

14.9

TENNESSEE BUREAU OF INVESTIGATION FORENSIC SERVICES DIVISION

Validation Review Form

Procedure Standard Verification/Performance Check on Thermo Scientific Nicolet iS10

Check the appropriate: New Validation ☐ Modification ☐ Performance Check ☒

This form is to be used as a coversheet for any new method, change in method, reagent or kit change. The Forensic Scientist appointed for procedure development/validation is to initial and date the appropriate box and attach documentation of required validation study results. Each applicable area listed below should be clearly labeled in the Validation Notebook (NO POST-IT NOTES).

Submit all information to the Quality Assurance Manager prior to implementation of the procedure/instrument.

NOTE: Each applicable area listed below should start with a typed summary about that particular section.	REVIEWED BY:	DATE COMPLETED:
Overall Validation Summary and Section Summaries are included	MBE	10/17/11
Parallel Testing Procedure	MBE	10/17/11
Accuracy	MBE	10/17/11
Limit of Detection (LOD) (if applicable)	N/A	
Limit of Quantitation (LOQ) (if applicable)	N/A	
Linearity & Range Established (if applicable)	N/A	
Specificity Range Established (if applicable)	N/A	
Precision	N/A	
Robustness - to include: Matrix		
Effects	N/A	
Cross Reactivity		
PH, Ionic Strength, Temperature		
Laboratory Procedure Approved (if applicable)	N/A	
LIMS Messages(s) and sample of Final Report Established (if applicable)	N/A	
Training and Competency Testing for each Examiner/Technician Completed or Proposed Training Plan Enclosed	N/A	
References are listed	N/A	
Technical Review of Completed Notebook	MBE	10/17/11

*If all technical staff training has not been completed, please include a proposed training plan and completion schedule.

Sign and date to indicate your acceptance of the procedure/instrument:

Unit Supervisor (if applicable) Glenn B. Everett

Technical Leader (if applicable) Glenn B. Everett

Regional Laboratory Supervisor Wm J. Lutz

Quality Assurance Manager Margaret P. Bash

THIS IS AN UNCONTROLLED COPY OF A CONTROLLED DOCUMENT

**Standard Verification Performance Check for the
Thermo Scientific Nicolet iS10 FTIR Serial # AKX1100576
with Golden Gate ATR Attachment**

Validation Procedure:

Ten certified drug standards were selected and tested for identification with this instrument. The standards selected are as follows:

Alprazolam – manufactured by Upjohn, Lot # 487RA
Caffeine – manufactured by Eastman Kodak, Lot # 355
Carisoprodol – manufactured by Alltech, Lot # 311 DC-0852
Cocaine base – manufactured by Merck, Lot # U 7472
Cocaine HCl – manufactured by Sigma, Lot # 50K1124
Diazepam – manufactured by Sigma, Lot # 105F0451
(+)-Methamphetamine – manufactured by Sigma, Lot # 34H01444
3,4-MDMA – manufactured by Sigma, Lot # 151 dc-7073-3
Pethidine – manufactured by SB Penick, Lot # 413NMN-027
Testosterone – manufactured by Sigma, Lot # 50H0345

Several of these standards were chosen because they are frequently encountered in case work and/or analyzed by ATR. All standards were run on the instrument neat – no extractions or washes were performed. When available, the same chemical lots utilized to create the current spectral library were used. The instrument's sampling area was cleaned and a background spectrum was collected between each standard run to rule out any possible cross-contamination

Accuracy:

Spectra collected from these samples were compared to the current spectral library on the instrument and a high match percentage (>95%) was obtained for each standard. The spectra were also compared to the standards by a trained forensic scientist, and each match was deemed as satisfactory for identification. The collected spectra as well as the standard spectra used for comparison are included.

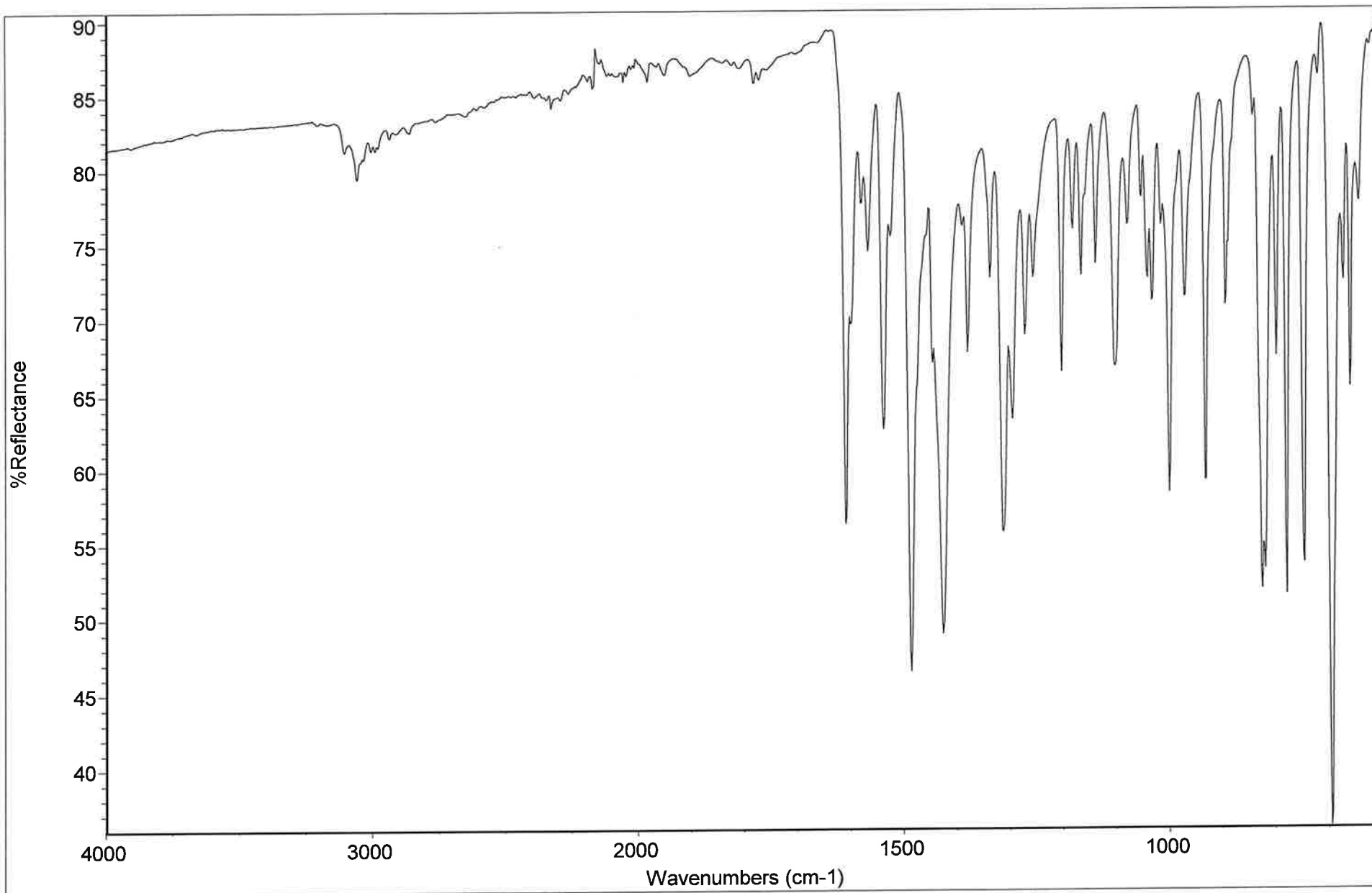
Since the Crime Lab does not use ATR for quantitations, Limits of Detection (LOD), Limits of Quantitation (LOQ), Linearity and Range, and Precision were not determined. Specificity and Robustness do not apply to this method.

Proposal for Performance Check on FTIR with Golden Gate ATR

All three TBI Crime Labs are currently using the Golden Gate ATR. Before being accepted for use by all three labs, it was treated by each lab as a new invalidated and unaccepted sampling technique. Therefore each lab proceeded to obtain ATR spectra of every unknown in their possession and to establish their own library of standards. ATR was found to be a valid sampling technique in all three labs. In addition ATR is a well-accepted scientific technique throughout the scientific community.

The Nashville Laboratory has recently purchased a new Thermo Fisher Nicolet iS10 FTIR. The Golden Gate ATR that was on the Avatar 360 that is being retired will be used with the new instrument. The new FTIR/ATR is configured exactly like the Avatar 360 was. In addition the software on the new instrument is essentially the same as the software on the instrument it replaces in that it is a newer version of the OMNIC software that all of our FTIR's use. Since this is an established sampling technique, there is no need to completely reapprove the validity of the instrument for drug identification. In addition FTIR is a scientifically proven technique and has been shown to give consistent and reliable data. This is data that can be used to unmistakably identify a compound. Therefore, essentially all that needs to be done is to verify that the new FTIR/ATR gives the same data as the original one gives.

To accomplish this we propose to run a series of 10 standards on the new instrument. These will include Cocaine HCl, Cocaine Base, and Methamphetamine, as these are the compounds that we analyze by FTIR most often. Parallel testing will be achieved by comparing the data to data already obtained on another FTIR/ATR (where possible the same lot numbers will be used). A forensic scientist will check the data for accuracy. After obtaining this data and comparing it to our FTIR/ATR standards, the new instrument will be submitted for approval.

