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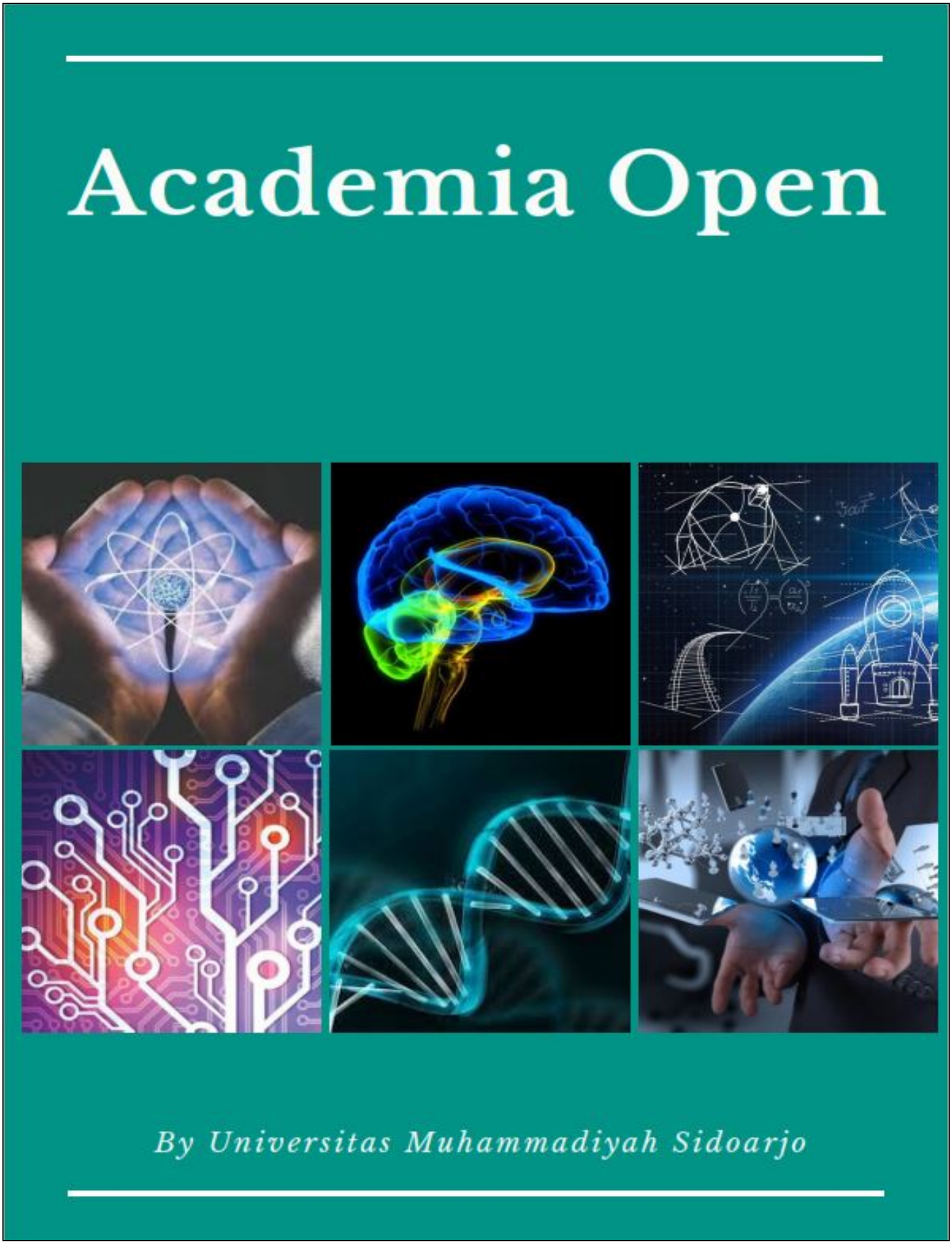

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Investigation Study of Cephalexin Capsule Content from Different Drug Companies Available in the Iraqi Pharmaceutical Market

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Abstract

This study aimed to evaluate the cephalexin content in different capsule formulations from various pharmaceutical companies in the Iraqi market, ensuring medication safety and efficacy. Utilizing computerized High-Performance Liquid Chromatography (HPLC), we analyzed the cephalexin (500 mg) capsules, employing a calibration curve plotted with varying concentrations of external standard cephalexin USP. The purity of cephalexin was further verified through U.V. and I.R. studies. Our quantitative analysis focused on determining the active ingredient's weight based on the area under the peak. The results affirmed that all samples were within the 90%-120% range permitted by the USP 2007 standards, with recoveries approximating 100%, indicating remarkable accuracy and precision. Interestingly, BRULEXIN brand demonstrated the closest recovery to 100%. These findings suggest the effectiveness of HPLC as a rapid, accurate, and sensitive method for pharmaceutical analysis, not only for cephalexin but potentially for other medications as well, highlighting its suitability for routine quality control in the pharmaceutical industry.

Highlights :

- All cephalexin capsule samples met the USP 2007 standard, indicating consistent quality in the Iraqi pharmaceutical market.
- High accuracy and precision of HPLC in quantifying active ingredients highlight its potential for broader pharmaceutical applications.
- BRULEXIN brand showed the closest to 100% recovery, underscoring the variability among different manufacturers.

Keywords : Cephalexin Capsules, HPLC Analysis, Pharmaceutical Quality Control, Iraqi Market, Drug Purity

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I ntroduction

Therapy against microbes:

Infectious diseases continue to be a leading cause of death and deteriorate living conditions for millions of people worldwide, even in the face of decades of significant advancements in their prevention and treatment. Since the Second World War, hundreds of chemotherapeutic agents have been created; the majority of these agents are strong and safe, and they include medications that are effective not just against bacteria but also against viruses, fungi, and parasites.

However, we now understand that when we create antimicrobial agents, microorganisms become more resistant to our greatest defenses and might launch new survival tactics in response[1].

Specific Hazard:

Selective toxicity is a key idea that underpins antimicrobial therapy. selective inhibition of the microorganism's growth without causing harm to the host. Penicillin and cephalosporin are effective antibacterial agents because they prevent the synthesis of peptidoglycan, which inhibits the growth of bacteria but not human cells. This type of selective toxicity is achieved by taking advantage of the differences between the metabolism and structure of the microorganism and the corresponding features of human cells[2].

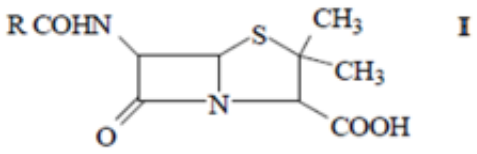
Choosing the Right Antimicrobial Agent:

Knowing the identity of the organism, its susceptibility to a certain agent, the infection site, patient characteristics, the agent's safety for the patient, and the cost of therapy are all necessary when choosing the best antimicrobial agent[3].

Antimicrobial Drug Classification:

Based on their chemical structure, the antibiotics that are produced and supplied today can be categorized into the following groups:

(a)Antibiotics Related to Penicillin: The β-lactam ring, also known as 2-azetidine in IUPAC notation, is present in the structures of all members of this group, which comprises[4]cephalosporin[5]and natural penicillin[6]



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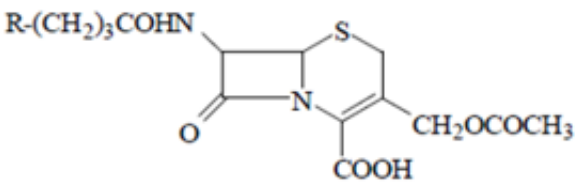

[2]

Figure 1.

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Cephalosporin Generation:

First Generation:

Owing to their vulnerability to β-lactamases, medications from the first generation, such as cephalexin, cephradine, cephaloridine, and cefaclor[7], have a rather restricted spectrum of activity against gram-negative strains of bacteria but good activity against gram-positive strains[8].

Second Generation

Compared to third-generation drugs[9], such as cefuroxime[10]have somewhat greater action against gram-negative bacteria. However, their activity is still significantly lower.

