collecting the data for seven batches of marijuana cigarettes and have submitted the data to the statistical department at RTI. The statistical tests confirm there are no statistical differences between the THC values obtained by the modified Lerner and Polytron methods. The P values for each batch are greater than the 0.05 value at the 95% confidence interval. The data was paired from two methods (modified Lerner and Polytron) within each batch. The Wilcoxon Signed Rank test on the differences was used to obtain all results. High correlation was reported between both methods.

Protocol 5854-010 was updated to include the Polytron method and is provided in Appendix B.

4.4 Analysis of Bulk Placebo and Active Marijuana Plant Material for Shipment

Quarterly quality control analysis was also performed on the placebo bulk plant material (Batch No. 9022-0598-111-1) and bulk high potency marijuana plant material (RTI Batch No. 8976-1001-26). The analytical method used for the analysis of bulk plant material at RTI utilizes the same method of analysis as described in Section 3.4. The updated data sheets are provided in Appendix A.

Table 2.

Quarterly Quality Control Analyses for Marijuana Cigarettes

Δ⁹-THC Content (%)

			J-12	State of the		E	atch No). (e) (1)	The Alex			States:	
	9223- 0199- 47	6567- 0891- 20	6567- 0194- 47	6567- 0496- 125	9022- 0598- 111	10368- 1002- 187	9497- 0499- 99	9497- 0499- 103	10074- 0301- 97	8976- 0701- 6-1	10604- 1202- 54A	10604- 0203- 95	10747- 1003- 180A
	14.146			Mary Carl				41.20.00		July	Dec.	Feb.	Oct.
Date of Manufacture	Jan. 1999	Aug. 1991	Jan. 1994	Apr. 1996	May 1998	Oct. 2002	Apr. 1999	Apr. 1999	March 2001	2001	2002	2003	2003
Original Assay	1.79	1.78	3.95	3.13	0.0013	0.001	3.42	2.93	3.80	6.30	6.89	6.34	8.38
Mar-99	-	-	-	-	0.004	•	-	-	•	- !	-	•	
Jun-99	1.70	1.90	3.31	3.23	0.005	•	-		-	-	-	•	
Jul-99	-	•	-	-	-		3.46	2.67	-	-	•	•	
Sep-99	1.74	1.90	3.43	2.93	0.003	•	•		-		<u>.</u>	-	•
Oct-99	-	-	•	•	<u> </u>	•	3.47	2.72	•	- -	-	<u> </u>	
Dec-99	1.75	1.82	3.46	3.33	0.003		-	0.66		-		-	-
Jan-00	<u> </u>	<u>-</u>	-	-	-	-	3.34	2.66	<u> </u>			_	
Mar-00	1.65	1.95	3.36	3.04	0.006	-	3.45	2.45					
Jun-00	1.94	2.07	3.78	3.21	0.008	-	3.59	3.08			 		
Sep-00	1.99	2.09	3.82	3.10	0.013		3.51	2.79	- -		<u> </u>		
Dec-00	1.87	1.96	3.67	3.02	0.018	-	3.33	2.19				 	-
Mar-01	1.91	1.99	3.71	3.35	0.014	-		3.23	 	-			-
Jun-01	2.13	2.25	4.49	3.42	0.002	•	3.87	3.13	3.33	-			
Sep-01	2.02	2.20	4.07	3.59	0.003	-	3.89	3.13	3.33	-	 	<u> </u>	
Dec-01	1.98	2.37	4.04	3.49	0.009	-	3.56		3.09		 	-	
Mar-02	1.97	2.14	4.05	3.43	0.004	-	3.96	3.07 2.72	2.80		 		 -
Jun-02	1.71	2.04	3.49	3.10	0.004	-	3.55	2.72	2.80	-	-	-	 -
Sep-02	1.82	2.03	3.55	3.00	0.003	-			2.89		 	 	+ -
Dec-02	1.72	1.76	3.65	3.26	0.003	-	3.63	2.92	2.89	6.30	6.89	 	+
Jan-03		-	-	-	•	-	- 0.65	270	2.90	6.48	7.00	6.34	+
Mar-03	1.74	1.83	3.68	2.97	0.006	0.001	3.65	2.70	2.90	6.57	6.71	5.75	+
June-03	1.73	1.98	3.53	3.02	0.005	0.007	3.32	2.67	2.95	6.44	0.71	6.03	+
Sep-03	1.70	1.78	3.27	3.04	0.002	0.004	3.30	2.53	2.70	0.44	7.18	0.00	8.38
Oct-03								L	<u> </u>	<u> </u>	1 /.18		0.30

Table 3.
Stability Study for Marijuana Cigarettes

Δ9-THC Content (%)

	9223-0199-47 (Low Potency)				9497-0499-9 High Potenc	9	5	497-0499-10 Mid Potency	ა	,	High Potency	•
Storage	Room (18 °C)	Retrigerator (4 °C)	Freezer (-18 °C)	Room (18 °C)	Retrigerator (4 °C)	Freezer (-18 °C)	Room (18 °C)	Refrigerator (4 °C)	Freezer (-18 °C)	Room (18 °C)	Refrigerator (4 °C)	Freezer (-18 °C)
Conditions Time 0	1.79			3.42	-	•	2.93	-	•	3.80	-	•
3 mo	2.01	1.91	1.89	3.43	3.30	3.25	2.60	2.70	2.53	•		•
4 mo			-	-		-	-	-	-	3.08	3.34	3.45
	1.72	1.68	1.96	3.00	3.24	3.08	2.56	2.76	2.67	-		· -
6 mo			-	-	-		-		-	2.85	3.16	3.42
7 mo	1.74	1.74	1.81	3.05	3.13	3.43	2.64	2.79	2.77	-	-	-
9 mo	1.74		•	_		•		-	-	3.08	3.09	3.58
10 mo		1.57	1.79	3.06	2.74	2.83	3.09	3.07	3.05		-	-
12 mo	1.64	1.07						-	•	2.89	3.11	3.30
13 mo		1.87	1,84	3.07	3.45	3.38	2.27	2.88	2.94		-	•
15 mo	1.58	1.07		-		-			-	2.72	2.56	2.96
16 mo		1.69	1.87	2.92	3.32	3.43	2.51	2.86	3.05	2.49	2.51	3.21
18 mo	1.79	1.74	1.88	3.02	3.41	3.30	2.47	2.75	2.84	-	-	-
21 mo	1.63	1.74	-	-			-	<u> </u>	-			
23 mo		1.66	1.99	3.42	3.46	4.15	2.93	3.19	3.27	2.22	2.77	3.14
24 mo	1.53	 	2.24	3.43	3.44	3.75	2.72	2.95	3.13	2.30	2.56	2.87
27 mo	1.76	1.61	2.12	2.95	3.69	4,12	2.44	3.13	3.44		-	-
30 mo	1.73	1.91		3.01	3.74	3.64	2.31	2.71	3.11	-	1 .	
33 mo	1.71	1.95	2.30		3.43	3.74	2.35	3.00	3.20	 		-
36 mo	1.58	1.83	2.11	2.99	-	3.43	2.02	2.43	2.81	 .	+	-
39 mo	1.46	1.84	1.99	2.44	3.09		2.07	2.40	2.89	 .	 .	
41 mo			-	2.35	2.88	3.50	-	2.40	-	 	 	 .
42 mo	1.24	1.63	1.74		-	-	-	 - 		 	 	
44 mo	1.33	1.71	1.92	<u> </u>	•	-		ļ	2.99	 	 	
46 mo	-	-	-	2.25	3.14	3.54	1.99	2.56		ļ. <u> </u>	+	
49 mo	1.18	1.63	1.67	2.09	2.85	3.57	1.92	2.34	2.68	 	•	$\dot{+}$
52 mo	1.21	1.61	1.78					<u></u>	<u> </u>	<u> </u>		<u></u>