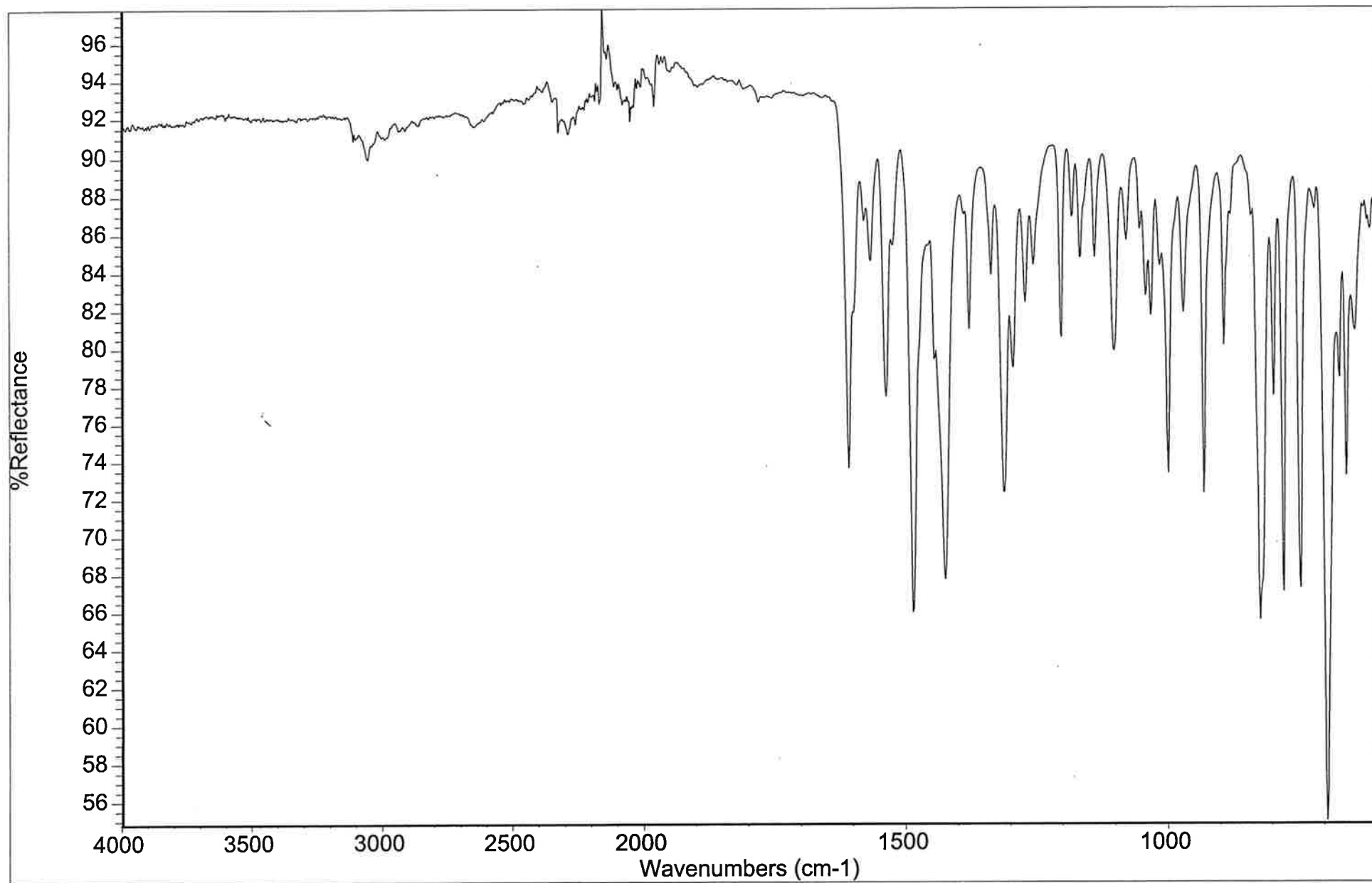


IR VERIFICATION - ALPRAZOLAM STANDARD UPJOHN LOT #487RA WHS

IR #6

WHS

Collection time: Mon Oct 10 08:36:56 2011 (GMT-04:00)

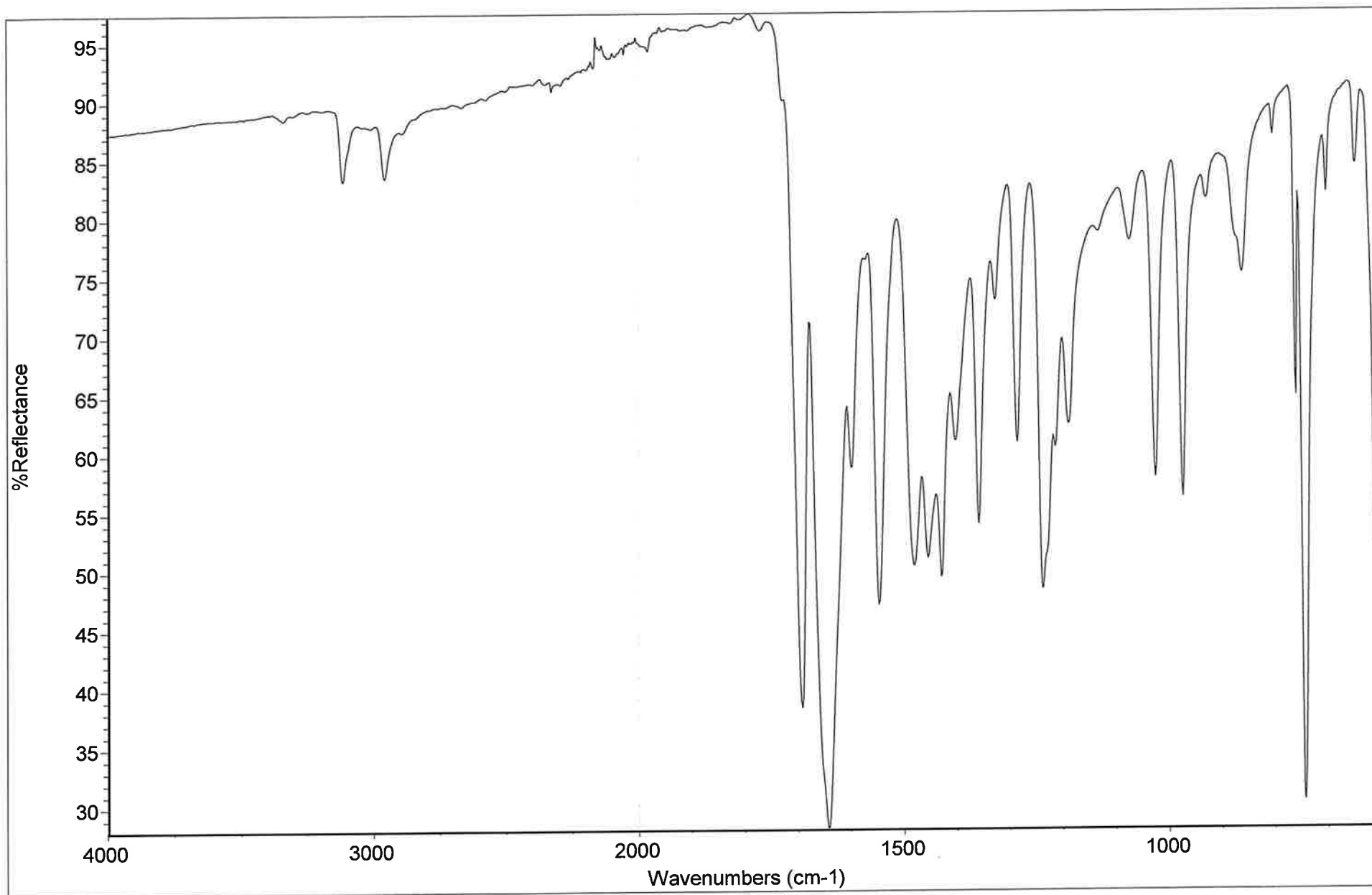


ALPRAZOLAM U31889 LOT #487RA

IR #4

WKS

Collection time: Mon Sep 15 14:10:07 2003

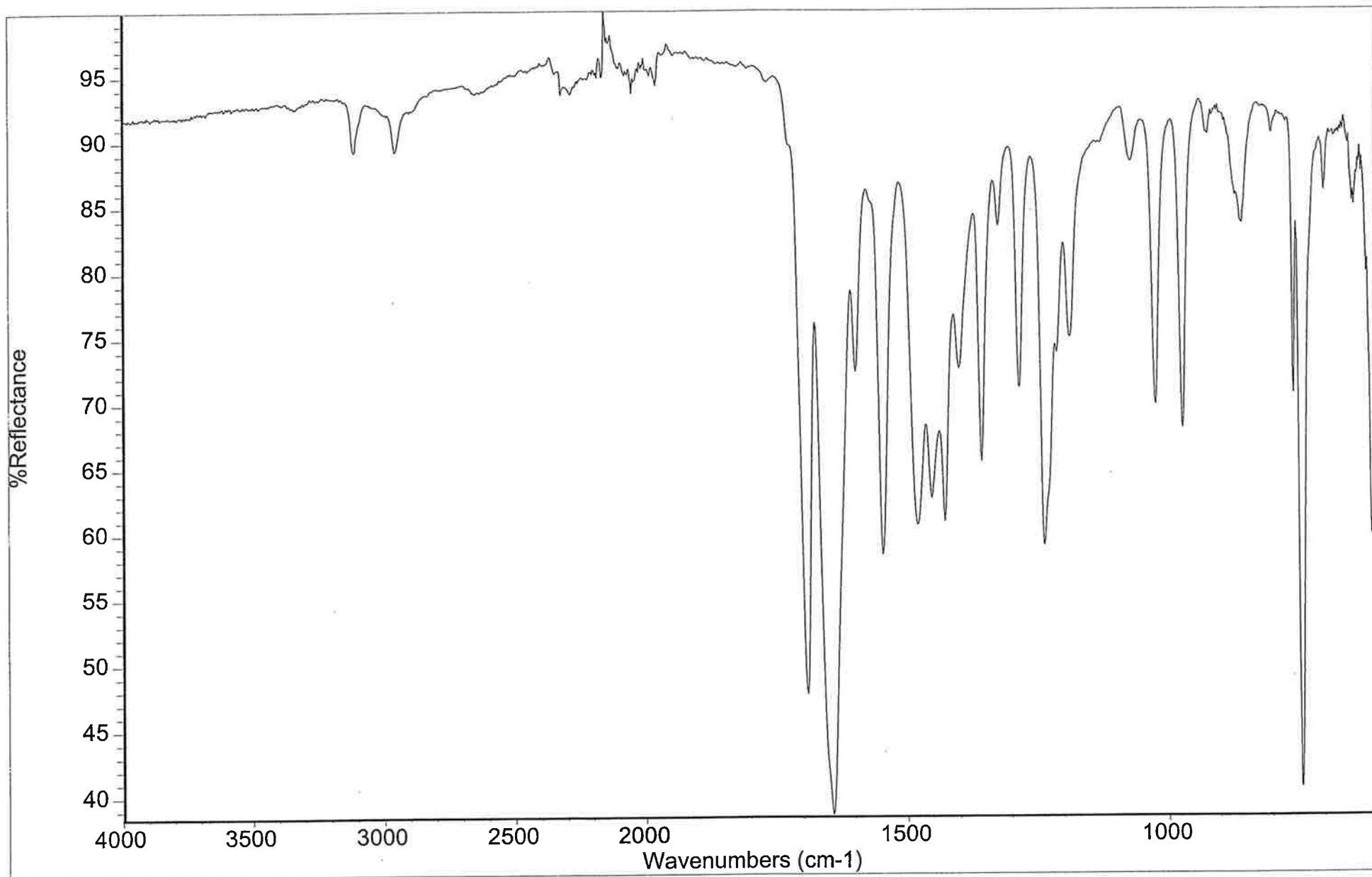


IR VERIFICATION - CAFFEINE STANDARD EASTMAN KODAK COMPANY LOT #355 WHS

IR #6

[Signature]

Collection time: Mon Oct 10 08:45:09 2011 (GMT-04:00)