Third Generation

Cefotaxime and ceftriaxone, for instance, exhibit a broad range of activity and greater stability against several β-lactamases, which render older generations of cephalosporins and other β-lactam antibiotics inactive[11].

Fourth Generation

Cephalosporins, including cefepime, exhibit a wider range of activity in contrast to third-generation antibiotics[12]. Additionally, the US Food and Drug Administration has given it approval for patients older than two months of age[13].

Cephalexin:

Explanation:

One of the first generation cephalosporins, cephalexinUSP[9]:7α-(D-Amino-α-phenylacetamido)-3-methy-3-cephemcarboxylic acid, was created specifically to be an orally active medication[14]. This β-lactam antibiotic shares structural and functional similarities with penicillin[15], but differs from penicillin due to its heterocyclic ring system[16]. Its antibacterial efficacy patterns are similar to those of ampicillin, but cephalexin is significantly more resistant to β-lactamase inactivation[17].

(C16H17N3O4S. H2 O) is the molecular formula[18]

Weight in molecules: (365.4)[19]

Pharmacokinetics :

When taken orally, cephalexin is almost entirely absorbed. meals cause a modest reduction in the total quantity of medicine absorbed when given with meals, but it also delays absorption, resulting in lower peak but longer lasting blood levels. 82% of oral cephalexin given to fasting patients is detected in their urine, whereas 73% of those given the medication concurrently with food had it in their urine[20].

Indications

Cephalexin is prescribed to treat infections caused by Gram-positive and Gram-negative bacteria that are sensitive. It treats infections of the urinary tract, particularly those that do not go away with other medications or that develop during pregnancy, as well as infections of the respiratory tract, skin, bone, otitis media[21], biliary tract infection, peritonitis, septicemia, meningitis, and meningitis [22].

Dose

The dosage for adults is 250 mg every 6 hours or 500 mg every 8–12 hours; for severe infections, this can be increased to 1-1.5 grams every 6–8 hours. The dosage for children is 25 mg/kg daily in divided doses, which can be doubled for severe infections or even to 100 mg/kg/day. Youngsters under one year old get 125 mg every twelve hours, those one to five years old get 125 mg every eight hours, and those five to twelve years old get 250 mg every eight hours[23].

Chromatography:

Explanation:

One physicochemical technique for separating complicated mixtures is chromatography. It was founded by the Italian-Russian botanist M. during the very beginning of the 20th century. S. Tswet, who translated the Greek term

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"color writing" to "chromatography," provided a very thorough explanation of the recently found phenomenon of adsorption-based separation of complex mixtures. Even though Tswet said in all of his writings that the vibrant image from his initial plant pigment separation process served as the inspiration for the name of his novel technique[24].

The basis for chromatographic separations is the forced movement of the liquid (mobile phase) containing the analyte mixture through the porous media and the variations in analyte-surface interactions that cause varying migration times for mixture components[25].

Classification

Two main chromatography classes are of relevance to organic chemists[26]. These are the following:

Liquid chromatography (LC)

Gas chromatography (GC).

Chromatography in Liquid Form:

is a technique for developing a mixture injected into a column pre-prepared with an appropriate stationary phase. The mixture is separated into its constituent parts by using the difference in retention capacity against the stationary phase to identify the constituent parts. This technique can be utilized for identification, purity testing, and quantitative determination on both liquid and soluble samples[27].

Chromatography with Gas

The process of separating substances that have been transferred to the gas phase based on differences in their polarity or boiling points is known as gas phase separation (GC). Solid samples must be dissolved in a solvent before being inserted directly into the GC apparatus; liquid samples can only be examined if they are sufficiently volatile. Samples are instantly converted to the gas phase during injection because they are exposed to a highly hot injection port. Simple boiling point changes are a major factor in the GC separation of organic molecules[28].

Chromatography on a thin layer (TLC)

High-Performance LC(HPLC)

Chromatography on a thin layer (TLC):

(TLC) is the most widely used technique for routine analysis because it is easy to use, can analyze several samples at once, uses bright, specific reactions, allows for two-dimensional separation, and is simpler to manipulate the stationary and mobile phases[29].

Using tiny amounts of a combination, TLC is helpful for the isolation and identification of unknown components. Alumina or silica placed on a glass or plastic plate serves as the stationary phase in TLC[30].

High-Performance LC:

Definition:

With the use of a stationary phase (sorbents packed inside the column) and a mobile phase (a flowing liquid), a sample is divided into its parts, or analytes, using the physical separation process known as high-performance liquid chromatography (HPLC). A chromatogram is produced by an online detector that tracks each separated component's concentration in the column effluent. For the quantitative examination of medications, biomolecules, polymers, and other organic compounds, high-performance liquid chromatography (HPLC) is the most popular analytical method[31]. Analyte affinity differences for the stationary phase surface continue to be the basis for analyte separation.

The primary and essential analytical technique used at every stage of drug discovery, development, and production is high-performance liquid chromatography (HPLC)[32].

Pharmaceutical stability tests are currently conducted primarily using HPLC [33].

HP LC apparatus building units [34] **:**

Typically, an HPLC system has the following primary parts:

Storage Tanks for Solvents:

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Keeping enough HPLC solvents on hand to support the system's continuous operation. These solvents may also be fitted with specific filters and an online degassing mechanism to protect them from environmental influences.

Pump

This ensures that the mobile phase flows through the system continuously; yet, the majority of contemporary pumps provide the regulated mixing of various solvents from various reservoirs (mobile phase gradient)[35]

The injector

This makes it possible to introduce (inject) the analytes combination into the mobile phase stream before it enters the column. The majority of contemporary injectors are auto-samplers, enabling preprogrammed injections of various sample volumes that are taken out of the vials in the auto-sampler tray[36]

Column

This is the main component of the HPLC system, which separates the analytes in the mixture. The interface with a large surface area formed by the mobile phase and stationary phase coming into contact is called a column. The majority of recent advances in chromatography have been focused on creating several strategies to improve this interfacial contact[37]

In a modern HPLC column, packing material (adsorbent) is placed inside a stainless steel or plastic tube that has been organized with end-fittings that are intended to maintain the packing material inside while enabling liquid to pass through and establish a sealed connection with the eluent inlet and outlet lines[38]

To allow the mobile phase to pass through and allow analytes to interact with the accessible surface, the stationary phase is held in place within the column[39]

Finder

This apparatus continuously records particular physical (and occasionally chemical) characteristics of the column effluent. A UV detector is the most often utilized detector in pharmaceutical analysis[40]

System fo r Data Acquisition and Control

The development of a computer-based system allowed for the control of all HPLC instrument parameters, including temperature, injection sequence, and eluent composition (mixing of different solvents). The system also collected data from the detector and continuously monitored the composition of the mobile phase, temperature, backpressure, and other system parameters[41]

Cephalosporin assay techniques:

Numerous analytical techniques, including titrimetric, spectrophotometric, and fluorimetric methods, have been employed for the analysis of cephalosporins due to their significant therapeutic value. voltammetric, potentiometric, chromatographic, and chemiluminescence techniques[42].

The cephalosporin antibiotic series separation issue has been addressed by high-performance liquid chromatography (HPLC) [43].

THE STUDY'S GOAL:

By assaying the various samples using the HPLC-UV method and comparing the results obtained with standard, this study aims to test cephalexin from various pharmaceutical companies in the Iraqi market to prove that the contents and the weight of each capsule are within the range of maximum difference allowed[44].

Experimental work

Chemicals and equipment

Acetonitrile, Potassium dihydrogen, Methanol , Cephalexin 250 mg vial USP reference standard as the monohydrate formof cephalexin.HPLC apparatus, Ultrasonic bath /Karl Kolb vibrater, Balance - Mettler, F.T. IR Spectrophotometer, melting point Apparatus, UV-spectrophotometer /carry 100 conc. (varian)[45]

Research Framework:

The 500 mg cephalexin capsule samples were obtained from several companies within the Iraqi pharmaceutical sector, as indicated in Tables 2-3.