Table 3.
Stability Study for Marijuana Cigarettes (continued)

Δ9-THC Content (%)

Storage Rcom (18 °C) Reirigerator Freezer (18 °C) Reirigerator Freezer (18 °C) Reirigerator Room Reirigerator (18 °C) Reirigerator Reirigerator (18 °C) Reirigerator Reirig	Ī	1.50		Batc	h No.	(水温域)	370
Storage		1	0604-0203-9	5	, 10	/4/-1003-10	س م
Conditions (18 °C) (4 °C) (-18 °C) (4 °C) (-18 °C) (4 °C) (-18 °C)	Storage			Freezer	Room	Refrigerator	Freezer
3 mo 4 mo 6.22 6.34 6.63 6 mo 7 mo 9 mo 10 mo 12 mo 13 mo 15 mo 16 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 44 mo 44 mo 44 mo 44 mo 46 mo			(4 °C)	(-18 °C)		(4 °C)	(-18 °C)
4 mo 6.22 6.34 6.63 6 mo 7 mo 9 mo 10 mo 12 mo 13 mo 15 mo 16 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	Time 0	6.34			8.38		
6 mo 7 mo 9 mo 10 mo 112 mo 13 mo 15 mo 16 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 44 mo 46 mo	3 mo						
7 mo 9 mo 10 mo 110 mo 12 mo 13 mo 15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 44 mo 446 mo	4 mo	6.22	6.34	6.63			
9 mo 10 mo 12 mo 13 mo 15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	6 mo						
10 mo 12 mo 13 mo 15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	7 mo						
12 mo 13 mo 15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	9 mo					ļ	
13 mo 15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	10 mo						
15 mo 16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	12 mo					 	
16 mo 18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	13 mo						
18 mo 21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	15 mo					<u> </u>	
21 mo 23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	16 mo					<u> </u>	
23 mo 24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	18 mo						
24 mo 27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	21 mo						
27 mo 30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	23 mo				ļ	ļ	<u> </u>
30 mo 33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	24 mo						<u> </u>
33 mo 36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	27 mo					ļ	
36 mo 39 mo 41 mo 42 mo 44 mo 46 mo	30 mo				<u> </u>	ļ	<u> </u>
39 mo 41 mo 42 mo 44 mo 46 mo	33 mo				ļ	_	<u> </u>
41 mo 42 mo 44 mo 46 mo	36 mo					<u> </u>	
42 mo 44 mo 46 mo	39 mo				<u> </u>	<u> </u>	
44 mo 46 mo	41 mo					 _	ļ
46 mo	42 mo					<u> </u>	ļ
	44 mo				<u> </u>		
	46 mo				ļ		<u> </u>
49 mo	49 mo				<u> </u>		<u> </u>

* Total THC (Free THC + THC Acids)

NOTE: Time zero for Batch 9223-0199-47 is 02/1999.

Time zero for Batch 9497-0499-99 is 05/1999.

Time zero for Batch 9497-0499-103 is 05/1999.

Time zero for Batch 10074-0301-97 is 04/2001.

Time zero for Batch 10604-0203-95 is 03/2003.

Time zero for Batch 10747-1003-180A is 10/2003.

Figure 2.
Stability Study of Low Potency Marijuana Cigarettes
Batch No. 9223-0199-47

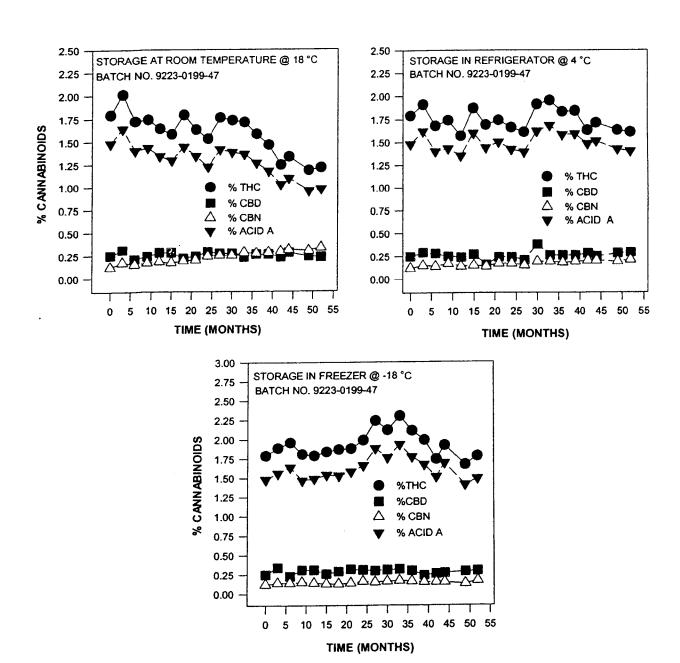


Figure 3.
Stability Study of Mid Potency Marijuana Cigarettes
Batch No. 9497-0499-103

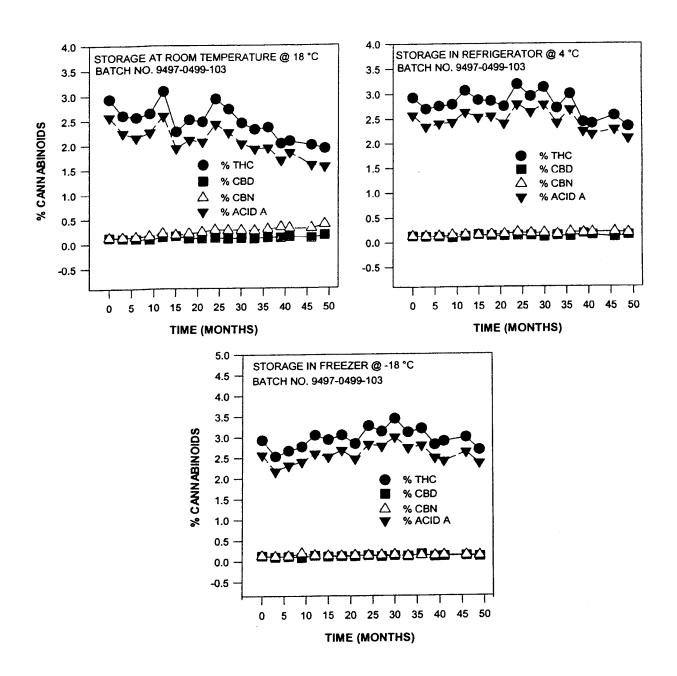
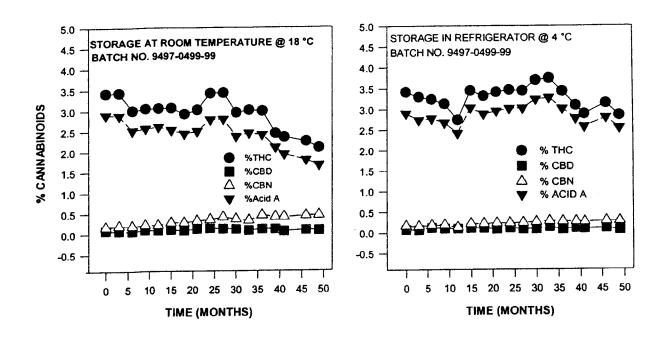