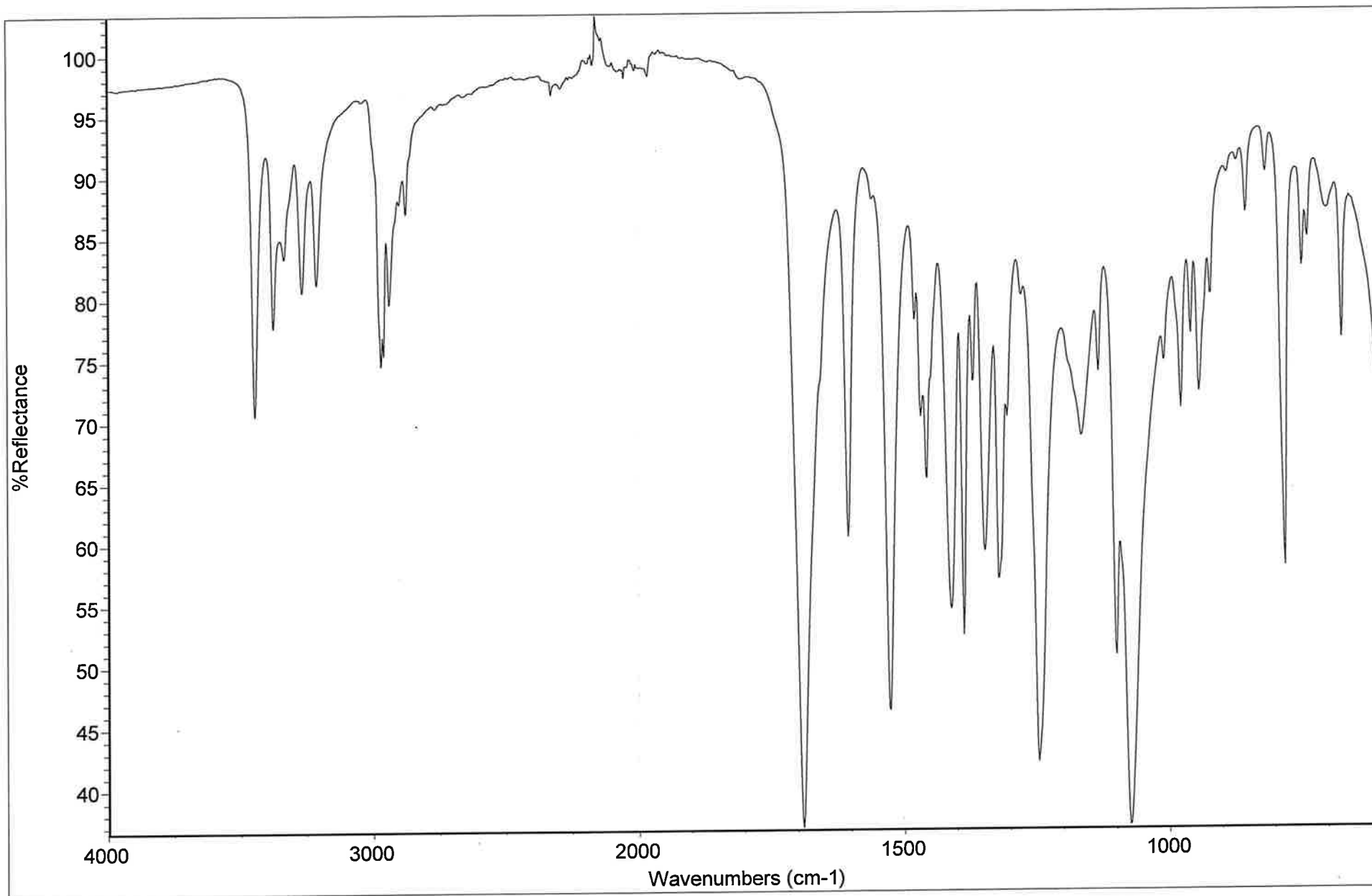


Caffeine Eastman Kodak Lot #355

IR #4

WHS

Collection time: Tue Sep 16 13:18:23 2003

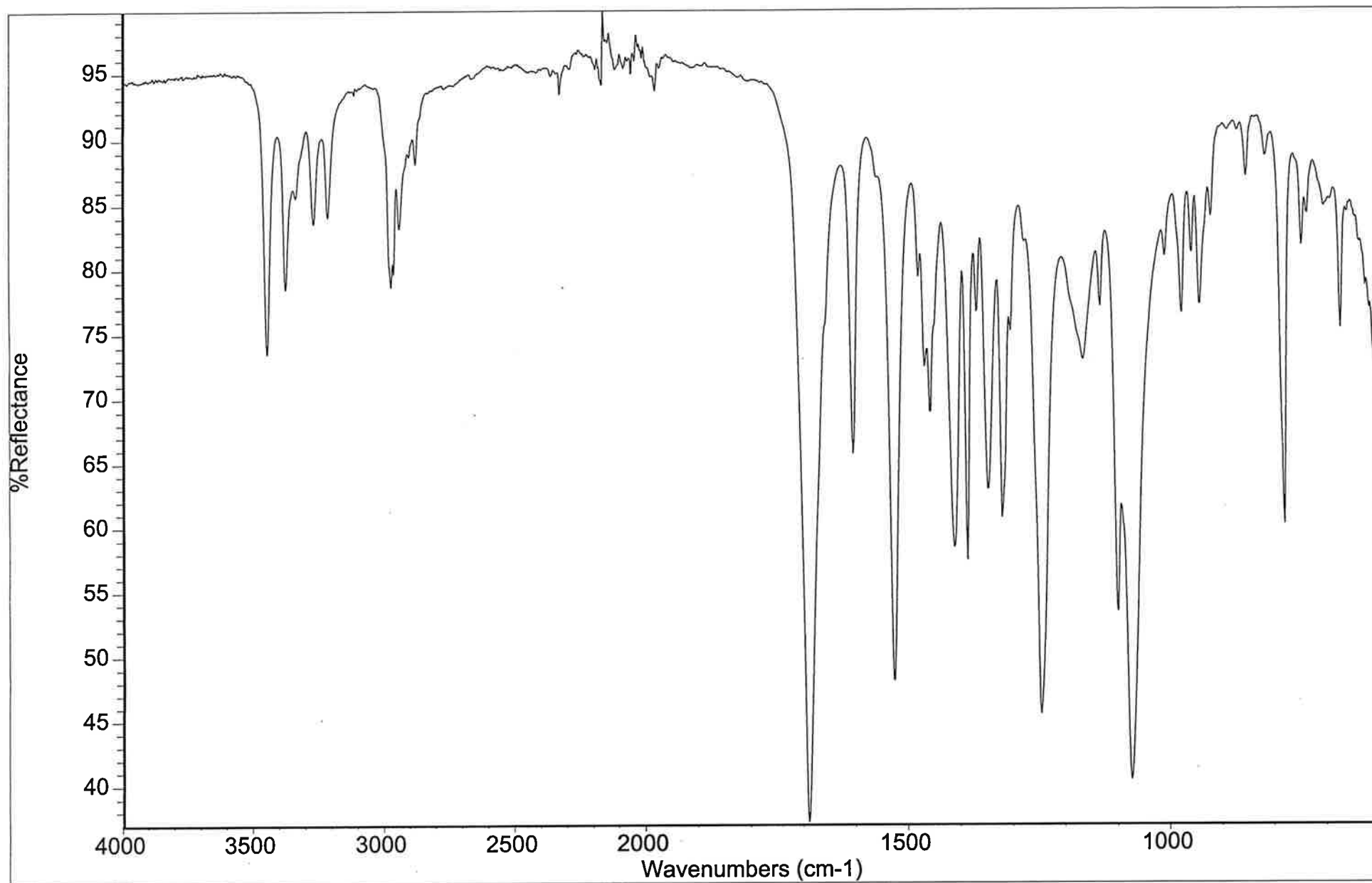


IR VERIFICATION - CARISOPRODOL STANDARD ALLTECH LOT#311 DC -0052 WHS

IR #6

AS

Collection time: Mon Oct 10 08:54:47 2011 (GMT-04:00)