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Type	Company	M.D.	E.D.	BATCH NO.	Average Capsule wt mg
A ACAFLEX	ACAI Iraq	-	6-2012	B-064	545
B CEPOFLEX	MISSION India	11-2008	04-2011	MGA833	545
C CEFALEXIN	KONTAM China	01-2009	01-2012	090136	582
D CELEXIN	HOVID Malaysia	10-2008	10-2011	V82	536
E APKEF	Ajanta India	12-2008	11-2010	AM0038L	550
F CEPHALEXIN	ASIA Syria	11-2008	11-2012	4821	560
G CEPHALONIN	N.D.I Iraq	-	3-2013	1	560
H CEPHALEXIN	SDI Iraq	1-2009	1-2013	B-3	575
I BRULEXIN	BRAWN India	11-2008	10-2011	BC118031	549

Table 1.

Qualitative UV-Spectrophotometric Analysis[46] :

To make a stock solution, 50 mg of cephalexin is dissolved in 100 ml of water in a volumetric flask. The solution exhibits maximum absorption at 262 nm, as indicated in figure (2-1) when 2 ml of the solution is diluted to 50 ml with water and tested between 220 nm and 300 nm.

This outcome is the same as the one that was documented [47], as seen in Figure (2-2)

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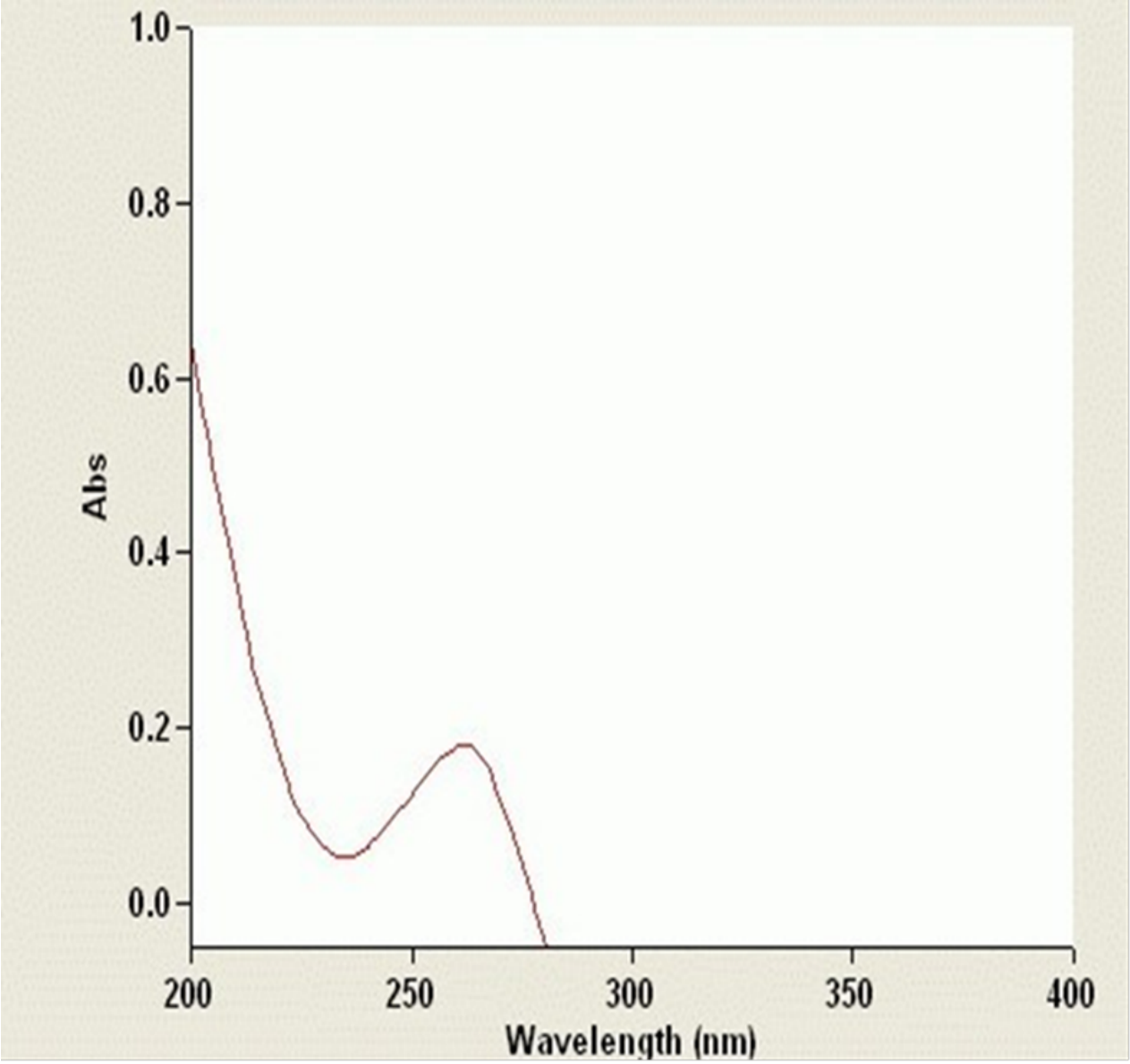

Figure 2. *(2-1) shows the cephalexin monohydrate standard's UV spectrum.*

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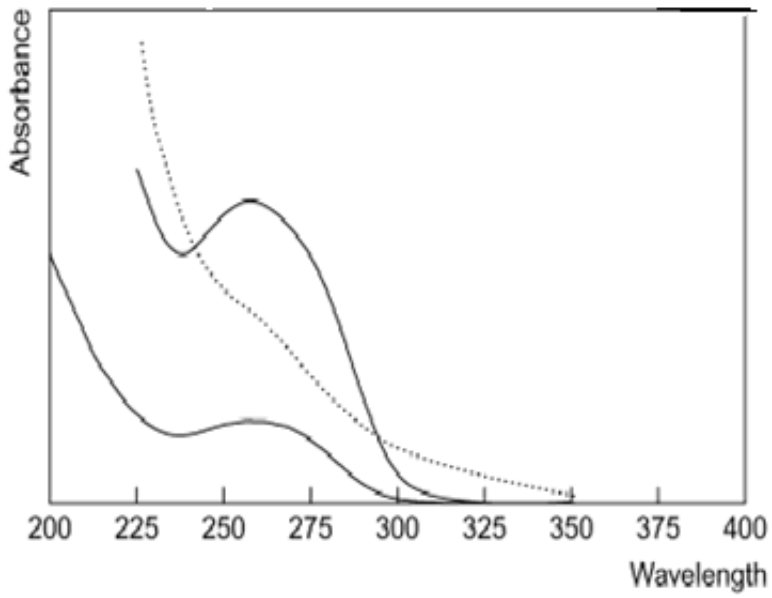

Figure 3. *(2-2): Recorded UV-spectrum of cephalexin monohydrate in Aqueous acid—258 and water—262 nm.*

I.R-qualitative spectrophotometric analysis:

I.R. spectrometry was used to evaluate the cephalexin powder; the cephalexin monohydrate KBr disk showed principal peaks at wave numbers 3044, 2614, 759, 1690, 1281, and 750 cm−1. Figure (2-3) is the outcome of the following data. (2-3).