Figure 4.
Stability Study of Mid Potency Marijuana Cigarettes
Batch No. 9497-0499-99



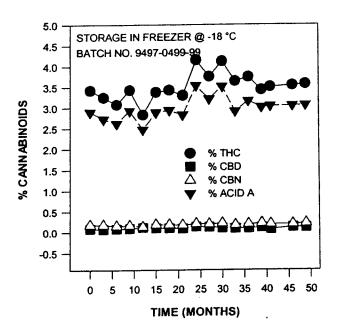


Figure 5.
Stability Study of Mid Potency Marijuana Cigarettes
Batch No. 10074-0301-97

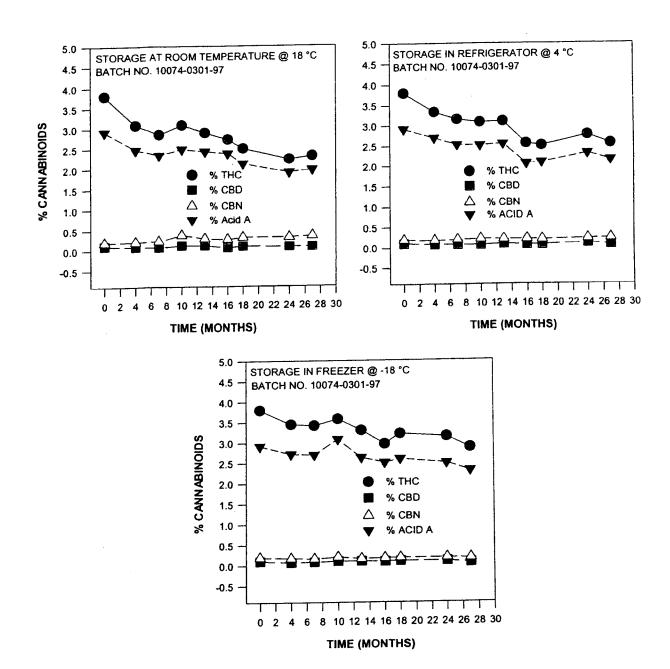
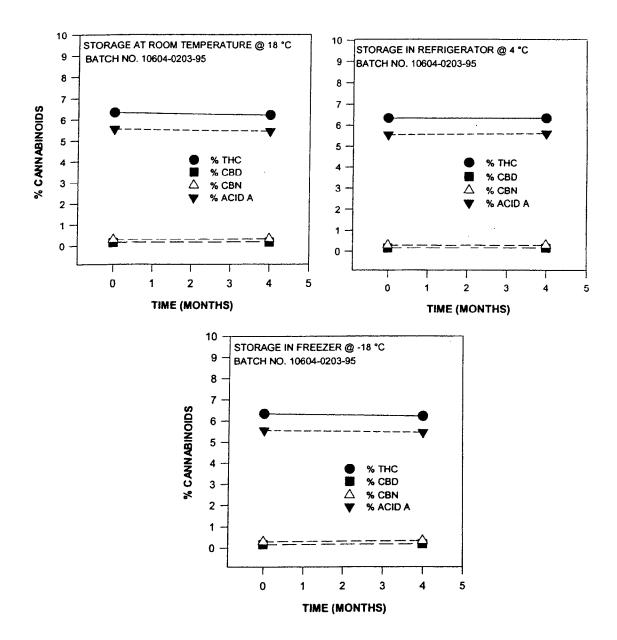


Figure 6
Stability Study of High Potency Marijuana Cigarettes
RTI Batch # 10604-0203-95



DATA SHEET

Marijuana Cigarettes

ID Number:

9223-0199-47-4410 through 9223-0199-47-4651

Marijuana:

Mississippi-grown Jamaican, Special Hybrid and Mexican

CJAF-95

828

CHYF-95

865, 874, 893, 899

CYHF-95

882

CMEF-95

871, 876

CJAF-97

CCOF-97

903, 905, 906, 907, 908

Holland-97

936 940

Size:

85 mm length x 25 mm circumference

Weight:

 0.779 ± 0.05 g average weight per cigarette overall; individual cans may vary from 0.655 g to 0.855 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content:

 $10.80 \pm 0.27\%$ average: ranges from 10.30% to 11.35%

 Δ^9 -THC Content:

GLC analysis of cigarette samples, $1.70\% \pm 0.15\%$

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; H.B. Fuller Co., Greensboro, NC;

Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning:

Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be

directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

9223-0199-47-4651, Frozen Contingency Can

Sample Type and Name: Marijuana Cigarettes, 1.70% Δ^9 -THC

71		1			4.	E.,	-	10	'n			4.1
k	(i	n	d	Ć	ıf	1	۱r	ia	ï	ν	si	S

Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC
TMS Derivative	1 Sample	Total Area by GLC

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Λ ⁹ -THC	0.50	1.64% ± 0.01%	1.87% ± 0.05%	1.59% ± 0.02%	1.70% ± 0.15%
Cannabidiol	0.36	0.23% ± 0.00%	0.29% ± 0.01%	0.23% ± 0.01%	0.25% ± 0.03%
Cannabinol	0.62	0.15% ± 0.01%	0.16% ± 0.01%	0.14% ± 0.01%	0.15% ± 0.01%
∆ ⁸ -THC	0.46	ND	ND	ND	ND

ND = Not Detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.21%
Δ ⁹ -THC Acid A	0.56	1.42%
∆9-THC Acid B	0.74	0.06%
Cannabichromene	0.17	0.08%
Cannabidiol	0.11	0.17%

DATA SHEET

Marijuana Cigarettes

ID Number:

6567-0891-20-3471 through 6567-0891-20-3643

Marijuana:

Mississippi-grown Mexican

CCOF-90 702

402-2, 708-9 CJAF-90 CK1F-88 394-7, 681

CK1F-90 401-2, 691, 698, 701, 703

687-9, 695, 696, 699, 704, 707, 709, 710 CMEF-90

694-9 CMEX-90

Size:

85 mm length x 25 mm circumference

Weight:

 0.689 ± 0.04 g average weight per cigarette overall; individual cans may vary from 0.599 g to 0.766 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $9.63 \pm 0.69\%$ average: ranges from 8.25% to 10.31%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 1.78% \pm 0.04%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

No. 4731 cigarette seam glue, Stuck of North Carolina; conforms with FDA

Compositional Requirement 121.2520

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning:

Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be

directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3),

589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

6567-0891-20-3642, Frozen Contingency Can

Sample Type and Name: Marijuana Cigarettes, 1.78% Δ^9 -THC

Apple of the second of the	M	des and	18 18 A. C.
Kind	_ 2	4	1
KIDA	nt.	Ana	IVSIS
1/11/0	· ·		.,

Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC
TMS Derivative	1 Sample	Total Area by GLC