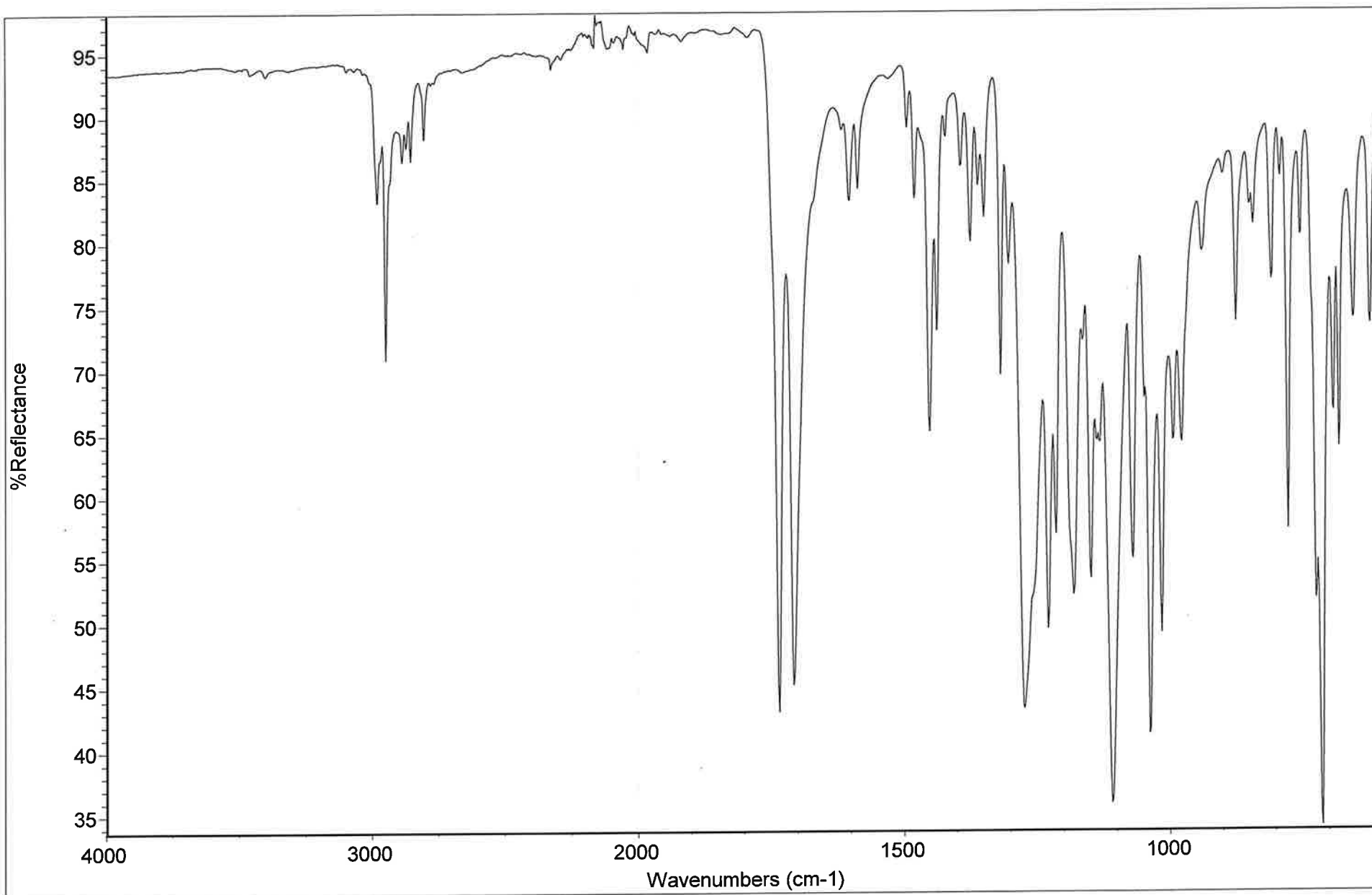


Carisoprodol Alltech Lot #311

IR #4

Witt

Collection time: Tue Sep 16 11:24:37 2003

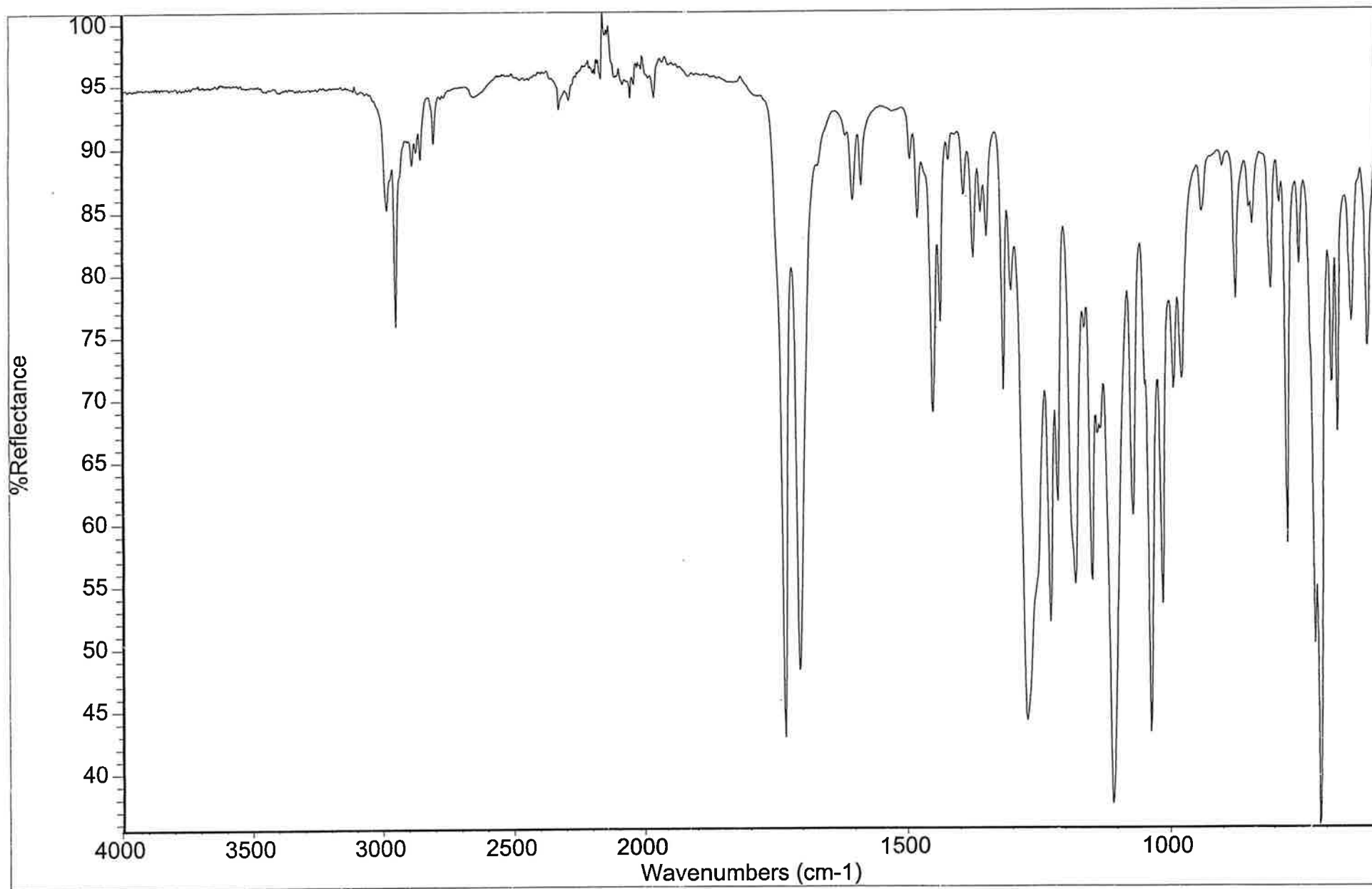


IR VERIFICATION - COCAINE BASE MERCK AND CO. LOT #U 7472 WHS

IR #6

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Collection time: Mon Oct 10 09:34:20 2011 (GMT-04:00)

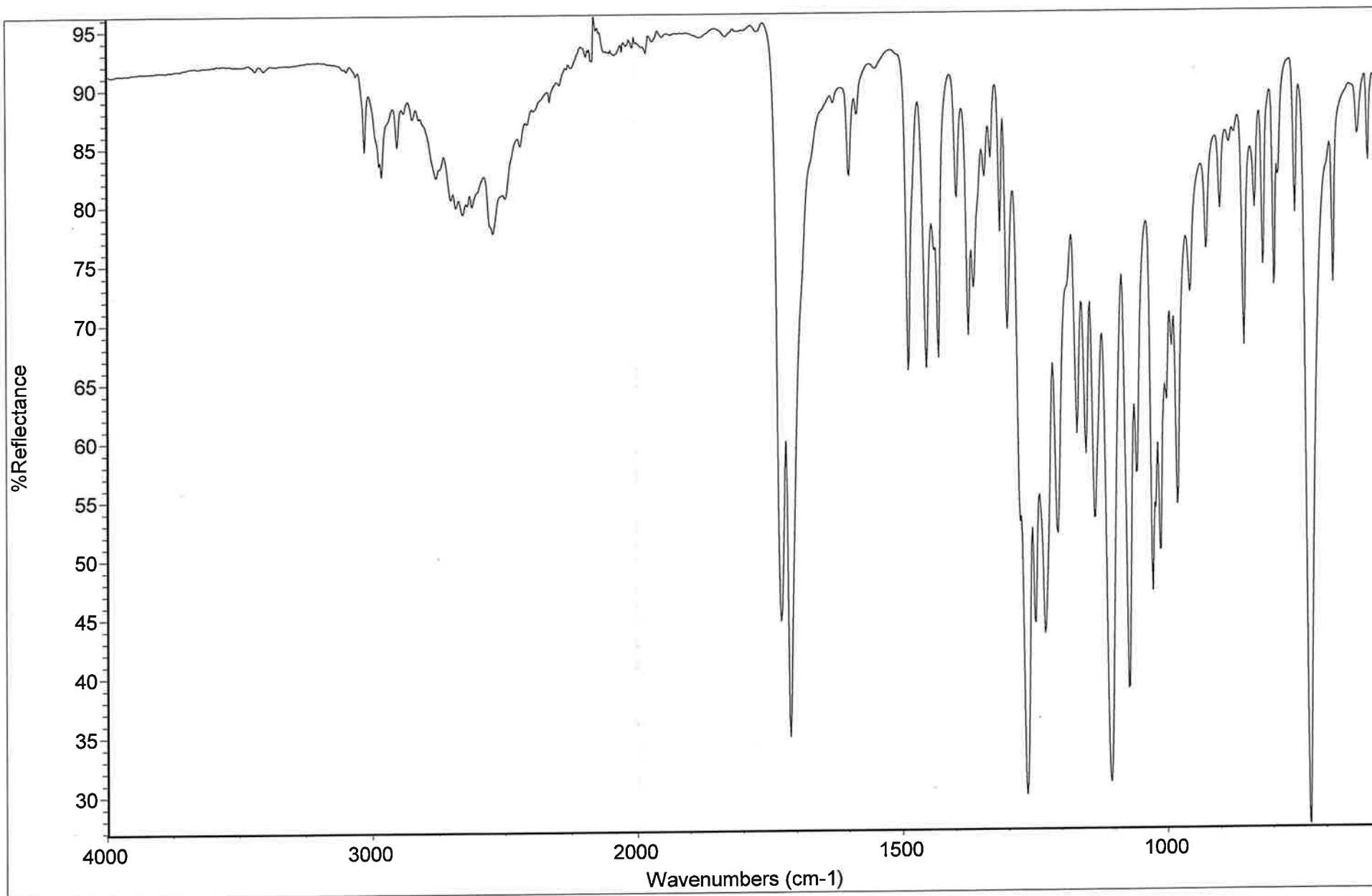


Cocaine Base Merck Lot #U7472

IR #4

[Handwritten signature]