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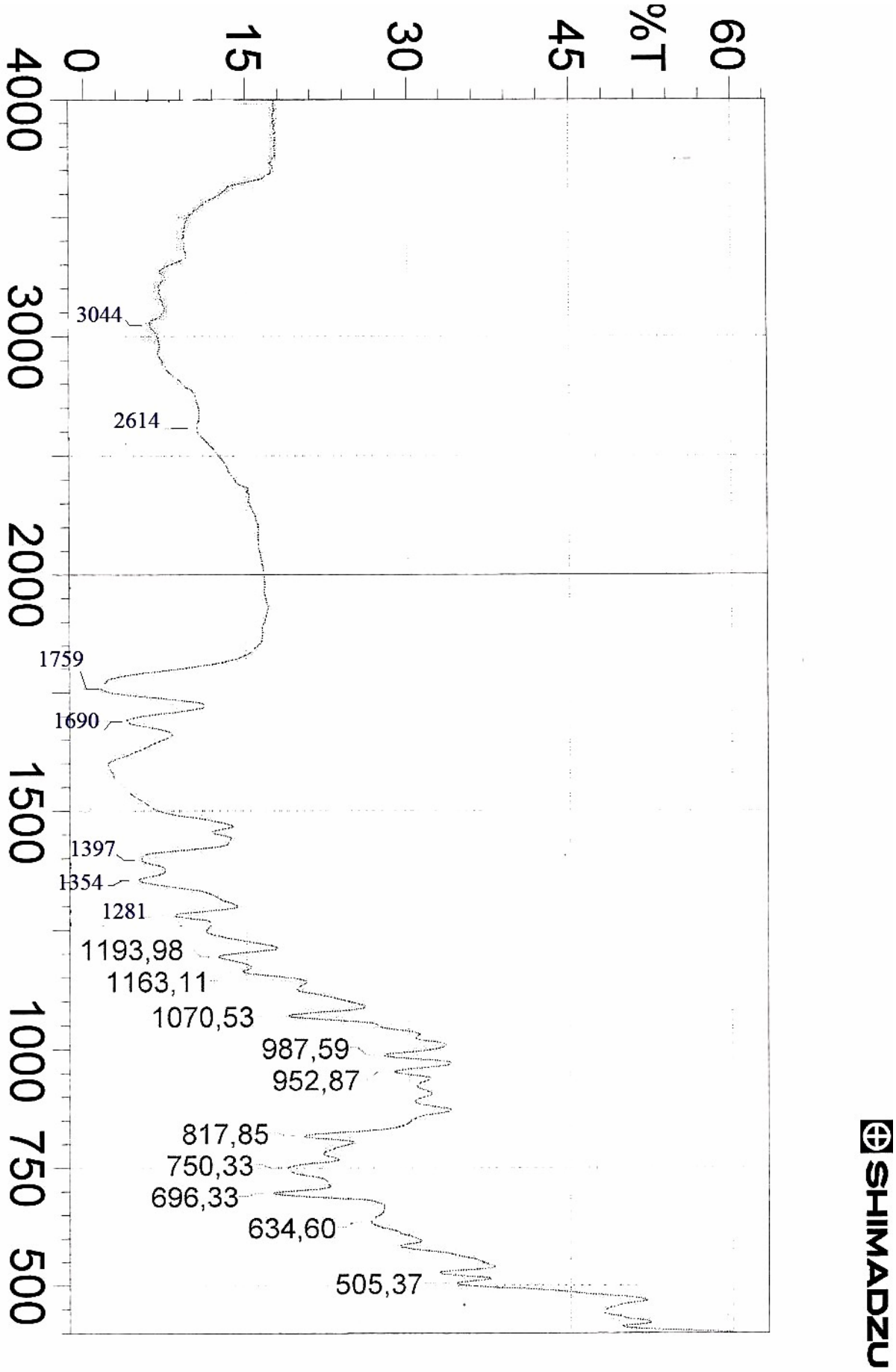

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Figure 4. *2–3: Cephalexin monohydrate standard IR spectrum (KBr disk)*

Method

HP LC-Based Assay Methodology [48] **:**

creating a calibration curve or standard curve that makes use of cephalexin USP as an external standard reference.

The standard powder was made as a stock solution from which several dilutions (0.1, 0.2, 0.3, 0.4, 0.5, and 0.6 mg/ml) were obtained. These dilutions were then injected into the HPLC system to determine the AUP for each dilution. Cephalexin concentration determination. in several pharmaceutical firms' capsules[49].

Chromatographic Examination:

The A column is made of stainless steel measuring 25 cm by 4.6 mm I.D. and filled with a stationary phase C (5 micrometers) (nucleoside C 18 is acceptable) , distilled water as diluent[50].

Mobile phase: two volumes of methanol, five volumes of acetonitrile, ten volumes of potassium dihydrogen orthophosphate solution (1.36% w/v), and eighty-three liters of water.- -Use the LPG mode.

-1.5 ml/min flow rate

-Time spent running: 5 minutes

-Inj. volume of 20µl

-with a 254 nm detector set

Setting Up the Calibration Curve and Standards Solution:

The powdered cephalexin USP was quantitatively dissolved in a diluent to produce a concentration of 0.5 mg/ml. Then, using a diluent phase, various quantities of this stock solution were diluted to 10 ml to create solutions with various concentrations. Each of these dilutions was then injected into the HPLC apparatus. The area under the peak (AUP) approach was used to achieve the results, as indicated in Table (2-2).

Volume of stock solution	Dilution	The Conc. In (mg/ml) x-axis	The AUP(kvolt) y-axis
00 ml	00 ml	00	00
2ml	10 ml	0.1	1452
4ml	10ml	0.2	3069
6ml	10ml	0.3	4567
8ml	10ml	0.4	6102
10ml	10ml	0.5	7461
12ml	12ml	0.6	9202

Table 2.

Plotting the conc allowed for the final determination of the calibration curve. of cephalexin vs the AUP, which is represented in fig. (2-4) and follows the linear equation (y= a+ b

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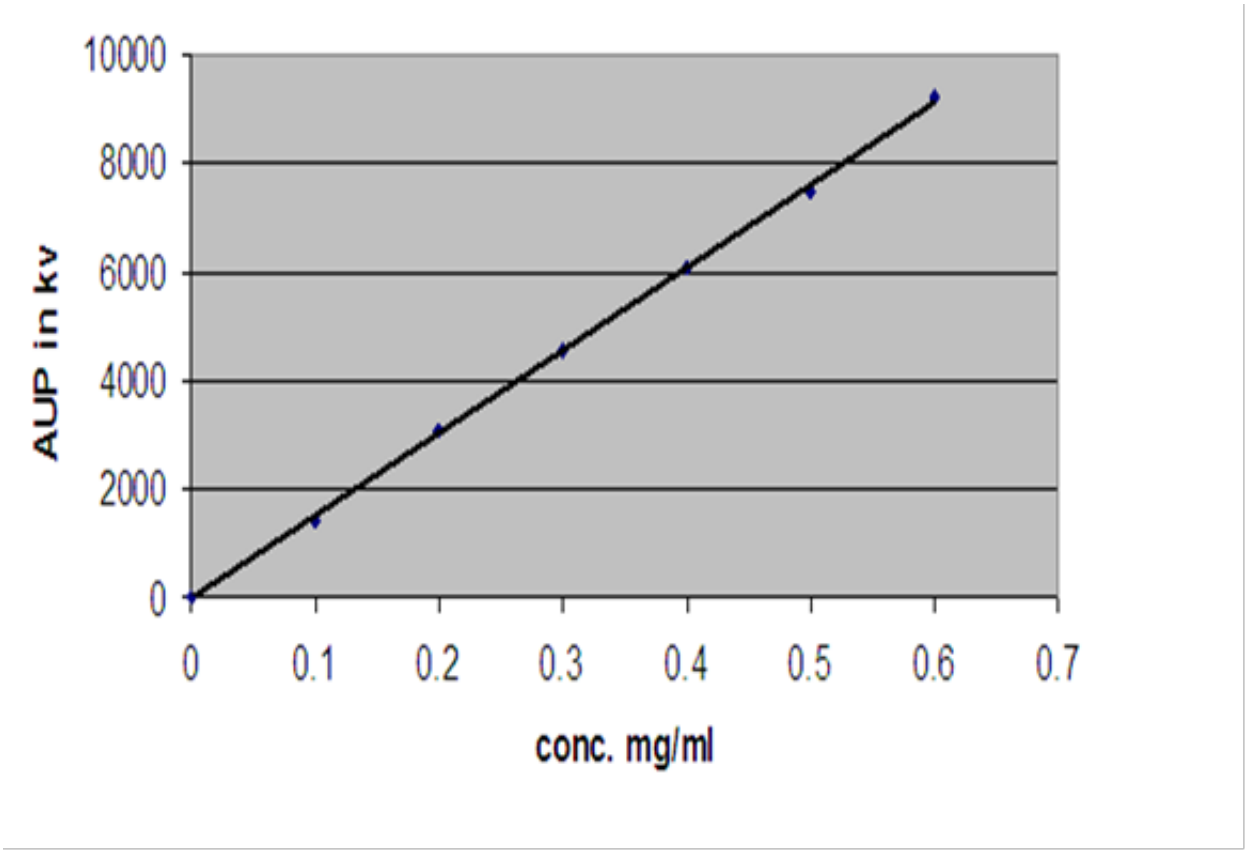

Figure 5. *(2-4): Cephalexin's calibration curve*

The following information is obtained by substituting the statistics application:

a=0.0

b=15189 the slop or regression coefficient

r2= 0.9995 the coefficient of determination

r= 0.9997 the correlation of coefficient

After that, the calculation's straight-line equation is rearranged to:

Y = 15189(X)

The conc. chromatogram (0.5 mg/ml). of the cephalexin standard solution is displayed in Fig. (2–5).