Nonderivatized Extract

RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
0.50	1.75% ± 0.00%	1.82% ±0.02%	1.77% ±0.05%	1.78% ± 0.04%
0.36	0.12% ± 0.03%	0.15% ±0.01%	0.15% ±0.01%	$0.14\% \pm 0.02\%$
0.62	0.11% ± 0.03%	0.14% ±0.00%	0.14% ±0.01%	$0.13\% \pm 0.02\%$
0.46	ND	ND	ND	ND
	0.50 0.36 0.62	0.50 1.75% ± 0.00% 0.36 0.12% ± 0.03% 0.62 0.11% ± 0.03%	0.50 1.75% ± 0.00% 1.82% ±0.02% 0.36 0.12% ± 0.03% 0.15% ±0.01% 0.62 0.11% ± 0.03% 0.14% ±0.00%	0.50 1.75% ± 0.00% 1.82% ±0.02% 1.77% ±0.05% 0.36 0.12% ± 0.03% 0.15% ±0.01% 0.15% ±0.01% 0.62 0.11% ± 0.03% 0.14% ±0.00% 0.14% ±0.01%

ND = Not Detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.12%
Δ ⁹ -THC Acid A	0.56	1.59%
∆9-THC Acid B	0.74	0.07%
Cannabichromene	0.17	0.07%
Cannabidiol	0.11	0.07%

Approved by:

<u>10 - 0 3 - 0 3</u> Date

DATA SHEET

Marijuana Cigarettes

ID Number:

6567-0194-47-3644 through 6567-0194-47-3828

Marijuana:

Mississippi-grown Mexican and Special Hybrid

CK1M-87 93-1, 93-20, 93-21 676, 678, 684 CK1F-88

93-32, 93-33, 93-36, 93-39, 93-45 CMEF-93

Size:

85 mm length x 25 mm circumference

Weight:

 0.734 ± 0.03 g average weight per cigarette overall; individual cans may vary from 0.687 g to 0.774 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content:

 $11.41 \pm 0.95\%$ average: ranges from 9.53% to 12.61%

Δ9-THC Content:

GLC analysis of cigarette samples, 3.27% \pm 0.24%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

No. 4731 cigarette seam glue, Stuck of North Carolina; conforms with FDA

Compositional Requirement 121.2520

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning:

Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be

directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well.

The use of a biological indicator for this monitoring process is recommended.

Date:

DATA SHEET

Marijuana Cigarettes

ID Number:

6567-0496-125-3829 through 6567-0496-125-4235

Marijuana:

Mississippi-grown Jamaican, Special Hybrid and Mexican

CJAF-95

831, 834

CHYB-95

835, 836, 837, 841, 842, 844, 845, 846, 848,

850, 852, 853, 870, 878, 889, 891

855, 877, 886 CMEF-95

Size:

85 mm length x 25 mm circumference

Weight:

 0.733 ± 0.05 g average weight per cigarette overall; individual cans may vary from 0.640 g to 0.864 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $12.54 \pm 0.49\%$ average: ranges from 11.01% to 13.22%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 3.04% \pm 0.21%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; H.B. Fuller Co., Greensboro, NC;

Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged and cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning:

Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be

directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

6567-0496-125-4235, Frozen Contingency Can

Sample Type and Name: High Potency Marijuana Cigarettes, 3.04% Δ^9 -THC

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhiet	4 Samples	Internal Standard by GL
Modified Lerner	2 Samples	internal Standard by GL
Polytron	2 Samples	Internal Standard by GL
TMS Derivative	1 Sample	Total Area by GLC

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Δ ⁹ -THC	0.50	3.06% ± 0.17%	3.24% ± 0.05%	2.83% ± 0.00%	3.04% ± 0.21%
Cannabidiol	0.36	0.17% ± 0.03%	0.18% ± 0.00%	0.14% ± 0.00%	$0.16\% \pm 0.02\%$
Cannabinol	0.62	0.12% ± 0.00%	0.12% ± 0.01%	0.10% ± 0.00%	$0.11\% \pm 0.01\%$
∆ ⁸ -THC	0.46	ND	ND	ND	ND

ND = Not Detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.28%
Δ ⁹ -THC Acid A	0.57	2.71%
Δ ⁹ -THC Acid B	0.74	0.05%
Cannabichromene	0.17	0.10%
Cannabidiol	0.12	0.06%

ND = Not Detected

DATA SHEET

Placebo Marijuana Cigarettes

ID Number:

9022-0598-111-4236 through 9022-0598-111-4409

Marijuana:

Placebo marijuana prepared by ethanol extraction of Mississippi-grown Mexican marijuana

CMEF-95

868, 875, 887, 869, 873, 883, 879, 863, 872, 880

CJAF-95

830, 833

CCOF-95

895

CHYF-95

849, 890, 888, 838, 866, 881, 854

Size:

85 mm length x 25 mm circumference

Weight:

 0.702 ± 0.40 g average weight per cigarette overall; individual cans may vary from 0.580 g

to 0.758 g average weight per cigarette; weight data expressed as average weight ±

standard deviation

Moisture Content: $12.43 \pm 0.45\%$ average: ranges from 11.59% to 13.29%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 0.002% \pm 0.00%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L cigarette rod seam adhesive; H.B. Fuller Co., Greensboro,

NC; Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with parafilm and

freezer tape.

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from NIDA and

their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be directed to: Kenneth

H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treatment Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

9022-0598-111-4409, Frozen Contingency Can

Sample Type and Name: Placebo Marijuana Cigarettes, 0.002% Δ^9 -THC

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC

Cannabinoid Content **Polytron Combined Average** Modified Lerner **Ethanol Soxhlet RRT** $0.002\% \pm 0.00\%$ 0.001% ±0.00% 0.50 0.003% ± 0.00% 0.003% ±0.00% Δ⁹-THC ND ND ND ND 0.46 ∆8-THC ND ND ND ND 0.36 Cannabidiol ND $0.000\% \pm 0.00\%$ ND $0.001\% \pm 0.00\%$ 0.62 Cannabinol

ND = Not Detected

Approved by:

DATA SHEET

Hand-Rolled Placebo Marijuana Cigarettes

ID Number:

10368-1002-187

Marijuana:

Placebo marijuana prepared by ethanol extraction of Mississippi-grown Mexican marijuana

CMEF-95

868, 875, 887, 869, 873, 883, 879, 863, 872, 880

CJAF-95

830, 833

CCOF-95

895

CHYF-95

849, 890, 888, 838, 866, 881, 854

Size:

70 mm length x 25 mm circumference

Weight:

 0.760 ± 0.11 g/cigarette average weight per cigarette overall. Weight data expressed as

average weight ± standard deviation

Moisture Content: 12.33 ± 0.83% average

 Δ^9 -THC Content: GLC analysis of cigarette samples, 0.004% \pm 0.00%

Paper:

70 mm Excel cigarette tubes; Dominion Cigarette Tube Co., Montreal, Canada

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer

to the attached document "General Information on Marijuana Cigarettes from NIDA and

their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Technical

questions about this material should be directed to: Kenneth H. Davis, Jr., at

(919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For

subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal

bacterial organisms which may put these patients at risk. Sterilization procedures

discussed by Ungerleider et al. or bacterial contamination (Cancer Treatment Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