Collection time: Tue Sep 16 15:18:05 2003

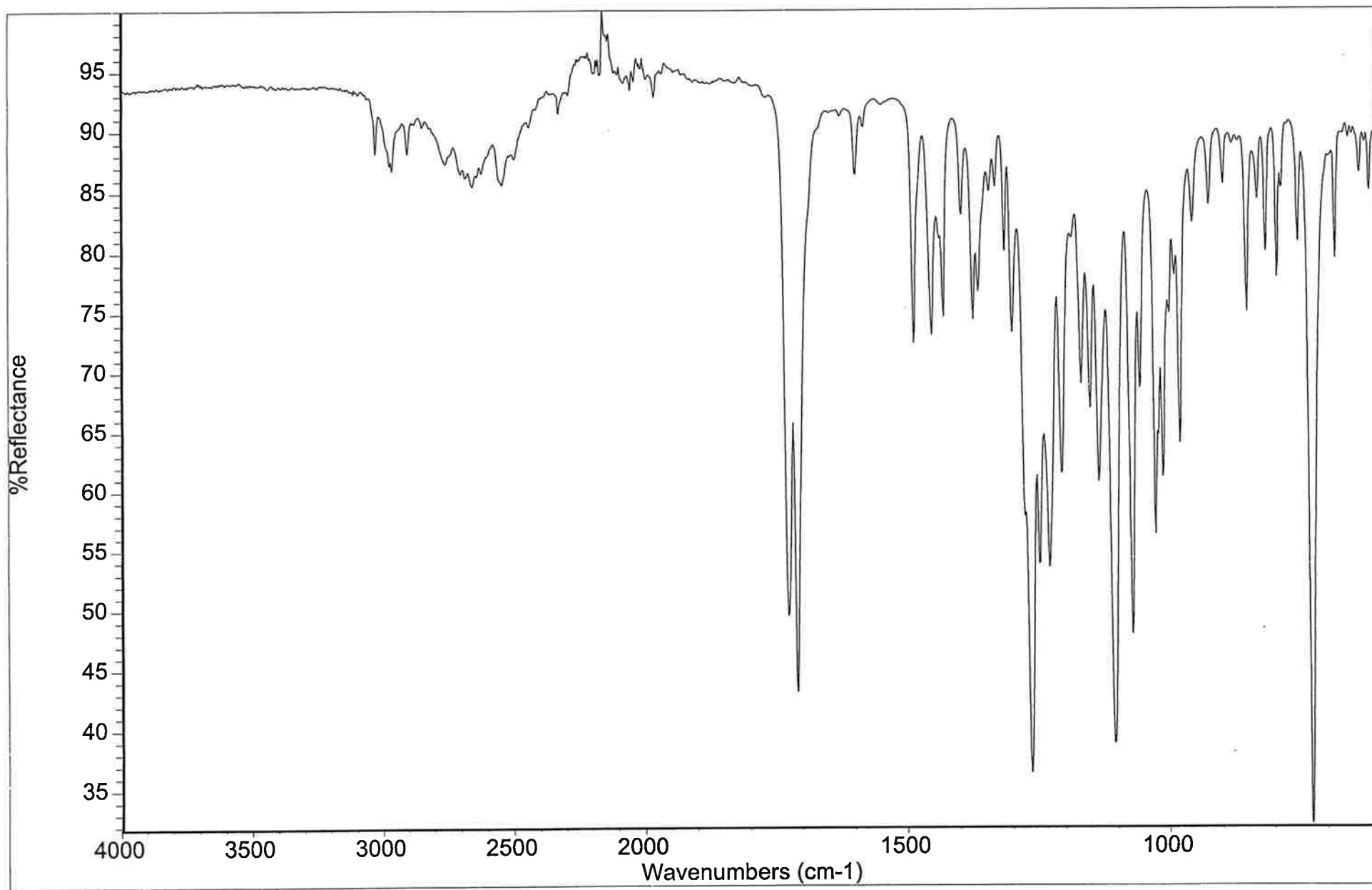


IR VERIFICATION - COCAINE HCL SIGMA LOT #50K1124 WHS

IR #6

WHS

Collection time: Mon Oct 10 09:40:53 2011 (GMT-04:00)

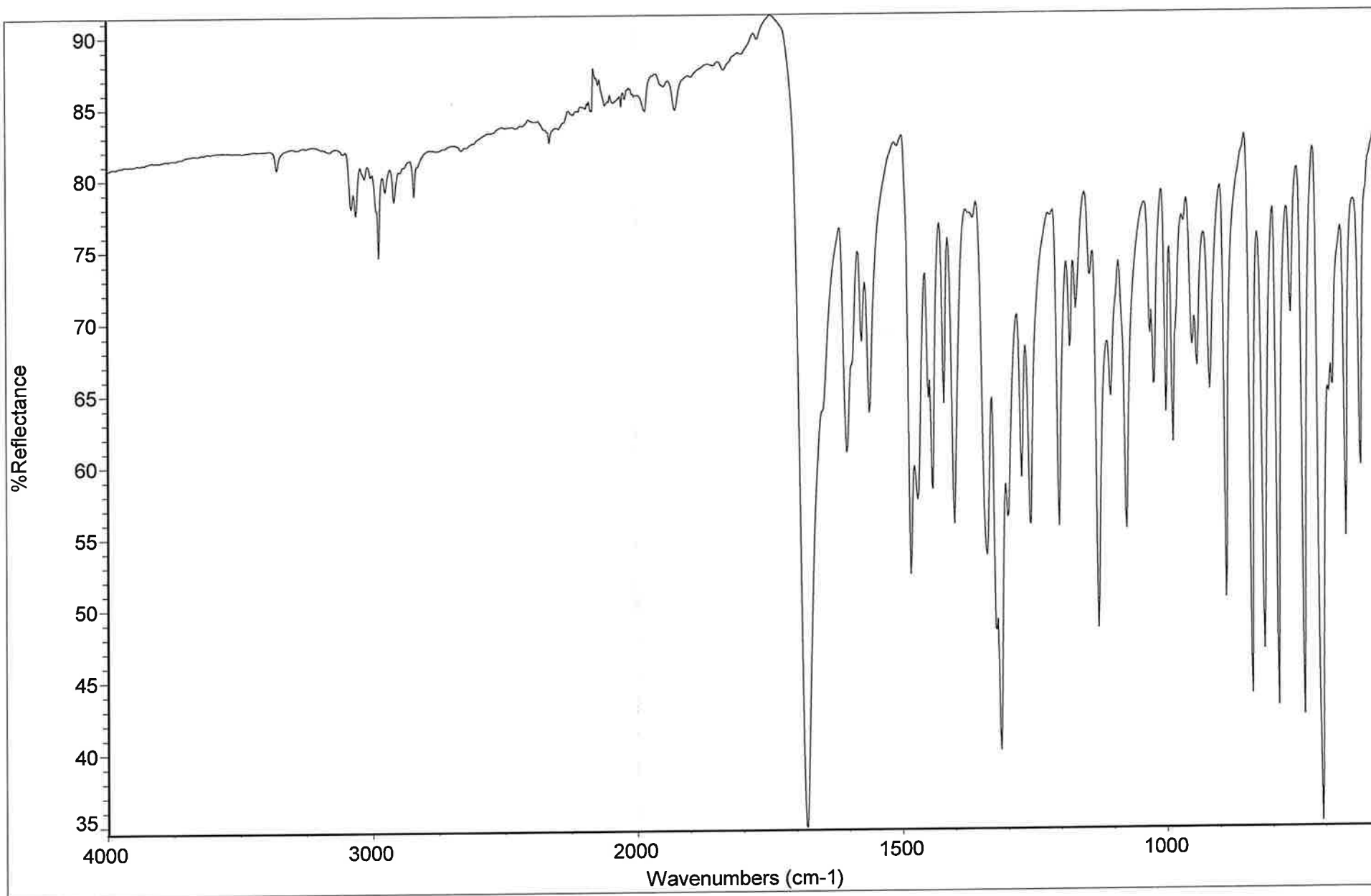


Cocaine HCl Sigma Lot #50K1124

IR #4

(Handwritten signature)

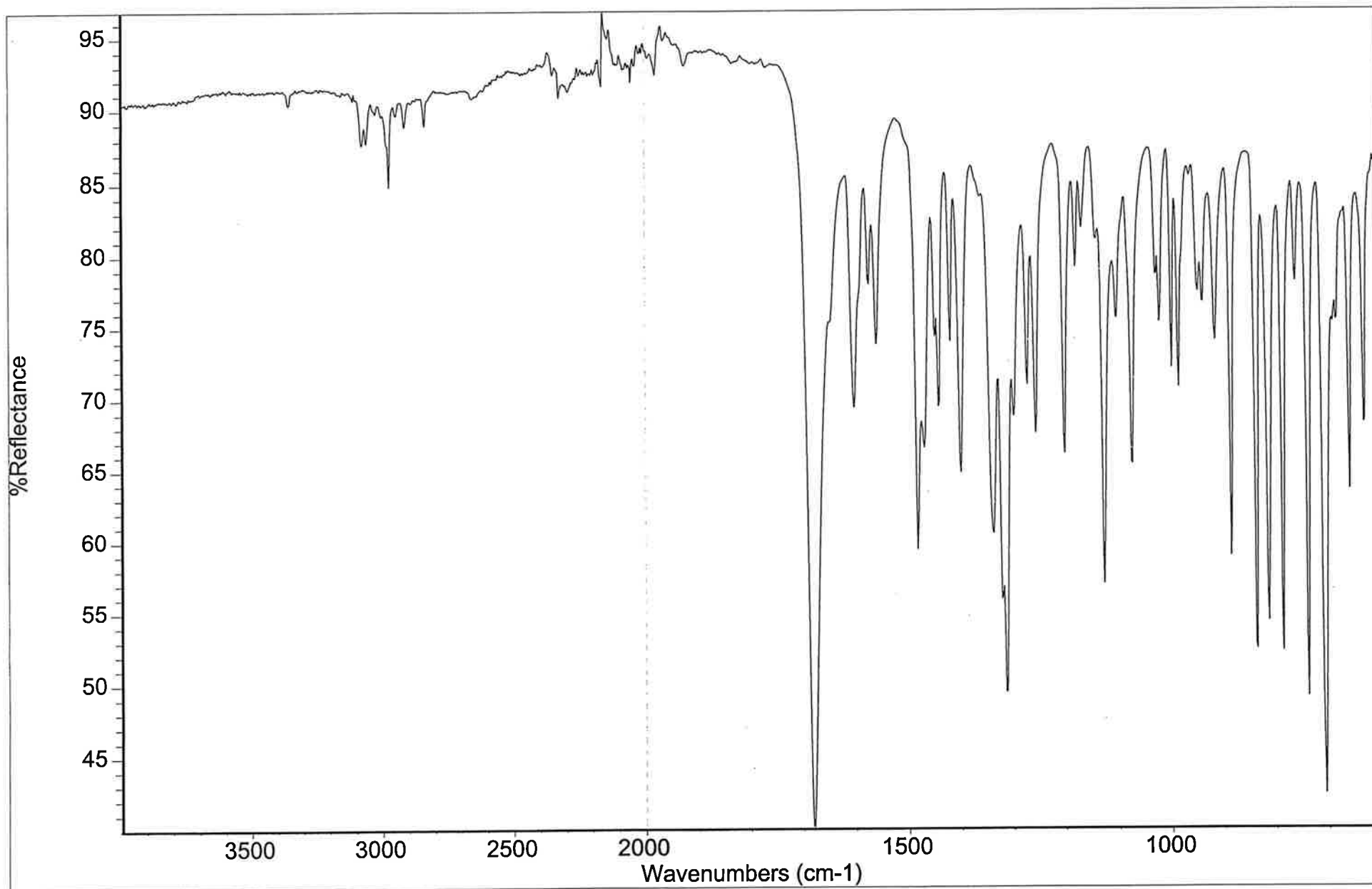
Collection time: Tue Sep 16 15:14:25 2003



IR VERIFICATION - DIAZEPAM STANDARD SIGMA LOT #105F0451 WHS

IR #6

Collection time: Mon Oct 10 09:47:10 2011 (GMT-04:00)