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Area % Report

Data File: C:\ChromGate\Enterprise\Projects\Default\Data\0.5cefaak006.dat
Method: C:\ChromGate\Enterprise\Projects\Default\Method\cefaaklaas.met
Acquired: 25/07/2009 13:16:50
Printed: 16/08/2009 13:14:13

Page 1 of 1

UV detector S
2500 Results

Retention Time	Area	Area %	Height	Height %
7.050	7461278	100.00	301983	100.00
Totals	7461278	100.00	301983	100.00

Figure 6. *(2–5): Cephalexin standard solution, 0.5 mg/ml area report.*

Assay and Sample Handling:

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Twenty capsules were empty as much as possible, and the average weight of each capsule was calculated by weighing the empty capsules.

A quantity of powder equal to roughly 50 mg of cephalexin was weighed and mixed with the combined contents before being put into a 100 ml volumetric flask.

After adding the diluent and mixing the contents with the help of sonycate, the volume was finished and mixed for the market using the same diluent. The AUP values were then averaged after the solution was put into the HPLC equipment three times.

To obtain the AUP, each of the nine samples is evaluated under identical circumstances as the external standard in the HPLC system. The conc is found by using the straight-line equation. of every specimen.

Results and Discussion

Table (3-1) displays the maximum percentage difference permitted, the average AUP, and the sample concentrations.

No.	Trade name	The Mean AUP Obtain from chromatography (kv)	Conc. (mg/ml)	maximum allowed differences
1	ACAFLEX ACIA	8079	0.53	504-585.9
2	CEPOFLEX	8312	0.55	504-585.9
3	CEFALEXIN KONTAM	8664	0.57	553.4-625.7
4	CELEXIN Hovid	8230	0.54	495.8-576.2
5	APKEF ajanta	8002	0.53	508.8-591.3
6	CEPHALEXIN	8181	0.54	518-602
7	CEPHALONIN NDI	8206	0.54	518-602
8	CEPHALEXIN SDI	8709	0.57	531.9-618.1
9	BRULEXIN Brawn	7885	0.52	507.8-590.2

Table 3.

Based on the information found in the table (3-1) where the conc. Once each AUP was established, we could compute the weight, error percentage, and recovery percentage relative to the standard, which is 500 mg. We could also compute the RSD% or C.V. as indicated in Table (3-2).

Y is equal to 15189(X).

X(MG) = Y(Kv)

15189 Determined Weight. = Conc. × 100 x 500 of the Sample 50

Error%= Calculate. What. - Standard. Weighing 100 lbs. What.

Calculated = Recovery%. What. X 100 Standard.wt.

The data in Table (3-2) show what. Cephalexin, error percentage, recovery percentage, and RSD percentage of the nine samples from various pharmaceutical firms.

NO.	DRUG Source	Weight of Cephalexin in mg	Error %	Recovery %	RSD 0r CV %
1	ACAI	532	6.4	106	0.018
2	548	9.6	109	0.144	
3	KONTAM	570	14	114	0.047
4	HOVID Malysia	542	8.4	108	0.153
5	532	6.4	106	0.019	
6	539	7.8	107.8	0.030	
7	N.D.I	541	8.2	108	0.080
8	SDI	574	14.8	114.8	0.011

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9	BRAWN	518	3.6	103.6	0.067

Table 4.

The nine tested sample chromatograms are displayed in figures (3-1) through (3-9)

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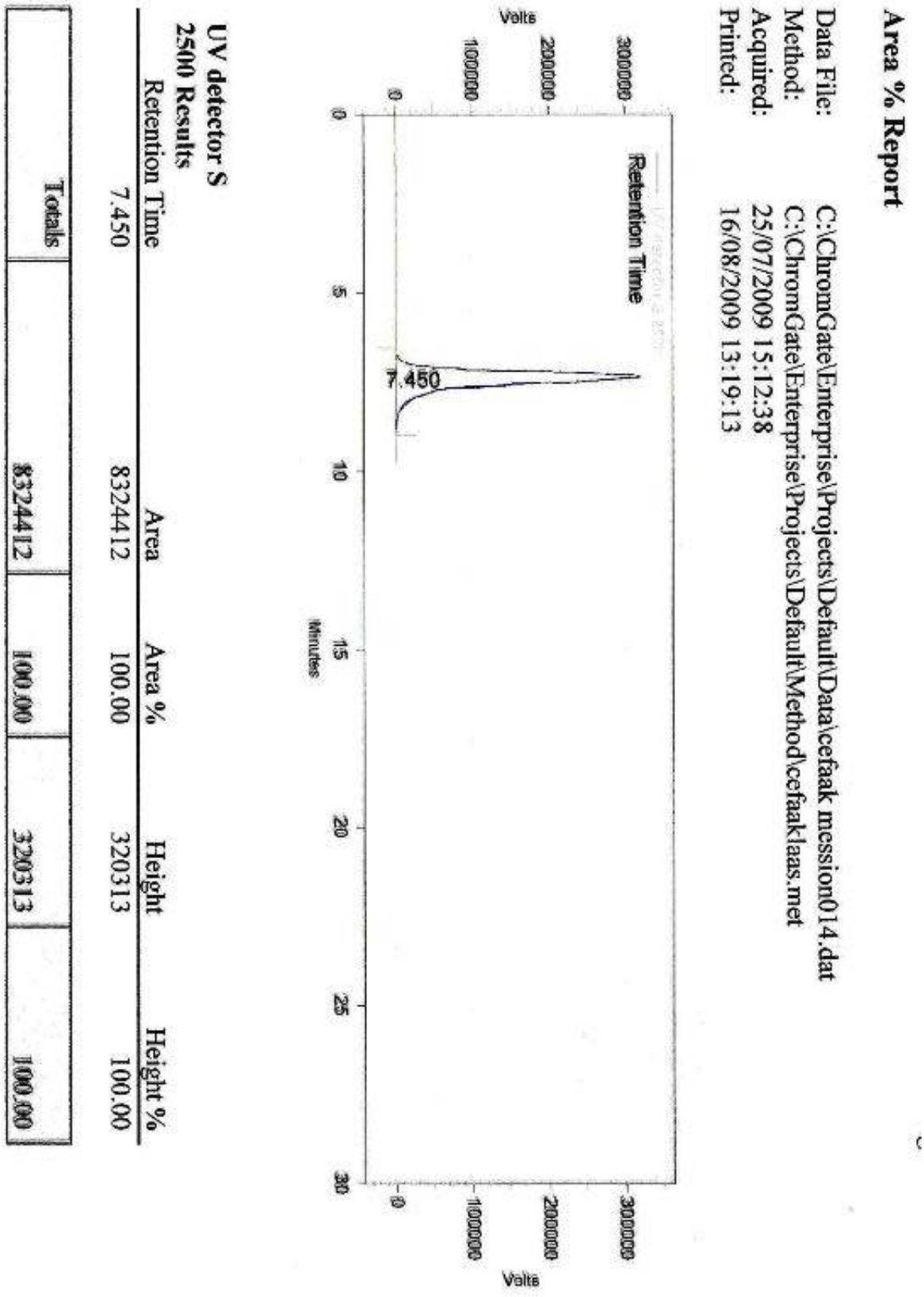

Area % Report

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Method: C:\ChromGate\Enterprise\Projects\Default\Method\cefaaklaas.met
Acquired: 25/07/2009 15:12:38
Printed: 16/08/2009 13:19:13