10368-1002-187

Sample Type and Name: Hand-Rolled Placebo Marijuana Cigarettes, 0.004% Δ^9 -THC

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC

		Ca	nnabinoid Content		
Control and Market 2000 - House Control and Control	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
∧ ⁹ -THC	0.50	0.003% ± 0.00%	0.003% ±0.00%	0.006% ±0.00%	0.004% ± 0.00%
Δ ⁸ -THC	0.46	ND	ND	ND	ND
Cannabidiol	0.36	ND	ND	ND	ND
Cannabinol	0.62	0.001% ± 0.00%	ND	0.001% ±0.00%	0.001% ± 0.00%

ND = Not Detected

DATA SHEET

Marijuana Cigarettes

ID Number:

9497-0499-99-4856 through 9497-0499-99-4987

Marijuana:

Mississippi-grown Marijuana CHYF-95 900 927 CHPF-97 959 PM 14076 PM 14410-2 960 961 PM 14094-1 979 CHUP-98 CHOF-98 951, 945

Size:

85 mm length x 25 mm circumference

Weight:

 0.790 ± 0.04 g average weight per cigarette overall; individual cans may vary from 0.673 g to 0.885 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $11.29 \pm 0.26\%$ average: ranges from 11.11% to 11.75%

Δ⁹-THC Content: GLC analysis of cigarette samples, 3.30% ± 0.41%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; H.B. Fuller Co., Greensboro, NC;

Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a biological indicator for this monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

9497-0499-99-4987, Frozen Contingency Can

Sample Type and Name: High Potency Marijuana Cigarettes, 3.30% Δ^9 -THC

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLO
Modified Lerner	2 Samples	Internal Standard by GL
	2 Samples	Internal Standard by GL
Polytron TMS Derivative	1 Sample	Total Area by GLC

Cannabinoid Content

Nonderivatized Extract

	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
50 ;	3.04% ± 0.09%	3.77% ± 0.00%	3.10% ±0.10%	3.30% ± 0.41%
36 (0.08% ± 0.02%	0.06% ± 0.00%	0.07% ±0.00%	0.07% ± 0.01%
		0.19% ± 0.00%	0.17% ±0.01%	0.18% ± 0.01%
	ND	ND	ND	ND
	36 (52 (0.08% ± 0.02% 0.18% ± 0.01%	36 0.08% ± 0.02% 0.06% ± 0.00% 32 0.18% ± 0.01% 0.19% ± 0.00%	36 0.08% ± 0.02% 0.06% ± 0.00% 0.07% ± 0.00% 32 0.18% ± 0.01% 0.19% ± 0.00% 0.17% ± 0.01% ND ND ND

ND = Not detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.38%
Δ ⁹ -THC Acid A	0.57	2.85%
Δ ⁹ -THC Acid B	0.74	0.07%
Cannabichromene	0.17	0.05%
Cannabidiol	0.12	0.02%

Date

DATA SHEET

Marijuana Cigarettes

ID Number:

9497-0499-103-4652-4855 through 9497-0499-103-4988-5032

Marijuana:

Mississippi-grown Marijuana 897 CHYF-95 932 CHPF-97 943 CJAF-98

952, 953, 955, 957 CHOF-98

963, 964 14409-1 980 CHPF-98 928 CHPF-97 975 CMEF-98

Size:

85 mm length x 25 mm circumference

Weight:

 0.813 ± 0.04 g average weight per cigarette overall; individual cans may vary from 0.698 g to 0.902 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $11.10 \pm 0.42\%$ average: ranges from 10.34% to 11.67%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 2.53% ± 0.19%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; H.B. Fuller Co., Greensboro, NC;

Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be directed to:

Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

September 2003

Approved by:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

9497-0499-103-5032, Frozen Contingency Can

Sample Type and Name: Mid Potency Marijuana Cigarettes, 2.53% Δ^9 -THC

Kind of Analysis	
Number of Samples with Duplicate Analysis	Quantitation Method
4 Samples	Internal Standard by GLC
2 Samples	Internal Standard by GLC
•	Internal Standard by GLC
1 Sample	Total Area by GLC
	Number of Samples with Duplicate Analysis 4 Samples 2 Samples 2 Samples

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Λ ⁹ -THC	0.50	2.32% ± 0.18%	2.59% ± 0.02%	2.68% ± 0.07%	2.53% ± 0.19%
Cannabidiol	0.36	0.12% ± 0.08%	0.10% ± 0.00%	0.16% ± 0.01%	$0.13\% \pm 0.03\%$
Cannabinol	0.62	0.13% ± 0.01%	0.13% ± 0.00%	0.15% ± 0.01%	0.14% ± 0.01%
Λ ⁸ -THC	_	ND	ND	ND	ND

ND = Not detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.28%
∆9-THC Acid A	0.57	2.20%
∆9-THC Acid B	0.74	0.05%
Cannabichromene	0.17	0.07%
Cannabidiol	0.12	0.07%

ND = Not detected

DATA SHEET

Marijuana Cigarettes

ID Number:

10074-0301-97-5033 through 5186

Marijuana:

Mississippi-grown Marijuana CHPF-00 1058 CHPF-00 CMEF-00 1068 CMEF-00 1078

Size:

85 mm length x 25 mm circumference

Weight:

 0.790 ± 0.049 g average weight per cigarette overall; individual cans may vary from 0.706 g to 0.850 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $9.79 \pm 0.24\%$ average: ranges from 9.39% to 10.15%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 2.76% ± 0.18%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; H.B. Fuller Co., Greensboro, NC;

Material Safety Data Sheet on File.

Packaging:

6 inch imes 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a biological indicator for this monitoring process is recommended.

Date:

Cannabinoid Analysis

performed by

Health Sciences

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

10074-0301-97

Sample Type and Name: High Potency Marijuana Cigarettes, 2.76% Δ9-THC

Kind of Analysis

Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC
TMS Derivative	1 Sample	Total Area by GLC

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Λ ⁹ -THC	0.50	2.64% ± 0.16%	2.97% ± 0.00%	2.68% ± 0.07%	2.76% ± 0.18%
Cannabidiol	0.36	0.26% ± 0.04%	0.28% ± 0.00%	0.29% ± 0.01%	$0.28\% \pm 0.02\%$
Cannabinol	0.62	0.51% ± 0.02%	0.53% ± 0.00%	0.53% ± 0.00%	0.52% ± 0.01%
Δ ⁸ -THC	_	ND	ND	ND	ND

ND = Not detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.50%
Δ ⁸ -THC Acid A	0.57	2.19%
Δ ⁹ -THC Acid B	0.74	0.07%
Cannabichromene	0.17	0.20%
Cannabidiol	0.12	0.07%

ND = Not detected

DATA SHEET

70 mm Hand-Rolled High Potency Marijuana Cigarettes (Prepared by the University of Mississippi)

ID Number:

8976-0701-6-1

Marijuana:

Mississippi-grown Marijuana, Lot #1104-0107-01, Batch #984

Size:

70 mm length x 25 mm circumference

Weight:

 $0.7875 \pm 0.02\%$ g/cigarette average weight per cigarette overall. Weight data expressed as average weight ± standard deviation (University of Mississippi data).

Moisture Content:

11.22 ± 0.17% average

Δ9-THC Content:

GLC analysis of cigarette samples, $6.44\% \pm 0.55\%$

Paper:

70 mm Excel cigarette tubes; Dominion Cigarette Tube Co., Montreal, Canada

Pre-Conditioning:

Cigarettes should usually be treated to raise the moisture content prior to use.