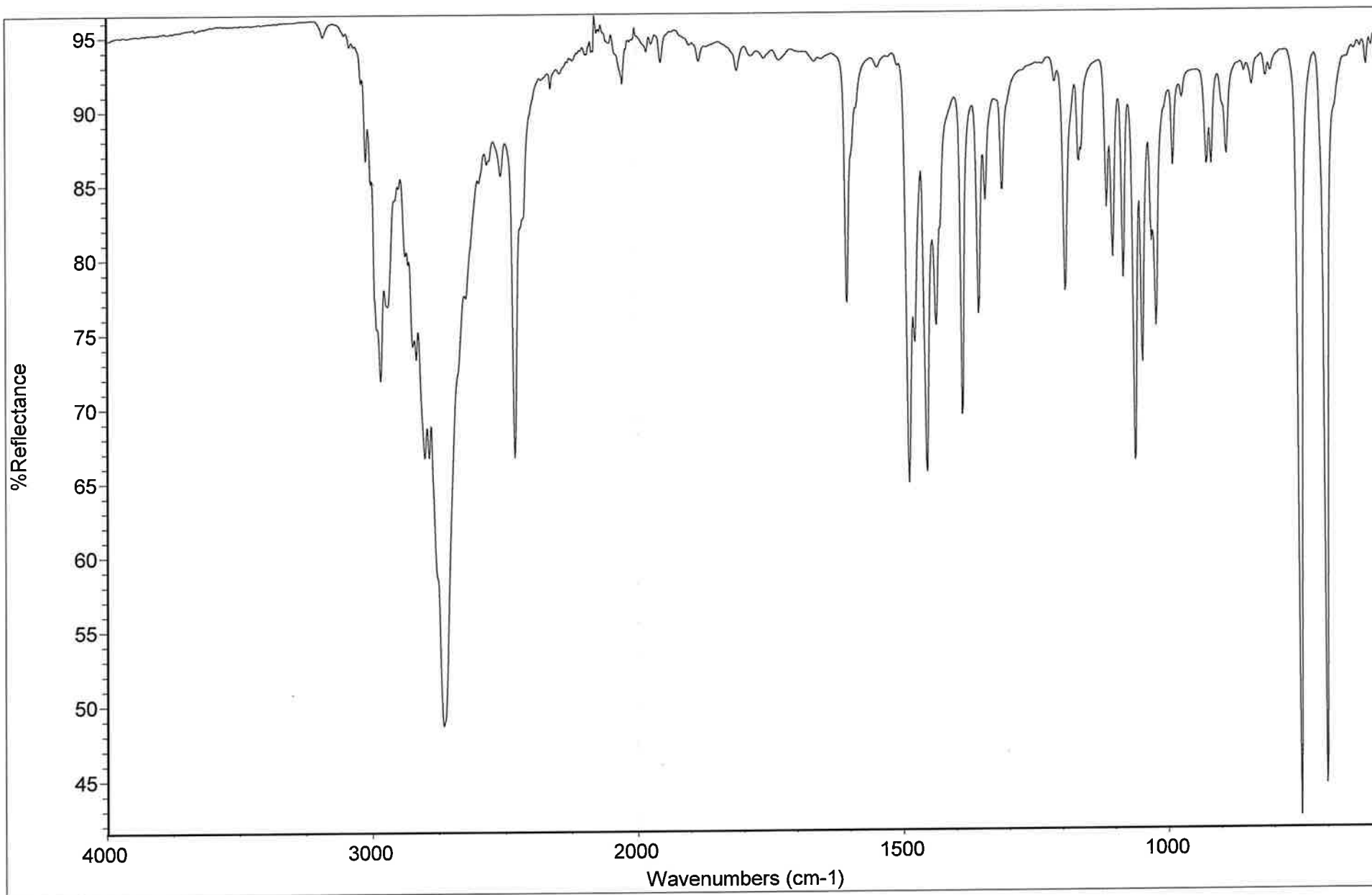


Diazepam Sigma Lot #105F0451

IR #4

WHS

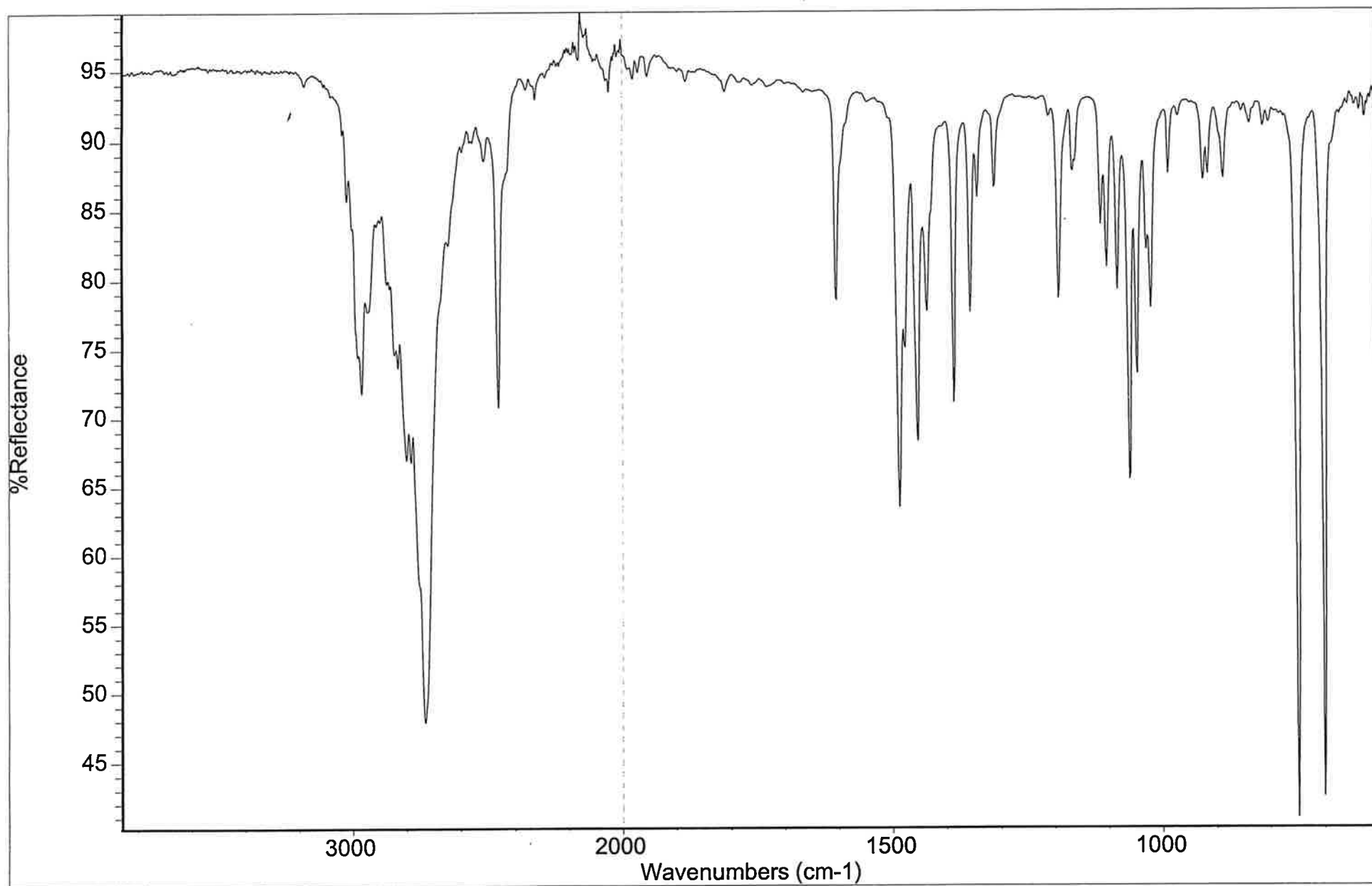
Collection time: Fri Sep 19 08:19:57 2003



IR VERIFICATION - (+)METHAMPHETAMINE STANDARD SIGMA LOT #34H0144 WHS

IR #6

Collection time: Mon Oct 10 09:53:49 2011 (GMT-04:00)

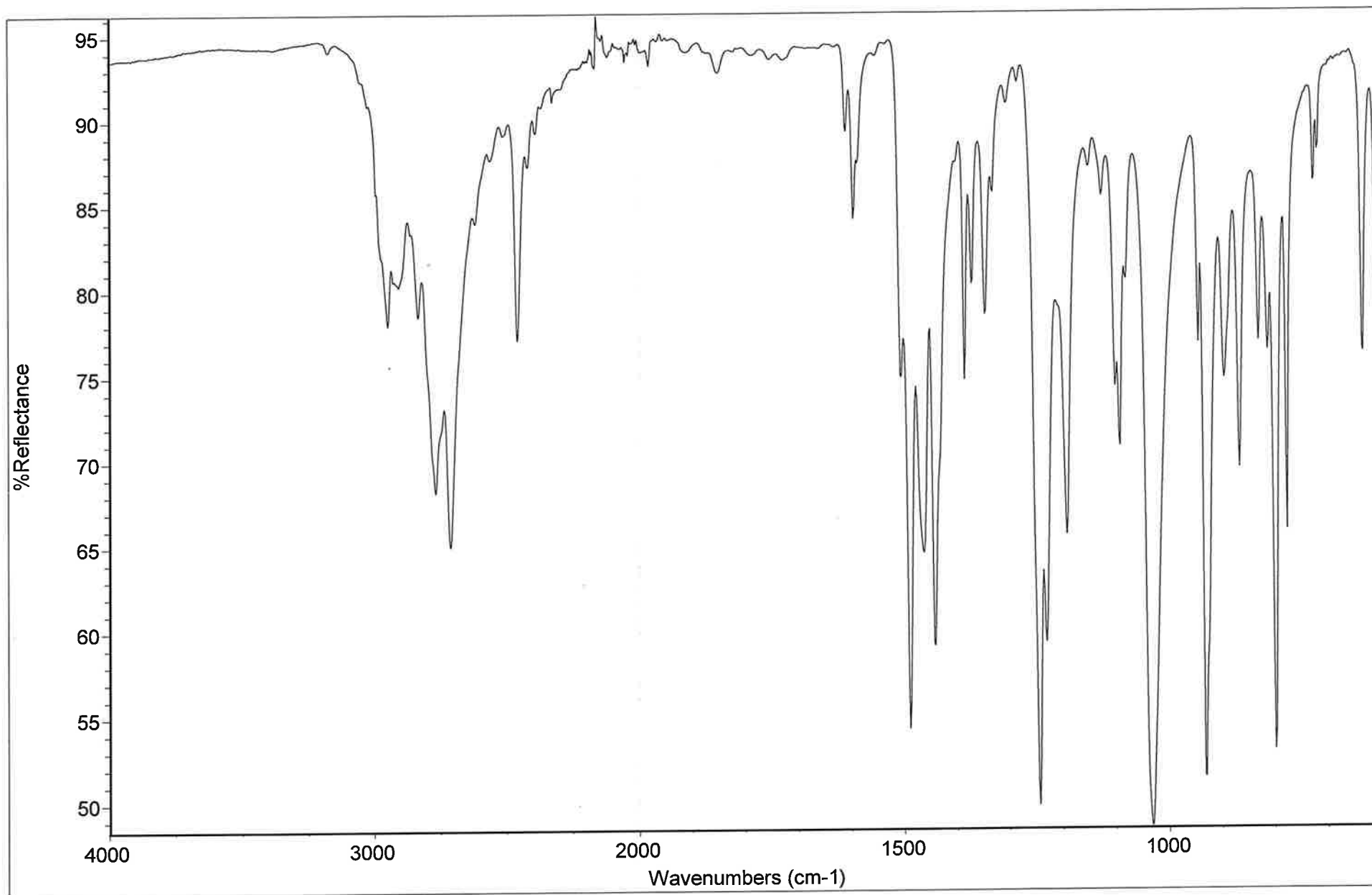


(+)-Methamphetamine HCl Sigma Lot #M-8750

IR #4

(Handwritten signature)