UV detector S
2500 Results

Retention Time	Area	Area %	Height	Height %
7.450	8324412	100.00	320313	100.00
Totals	8324412	100.00	320313	100.00

Figure 7. ***(3-1): mission capsule area report***

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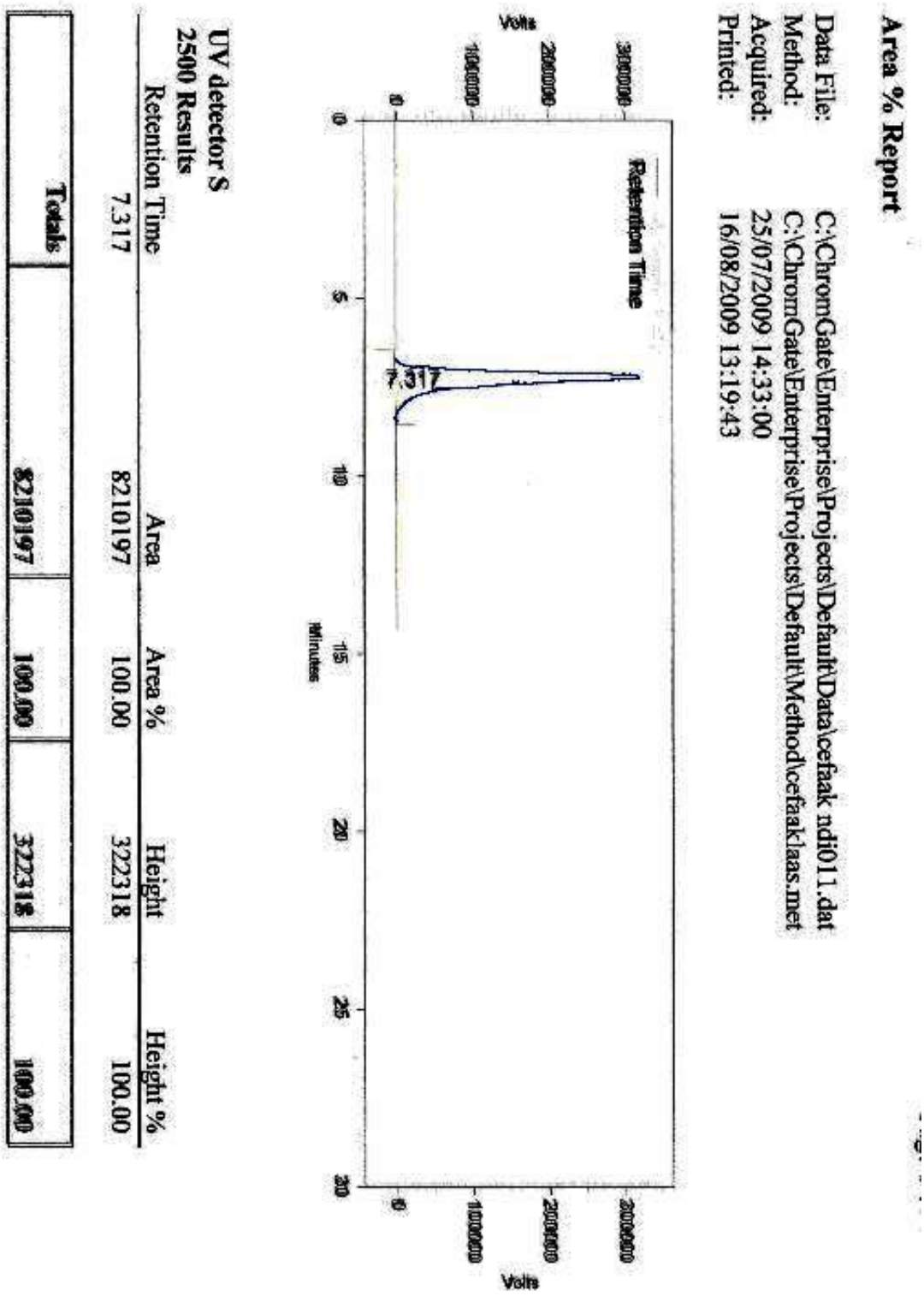