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Technical questions about this material should be directed to: Kenneth H. Davis,

Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY.

For subjects with severe pulmonary impairment or those undergoing

immunosuppressant therapy in conjunction with chemotherapy, it is recommended

that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these

patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a biological indicator for this

monitoring process is recommended.

Date:

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

8976-0701-6-1

Sample Type and Name:

70 mm Hand-Rolled High Potency Marijuana Cigarettes (Prepared by the University of Mississippi), 6.44% $\Delta^9\text{-THC}$

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLO
Modified Lerner	2 Samples	Internal Standard by GLC
	2 Samples	internal Standard by GLC
Polytron TMS Derivative	1 Sample	Total Area by GLC

Cannabinoid Content

Nonderivatized Extract

		_		المستنب والمستنب والمستنب والمستنب	
	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
		0.750/ 1.0.509/	6.77% ± 0.00%	5.80% ± 0.00%	6.44% ± 0.55%
Δ ⁹ -THC	0.50	6.75% ± 0.56%	0.1770 ± 0.0070		ND
∆ ⁸ -THC	_	ND	ND	ND	ND
Δ-1ΠC			0.040/ + 0.009/	0.02% ± 0.01%	0.01% ± 0.01%
Cannabidiol	0.36	0.01% ± 0.01%	0.01% ± 0.00%	0.02 /0 ± 0.01 /0	
	0.62	0.04% ± 0.02%	0.02% ± 0.00%	$0.01\% \pm 0.00\%$	$0.02\% \pm 0.02\%$
Cannabinol	0.62	0.04% ± 0.02%	0.02,0 2 0.00.0		

ND = Not detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	1.32%
Δ ⁹ -THC Acid A	0.57	5.07%
Δ ⁹ -THC Acid B	0.74	0.05%
Cannabichromene	0.17	0.01%
Cannabidiol	0.12	0.00%

ND = Not detected

10-03-03

RTI INTERNATIONAL*

DATA SHEET

70 mm Hand-Rolled High Potency Marijuana Cigarettes

ID Number:

10604-1202-54A

Marijuana:

Mississippi-grown marijuana, Batch #1182/1186

Size:

70 mm length x 25 mm circumference

Weight:

 0.791 ± 0.16 g/cigarette average weight per cigarette overall. Weight data expressed as

average weight ± standard deviation

Moisture Content: 11.46 \pm 0.67% average: 10.5% to 12.59%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 7.18% ± 0.35%

Paper:

70 mm Excel cigarette tubes; Dominion Cigarette Tube Co., Montreal, Canada

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from NIDA and

their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Technical

questions about this material should be directed to: Kenneth H. Davis, Jr., at

(919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal

bacterial organisms which may put these patients at risk. Sterilization procedures

discussed by Ungerleider et al. or bacterial contamination (Cancer Treatment Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

October 2003

Cannabinoid Analysis performed by **Health Sciences RTI International**

Date Performed:

10-7-2003

Sample Number:

10604-1202-54A

Sample Type and Name: 70 mm Hand-Rolled High Potency Marijuana Cigarettes, 7.18% Δ9-THC

Kind of Analysis

Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC
TMS Derivative	1 Sample	Total Area by GLC.

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Δ ⁹ -THC	0.50	7.01% ± 0.21%	7.58% ± 0.07%	6.94% ± 0.23%	7.18% ± 0.35%
Δ ⁸ -THC	0.46	ND	. ND	ND	ND
Cannabidiol	0.36	0.20% ± 0.06%	0.22% ± 0.02%	0.24% ± 0.03%	0.22% ± 0.02%
Cannabinol	0.62	0.16% ± 0.01%	0.16% ± 0.00%	0.15% ± 0.01%	0.16% ± 0.01%

ND = Not Detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.28%
Δ ⁹ -THC Acid A	0.57	6.82%
Δ9-THC Acid B	0.74	0.07%
Cannabichromene	0.17	0.18%
Cannabidiol	0.12	0.04%

ND = Not Detected

RESEARCH TRIANGLE INSTITUTE

DATA SHEET

Marijuana Cigarettes

ID Number:

10604-0203-95-5187 through 5403

Marijuana:

Mississippi-grown Marijuana CHPF-01 1105 CHPF-01 1106 1107 CHPF-01 1108 CHPF-01 1120 CHPF-01

Size:

85 mm length x 25 mm circumference

Weight:

 0.734 ± 0.05 g average weight per cigarette overall; individual cans may vary from 0.632 g to 0.853 g average weight per cigarette; weight data expressed as average

weight ± standard deviation

Moisture Content: $11.32 \pm 0.63\%$ average: ranges from 10.41% to 12.70%

 Δ^9 -THC Content: GLC analysis of cigarette samples, 6.03% ± 0.39%

Paper:

No. 12853 cigarette paper, Ecusta Paper Company

Glue:

Product Number WB-3921L; HB Fuller Lot 2020730451, H.B. Fuller Co., Greensboro,

Material Safety Data Sheet on File.

Packaging:

6 inch x 5 inch high slip cover cans with styrofoam pads and filter paper sheets above and below the cigarettes, packed by weight to contain approximately 300 cigarettes per can, and if necessary, wedged with cotton plugs to insure tightness, sealed with

parafilm and freezer tape.

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer to the attached document "General Information on Marijuana Cigarettes from

NIDA and their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Net weights of contents of cans may vary by 3 to 5% from values listed on the label due to change in moisture content. Technical questions about this material should be directed to: Kenneth H. Davis, Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal bacterial organisms which may put these patients at risk. Sterilization procedures discussed by Ungerleider et al. for bacterial contamination (Cancer Treat Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a biological indicator for this monitoring process is recommended.

Date:

September 2003

Cannabinoid Analysis performed by

Health Sciences

Research Triangle Institute

Date Performed:

09-10-2003

Sample Number:

10604-0203-95

Sample Type and Name: High Potency Marijuana Cigarettes, 6.03% Δ9-THC

							is	

	Kind of Analysis	
Extraction Method	Number of Samples with Duplicate Analysis	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	Internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC
TMS Derivative	1 Sample	Total Area by GLC

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Λ ⁹ -THC	0.50	5.63% ± 0.16%	6.40% ± 0.04%	6.05% ± 0.03%	6.03% ± 0.39%
Cannabidiol	0.36	0.06% ± 0.01%	0.07% ± 0.00%	0.06% ± 0.00%	0.06% ± 0.01%
Cannabinol	0.62	0.18% ± 0.01%	0.21% ± 0.00%	0.20% ± 0.01%	0.20% ± 0.02%
∆8-THC		ND	ND	ND	ND

ND = Not detected

Derivatized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.62%
Δ ⁹ -THC Acid A	0.57	5.29%
∆9-THC Acid B	0.74	0.12%
Cannabichromene	0.17	0.04%
Cannabidiol	0.12	0.02%

ND = Not detected

RTI INTERNATIONAL*

DATA SHEET

70 mm Hand-Rolled High Potency Marijuana Cigarettes

ID Number:

10747-1003-180A

Marijuana:

Mississippi-grown marijuana, Batch #1182/1183/1195

Size:

70 mm length x 25 mm circumference

Weight:

 0.743 ± 0.14 g/cigarette average weight per cigarette overall. Weight data expressed as

average weight ± standard deviation

Moisture Content: 12.50 ± 0.12% average

 Δ^9 -THC Content: GLC analysis of cigarette samples, 8.38% ± 0.41%

Paper:

70 mm Excel cigarette tubes; Dominion Cigarette Tube Co., Montreal, Canada

Pre-Conditioning: Cigarettes should usually be treated to raise the moisture content prior to use. Please refer

to the attached document "General Information on Marijuana Cigarettes from NIDA and

their use in Therapeutic Programs".