Collection time: Mon Sep 22 14:23:20 2003

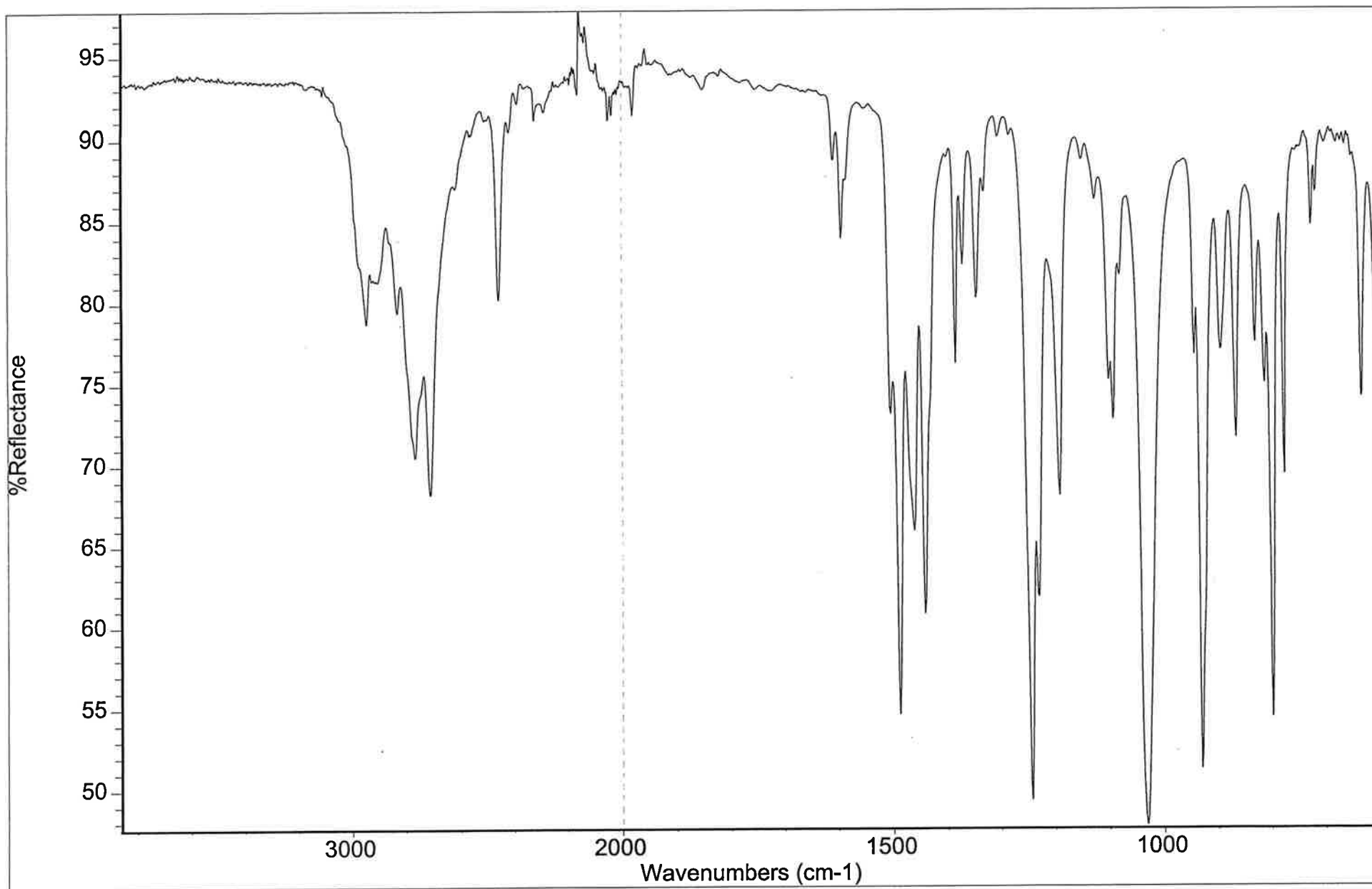


IR VERIFICATION - 3,4 MDMA STANDARD ALLTECH LOT#151 DC-7073-3 WHS

IR #6

CS

Collection time: Mon Oct 10 10:04:12 2011 (GMT-04:00)