Figure 8. ***(3-2): NDI capsule area report***

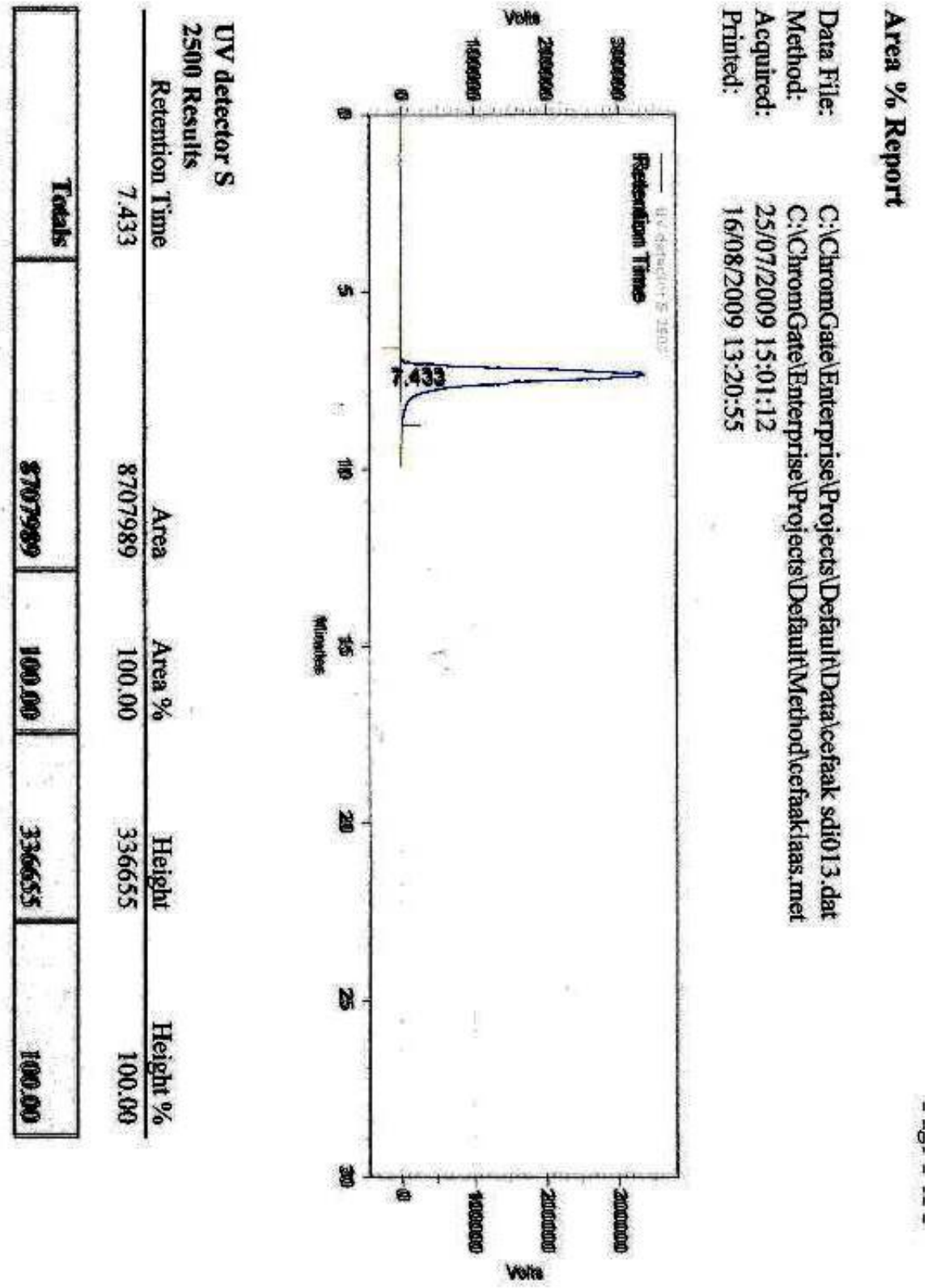

Figure 9. ***(3-3): SDI capsule area report***

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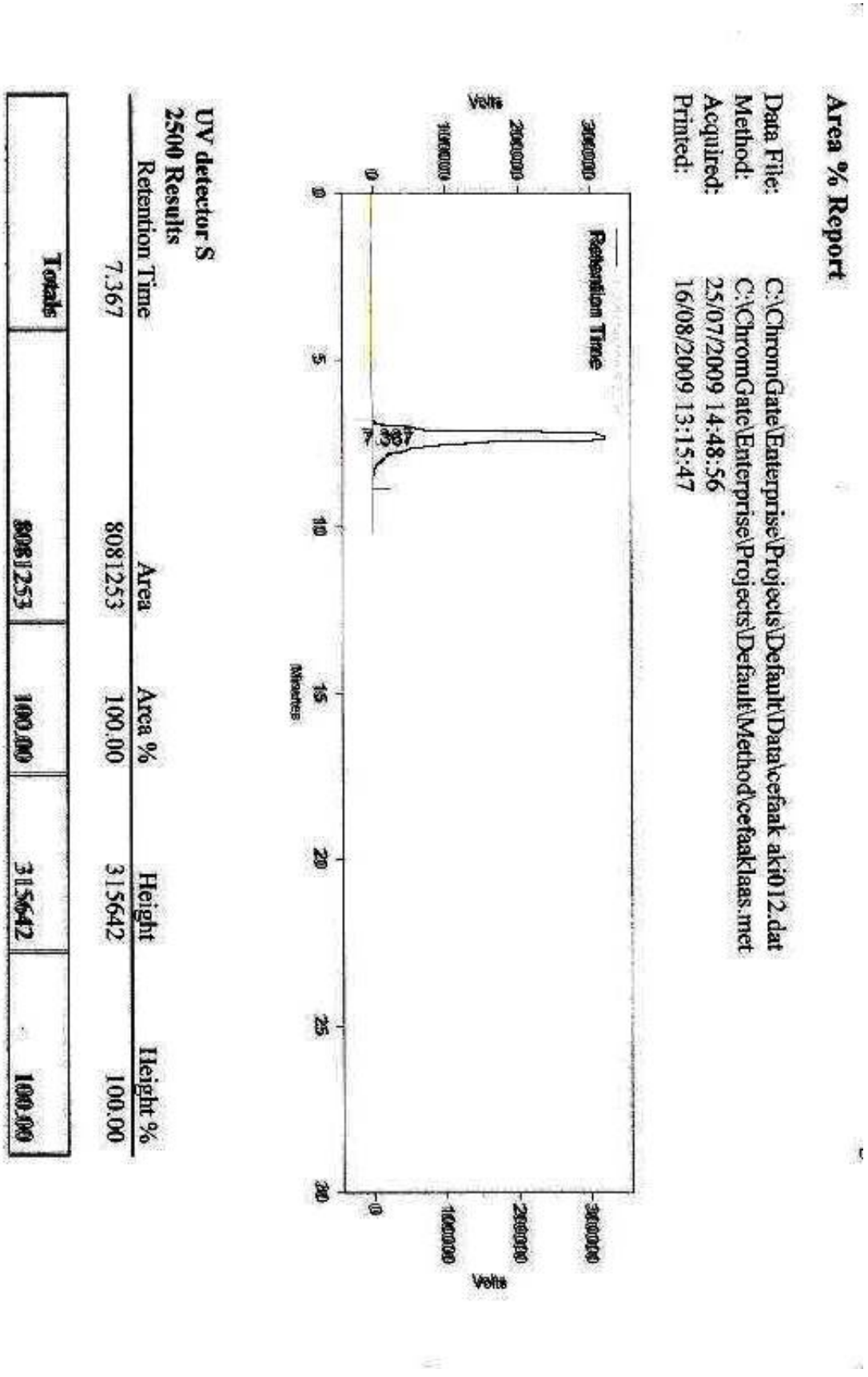

Figure 10. ***(3-4):Acia capsule area report***

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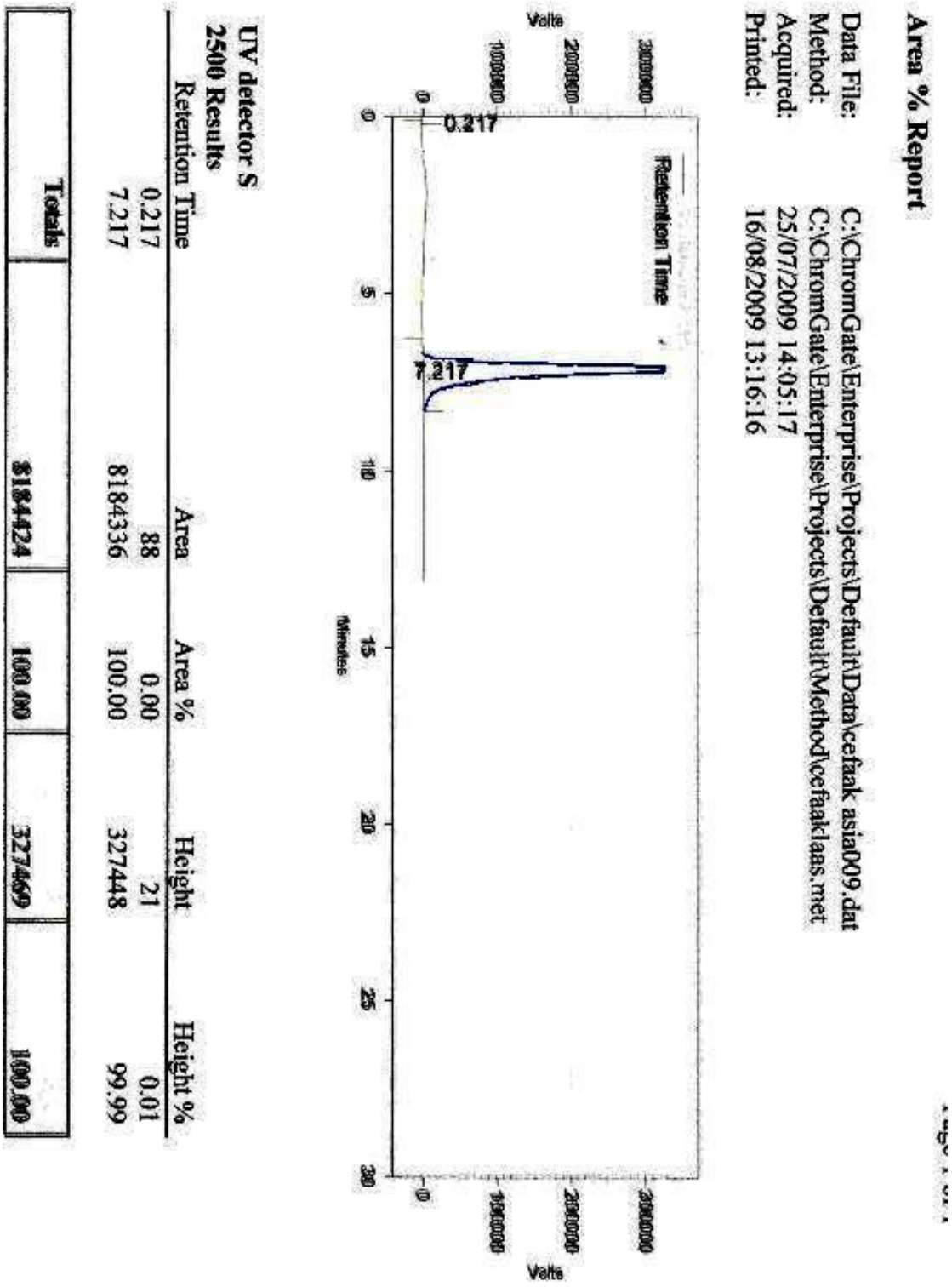

Area % Report

Data File: C:\ChromGate\Enterprise\Projects\Default\Data\cefaak asia009.dat
Method: C:\ChromGate\Enterprise\Projects\Default\Method\cefaaklaas.met
Acquired: 25/07/2009 14:05:17
Printed: 16/08/2009 13:16:16