Storage:

Frozen storage is recommended.

Please Note:

Marijuana cigarettes are fragile, please handle with great care. Technical

questions about this material should be directed to: Kenneth H. Davis, Jr., at

(919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY. For subjects with severe pulmonary impairment or those undergoing immunosuppressant therapy in conjunction with chemotherapy, it is recommended that cigarettes be sterilized before use. It has been reported that marijuana cigarettes contain several common fungal

bacterial organisms which may put these patients at risk. Sterilization procedures

discussed by Ungerleider et al. or bacterial contamination (Cancer Treatment Reports, 66 (3), 589-590, 1982) should be effective for fungal contamination as well. The use of a

biological indicator for this monitoring process is recommended.

Date:

Cannabinoid Analysis performed by **Health Sciences RTI** International

Date Performed:

10-7-2003

Sample Number:

10747-1003-180A

Sample Type and Name: 70 mm Hand-Rolled High Potency Marijuana Cigarettes, 8.38% Δ^9 -THC

Kind of Analysis

Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method	
Ethanol Soxhiet	4 Samples	Internal Standard by GLC	
Modified Lerner	2 Samples	Internal Standard by GLC	
Polytron	2 Samples	Internal Standard by GLC	
TMS Derivative	1 Sample	Total Area by GLC	

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
∆ ⁹ -THC	0.50	8.04% ± 0.32%	8.25% ± 0.03%	8.84% ± 0.09%	8.38% ± 0.41%
∆ ⁸ -THC	0.46	ND	ND	ND	ND
Cannabidiol	0.36	0.17% ± 0.01%	0.15% ± 0.00%	0.23% ± 0.03%	0.18% ± 0.04%
Cannabinol	0.62	0.16% ± 0.01%	0.18% ± 0.01%	0.19% ± 0.00%	0.18% ± 0.02%

ND = Not Detected

Derivatized Extract

	RRT	Differential (TMS Derivative	
Δ ⁹ -THC	0.22	0.35%	
Δ ⁹ -THC Acid A	0.57	7.95%	
Δ ⁹ -THC Acid B	0.74	0.09%	
Cannabichromene	0.17	0.14%	
Cannabidiol	0.12	0.04%	

ND = Not Detected

RTI INTERNATIONAL*

DATA SHEET

Placebo Marijuana Plant Material, Bulk

ID Number:

9022-0598-111-1

Marijuana:

Placebo marijuana prepared by ethanol extraction of Mississippi-grown Mexican

marijuana

CMEF-95

868, 875, 887, 869, 873, 883, 879, 863, 872, 880

CJAF-95

830, 833

CCOF-95

895

CHYF-95

849, 890, 888, 838, 866, 881, 854

Moisture Content:

15.37 \pm 0.10% average: ranges from 15.26% to 15.45%

Δ9-THC Content:

GLC analysis of bulk Placebo Plant Material samples, 0.015% \pm 0.01%

Quantity:

Reference:

Storage:

Frozen storage is recommended.

Please Note:

Technical questions about this material should be directed to: Kenneth H. Davis, Jr.,

at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE ONLY.

Date:

September 2003

Cannabinoid Analysis performed by **Health Sciences** RTI INTERNATIONAL

Date Performed:

09-10-2003

Sample Number:

9022-0598-111-1

Sample Type and Name: Placebo Marijuana Plant Material, Bulk, $0.015\%~\Delta^9$ -THC

Kind of Analysis

Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method
Ethanol Soxhlet	4 Samples	Internal Standard by GLC
Modified Lerner	2 Samples	internal Standard by GLC
Polytron	2 Samples	Internal Standard by GLC

Cannabinoid Content

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average
Δ ⁹ -THC	0.50	0.004% ± 0.00%	0.020% ±0.00%	0.022% ± 0.00%	0.015% ± 0.01%
Δ ⁸ -THC	0.46	ND	ND	ND	ND
Cannabidiol	0.36	0.001% ± 0.00%	0.001% ±0.00%	0.001% ± 0.00%	0.001% ± 0.00%
Cannabinol	0.62	0.001% ± 0.00%	0.001% ±0.00%	0.003% ± 0.00%	0.002% ± 0.00%

ND = Not Detected

RTI INTERNATIONAL

DATA SHEET

High Potency Marijuana Plant Material, Bulk

ID Number:

8976-1001-26 (UMISS Batch No. 1182/1186)

Moisture Content:

9.63 ± 0.31% average

 Δ^9 -THC Content:

GLC analysis of bulk High Potency Marijuana Plant Material samples,

 $6.84\% \pm 0.69\%$

Quantity:

Reference:

Storage:

Frozen storage is recommended.

Please Note:

Technical questions about this material should be directed to: Kenneth H. Davis,

Jr., at (919) 541-6709.

Caution:

NEW DRUG - LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE

ONLY.

Date:

September 2003

Approved by:

10-03-03

Cannabinoid Analysis performed by **Health Sciences RTI** International

Date Performed:

09-10-2003

Sample Number:

8976-1001-26 (UMISS Batch No. 1182/1186)

Sample Type and Name: High Potency Marijuana Plant Material, Bulk, 6.84% Δ^9 -THC

Kind of Analysis

Extraction Method	Number of Samples with Duplicate Analyses	Quantitation Method	
Ethanol Soxhlet	4 Samples	Internal Standard by GLC	
Modified Lerner	2 Samples	Internal Standard by GLC	
TMS Derivative	.1 Sample	Total Area by GLC	

Cannabinoid Content

Nonderivatized Extract

	RRT	Ethanol Soxhlet	Modified Lerner	Polytron	Combined Average	
Δ ⁹ -THC	0.50	6.89% ± 0.02%	6.12% ± 0.02%	7.50% ± 0.00%	6.84% ± 0.69%	
Δ ⁸ -THC	0.46	ND	ND	ND	ND	
Cannabidiol	0.36	0.24% ± 0.03%	0.11% ± 0.00%	0.28%± 0.01%	0.21% ± 0.09%	
Cannabinol	0.62	0.07% ± 0.01%	0.04% ± 0.00%	0.05% ± 0.00%	0.05% ± 0.02%	

ND = Not Detected

Derivitized Extract

	RRT	Differential (TMS Derivative)
Δ ⁹ -THC	0.22	0.30%
Δ ⁹ -THC Acid A	0.57	6.46%
Δ ⁹ -THC Acid B	0.74	0.07%
Cannabichromene	0.17	0.16%
Cannabidiol	0.12	0.05%

Approved by:

Proprietary	

6.0 SHIPMENTS

Shipments of marijuana cigarettes to qualified recipients were made during this reporting period as directed by NIDA and the University of Mississippi. Table 5 reflects shipments made during this annual report period. RTI received 30 shipment orders during this annual reporting period, of which 29 were completed. Shipment to period is pending (Table 5) until all pertinent documents are received.