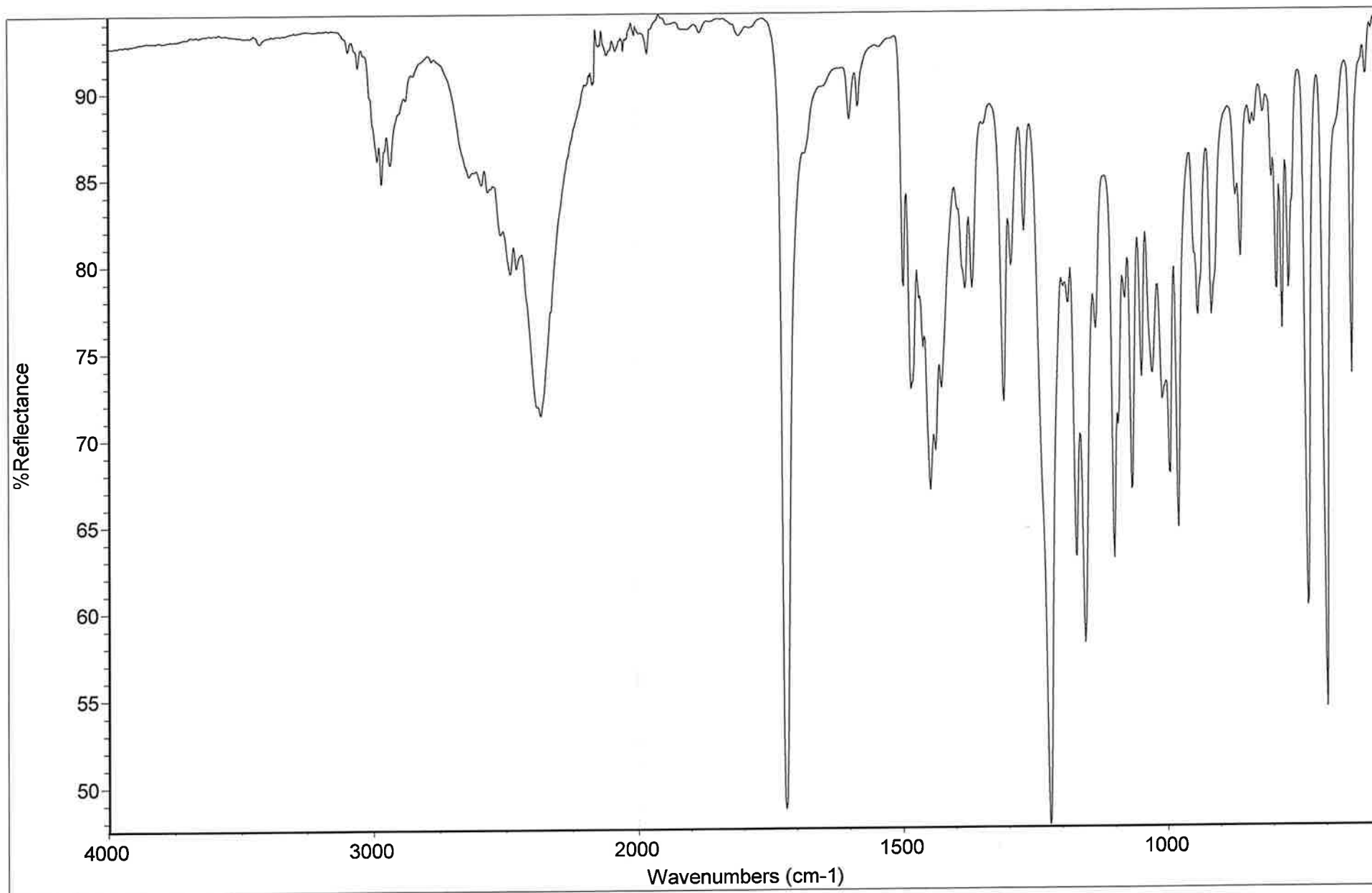


(+,-)-3,4-Methylenedioxymethamphetamine (MDMA) HCl Sigma Lot #60K4096

IR #4

WHT

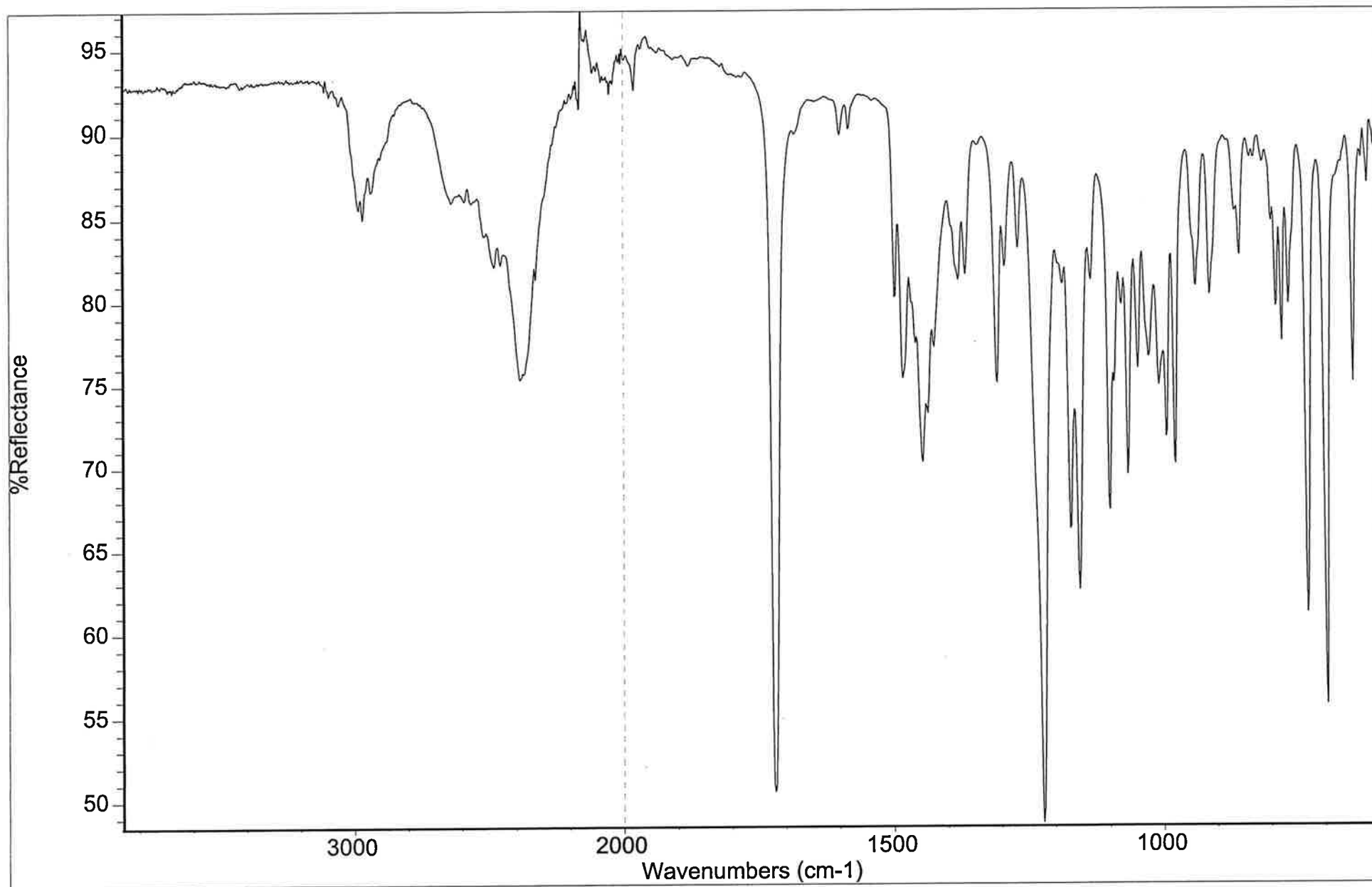
Collection time: Tue Sep 23 11:18:07 2003



IR VERIFICATION - PETHIDINE STANDARD SB PENICK LOT #413 NMN-027 WHS

IR #6

 Collection time: Mon Oct 10 10:21:59 2011 (GMT-04:00)

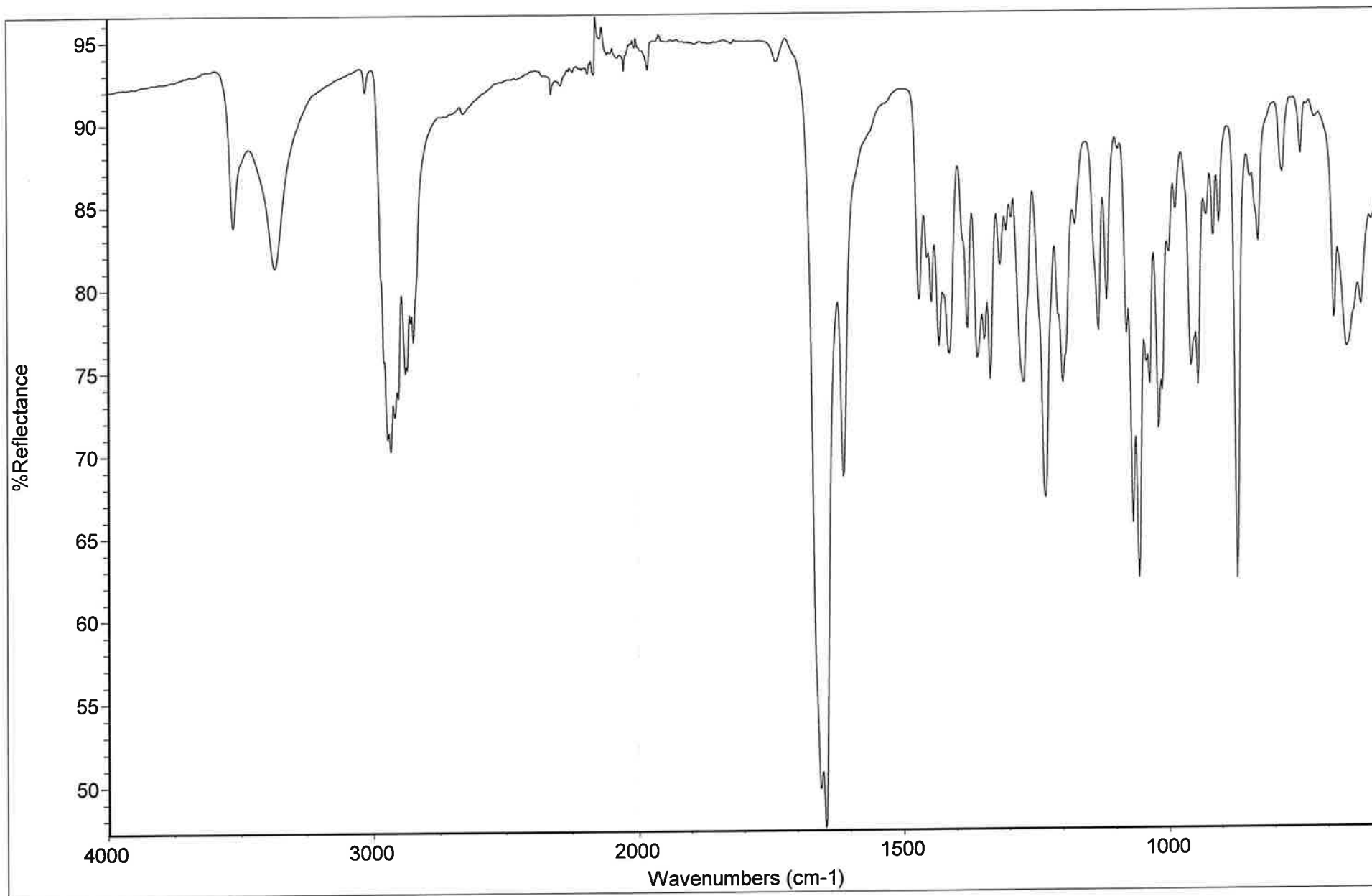


Pethidine HCl S. B. Penick Lot #0501

IR #4

Handwritten signature/initials

Collection time: Thu Sep 25 15:39:22 2003

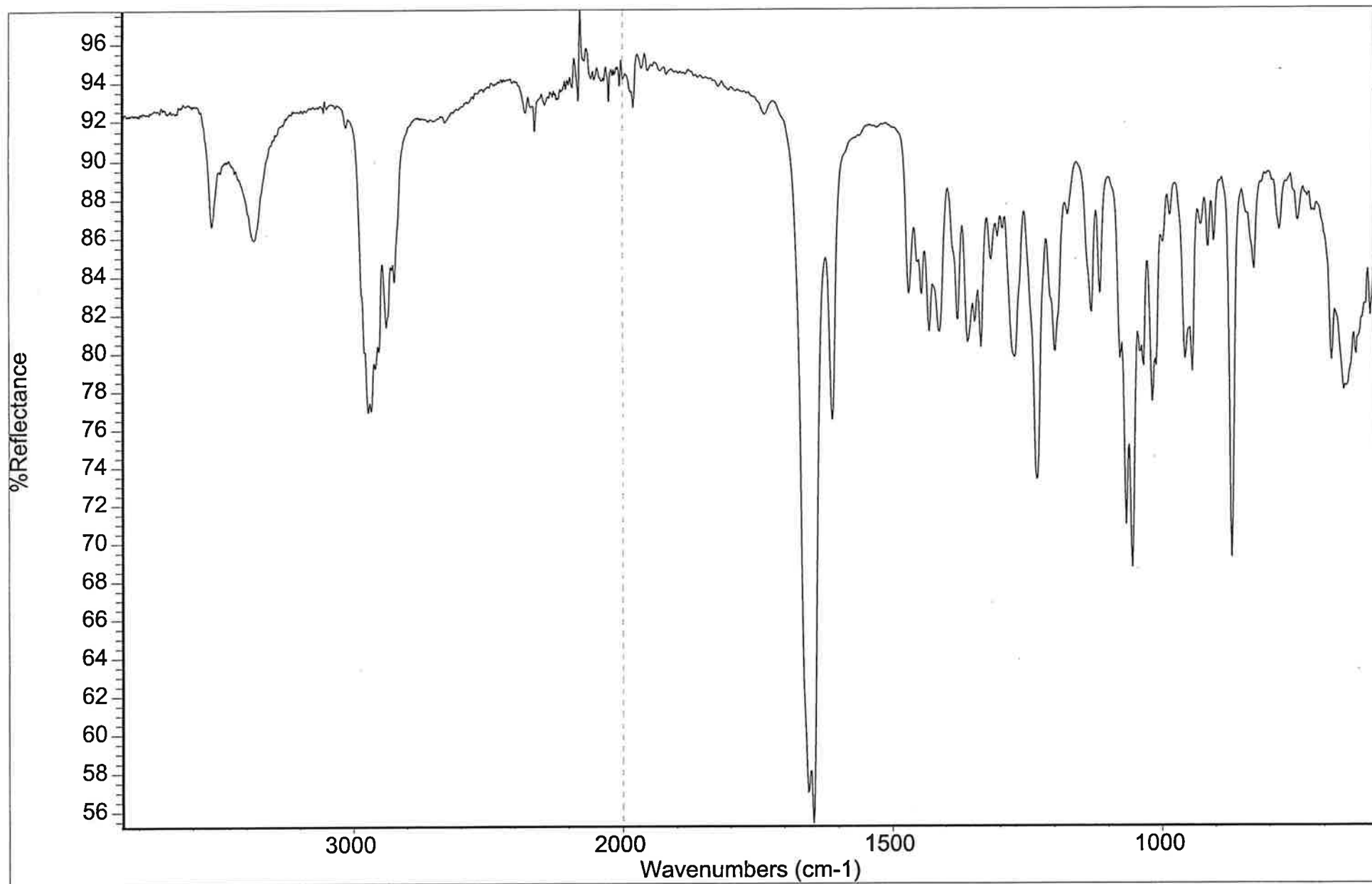


IR VERIFICATION - TESTOSTERONE STANDARD SIGMA LOT #50H0345 WHS

IR #6

[Signature]

Collection time: Mon Oct 10 10:31:55 2011 (GMT-04:00)



Testosterone Sigma Lot #50H0345

IR #4

(Handwritten signature)

Collection time: Fri Sep 26 14:27:09 2003