7.0 PROJECT ADMINISTRATION

Throughout this reporting period, the RTI project leaders have communicated with personnel at the University of Mississippi and NIDA to ensure that the project work proceeded smoothly. Project personnel have also communicated with various investigators regarding questions about cigarettes supplied from this program.

As stated previously, we successfully completed the preparation of high potency marijuana cigarettes in February 2003.

The Batch Production Record for the recently prepared marijuana cigarette Batch No. 10604-0203-95 will be sent to UMISS after audit by our QA specialist.

In addition, our drug records personnel completed the UNDEA report in March 2003. This report includes extensive information about transactions carried out under this contract. The Bi-Annual Vault Inventory was completed in July 2003 in compliance with DEA regulations.

A site visit with Drs. Hari Singh and Rao Rapaka of NIDA, Mr. Kevin Gormley and members of the RTI project team occurred on August 22, 2003. The visit focused primarily on other NIDA contracts at RTI.

During this reporting period, we identified a typographical error in the labeling of a small batch of hand-rolled cigarettes supplied to a researcher. These cigarettes, which were unused, were recovered from the researcher and replaced with additional cigarettes from the same master batch.

Analysis was performed on the returned cigarettes to confirm the %THC content. The results of our capillary GC analysis indicate that the average Δ^9 -THC content was 7.11%, which confirmed the %THC content of the returned cigarettes.

We are following an enhanced procedure for the preparation and shipment of NIDA materials to researchers. The emphasis is on carefully documented procedures witnessed by a second person and performed in a manner to authenticate the identity and integrity of samples for shipment.

We are relocating the laboratory facilities for this project from Hermann Laboratory Building Room 102 to Room 202 to accommodate the installation of a new Sample Preparation Facility in HLB 102.

Proprietary		•
		1
		!
		•
		İ
		1
		ļ
		!

Table 5. Shipments of Marijuana Cigarettes

Order No.	Researcher	NIDA Received Date	RTI Received Date	Date of Shipment	Batch Shipped	Amount Requested	Amount Shipped
9918	Doctor Name	11/07/02	11/14/02	12/18/02	9022-0598-111-1 8976-0900-24-1 8976-1000-24-2 8976-1001-24-3	36 g 36 g 36 g 36 g	36 g 36 g 36 g 36 g
9922		11/12/02	11/14/02	11/19/02	6567-0496-125	3 cans	3 cans
9945		11/21/02	12/02/02	12/16/02	8976-1001-26 (Bag 2 of 2)	250 g	250 g
9963		12/04/02	12/16/02	01/07/03	10368-1002-187 6567-0891-20-OPEN 8976-0701-6-1 9022-0598-111-OPEN	70 cigarettes 25 cigarettes 50 cigarettes 25 cigarettes	·70 cigarettes 25 cigarettes 50 cigarettes 25 cigarettes
9966		12/04/02	12/10/02	12/16/02	6567-0496-125	4 cans	4 cans
9970		12/10/02	12/16/02	01/07/03	9497-0499-99-OPEN 9022-0598-111-OPEN	15 cigarettes 30 cigarettes	15 digarettes 30 digarettes
9972		12/11/02	12/16/02	01/07/03	6567-0891-20-OPEN 9497-0499-99-OPEN 8976-0701-6-1 10368-0302-39	5 cigarettes 5 cigarettes 5 cigarettes 5 cigarettes	5 cigarettes 5 cigarettes 5 cigarettes 5 cigarettes
10007		01/09/03	01/13/03	01/15/03	6567-0496-125	4 cans	4 cans
10044		01/30/03	02/06/03	02/13/03	6567-0496-125	6 cans	6 cans
10053		02/05/03	02/06/03	03/19/03	9022-0598-111	1 can	1 can
10079		02/21/03	02/24/03	02/27/03	6567-0496-125	2 cans	2 cans
10107		03/12/03	03/24/03	04/02/03	9223-0199-47-OPEN 9497-0499-99-OPEN 9022-0598-111-OPEN	70 cigarettes 70 cigarettes 50 cigarettes	70 cigarettes 70 cigarettes 50 cigarettes
10130		03/26/03	03/31/03	04/02/03	6567-0496-125	4 cans	4 cans
10150	-	04/07/03	04/15/03	04/16/03	6567-0496-125	2 cans	2 cans
10159	1	04/14/03	04/17/03	05/05/03	10368-1002-187 6567-0891-20-OPEN 9497-0499-99-OPEN 9022-0598-111-OPEN	40 cigarettes 60 cigarettes 150 cigarettes 160 cigarettes	40 cigarettes 60 cigarettes 150 cigarettes 160 cigarettes
10167		04/17/03	04/23/03	05/12/03	10368-1002-187 6567-0891-20-OPEN 10604-1202-54A	6 cigarettes 2 cigarettes 9 cigarettes	6 cigarettes 2 cigarettes 9 cigarettes
10170		04/21/03	04/23/03	05/14/03	9497-0499-99-OPEN 9022-0598-111-OPEN	15 cigarettes 20 cigarettes	15 cigarettes 20 cigarettes
10187		05/01/03	05/05/03	05/14/03	9497-0499-99	5 cans	5 cans
10243	-	06/13/03	06/19/03	07/22/03	9497-0499-99-OPEN 9022-0598-111-OPEN	30 cigarettes 40 cigarettes	30 cigarettes 40 cigarettes
10282	- I	07/08/03	07/10/03	07/14/03	6567-0496-125	6 cans	6 cans
10285	i	07/08/03	07/14/03	08/13/03	8976-1001-26	250 g	250 g
10287		07/10/03	07/14/03	08/06/03	10368-1002-187 6567-0891-20 10604-1202-54A 9022-0598-111-OPEN	120 cigarettes 50 cigarettes 120 cigarettes 60 cigarettes	120 cigarettes 50 cigarettes 120 cigarettes 60 cigarettes
10344		08/19/03	08/22/03	10/14/03	9497-0499-99	2 cans	2 cans
10335		08/12/03	09/29/03/	Pending Authorization from UMISS	9497-0499-99-OPEN 9022-0598-111-OPEN	150 cigarettes 150 cigarettes	pending
		N/A	N/A	09/24/03	10604-1202-54A	9 Replacement Cigarettes	9 Replacement Cigarettes

Table 5. (continued) Shipments of Marijuana Cigarettes

Order No.	Researcher	NIDA Received Date	RTI Received Date	Date of Shipment	Batch Shipped	Amount Requested	Amount Shipped
10309	Doctor Name	07/25/03	08/04/03	08/18/03	6567-0496-125-OPEN 9022-0598-111-OPEN	40 cigarettes 40 cigarettes	40 cigarettes 40 cigarettes
10320		08/01/03	08/07/03	08/25/03	6567-0496-125	4 cans	4 cans
10399		10/01/03	10/06/03	10/27/03	10604-0203-95	6 cans	6 cans
10395		09/30/03	10/06/03	10/20/03	9497-0499-99	3 cans	3 cans
10412		10/07/03	10/13/03	10/16/03	9497-0499-99	5 cans	5 cans
10409		10/03/03	10/13/03	10/22/03	8976-1001-26	0.150 kg	0.150 kg

Original order No. 10167 was shipped on May 12, 2003.