UV detector S
2500 Results

Retention Time	Area	Area %	Height	Height %
0.217	88	0.00	21	0.01
7.217	8184336	100.00	327448	99.99
Totals	**8184424**	**100.00**	**327469**	**100.00**

Figure 11. ***(3-5): capsule area report***

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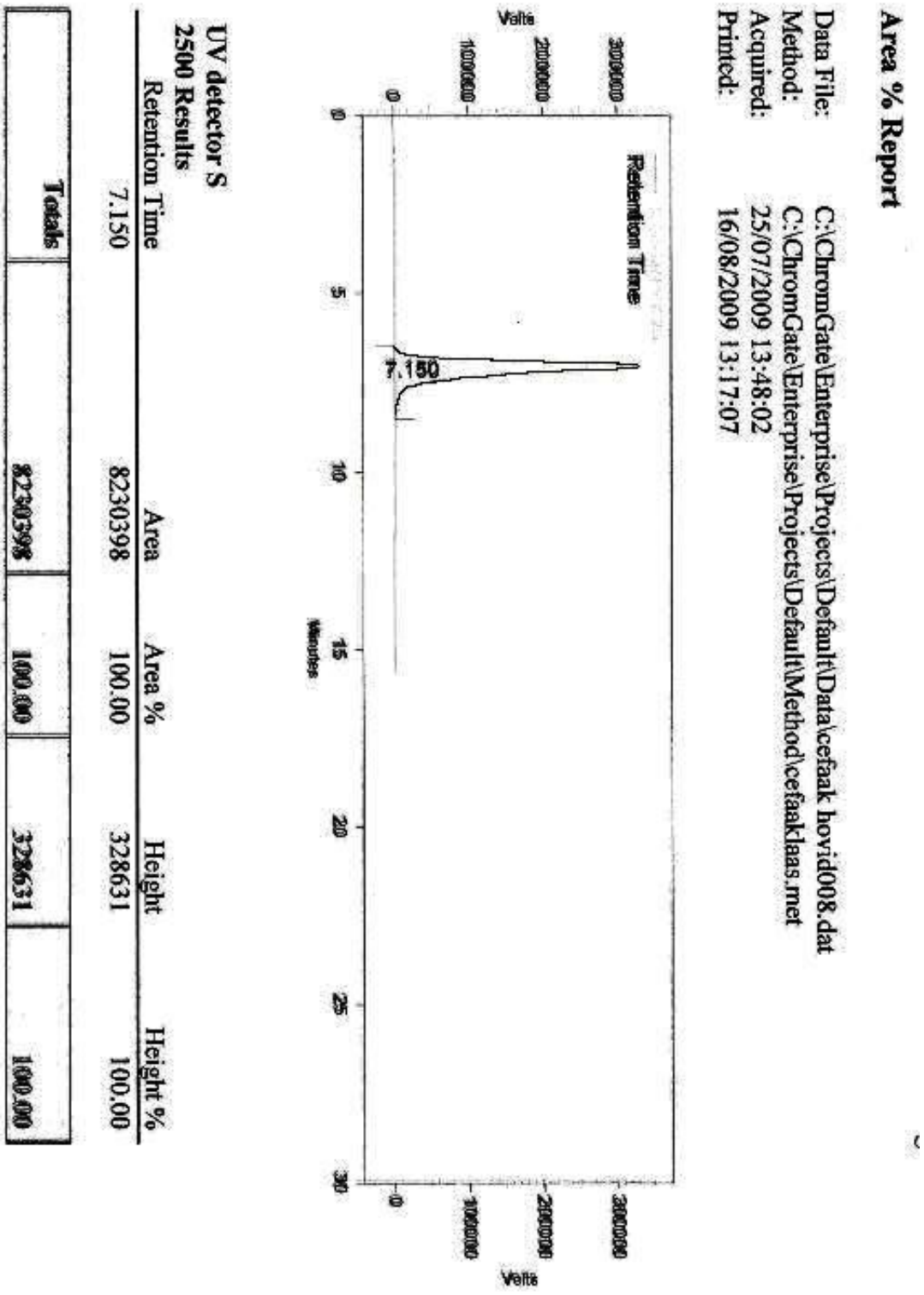

Figure 12. ***(3-6): Hovid capsule area report***

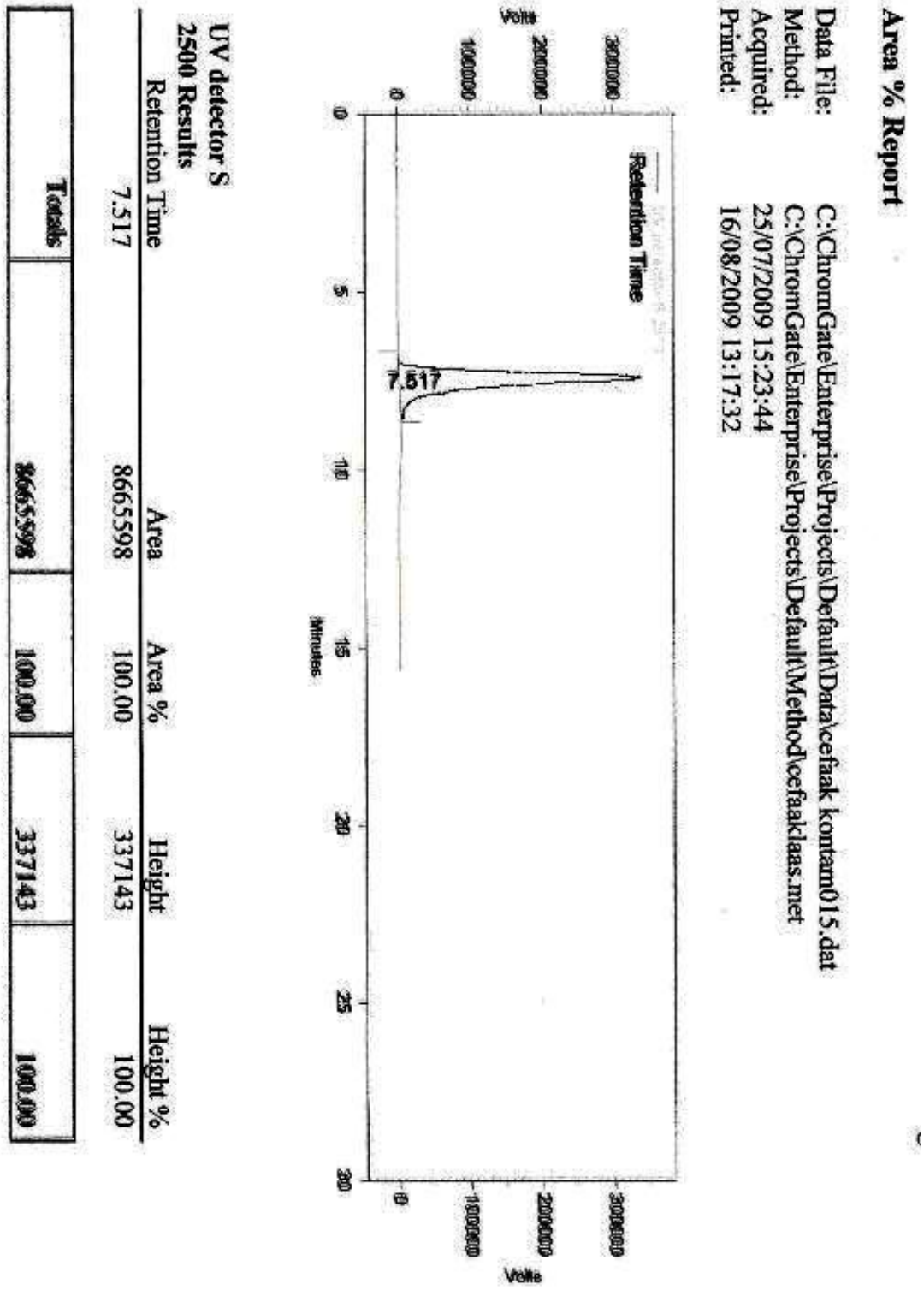

Figure 13. ***(3-7): Kontam capsule area report***

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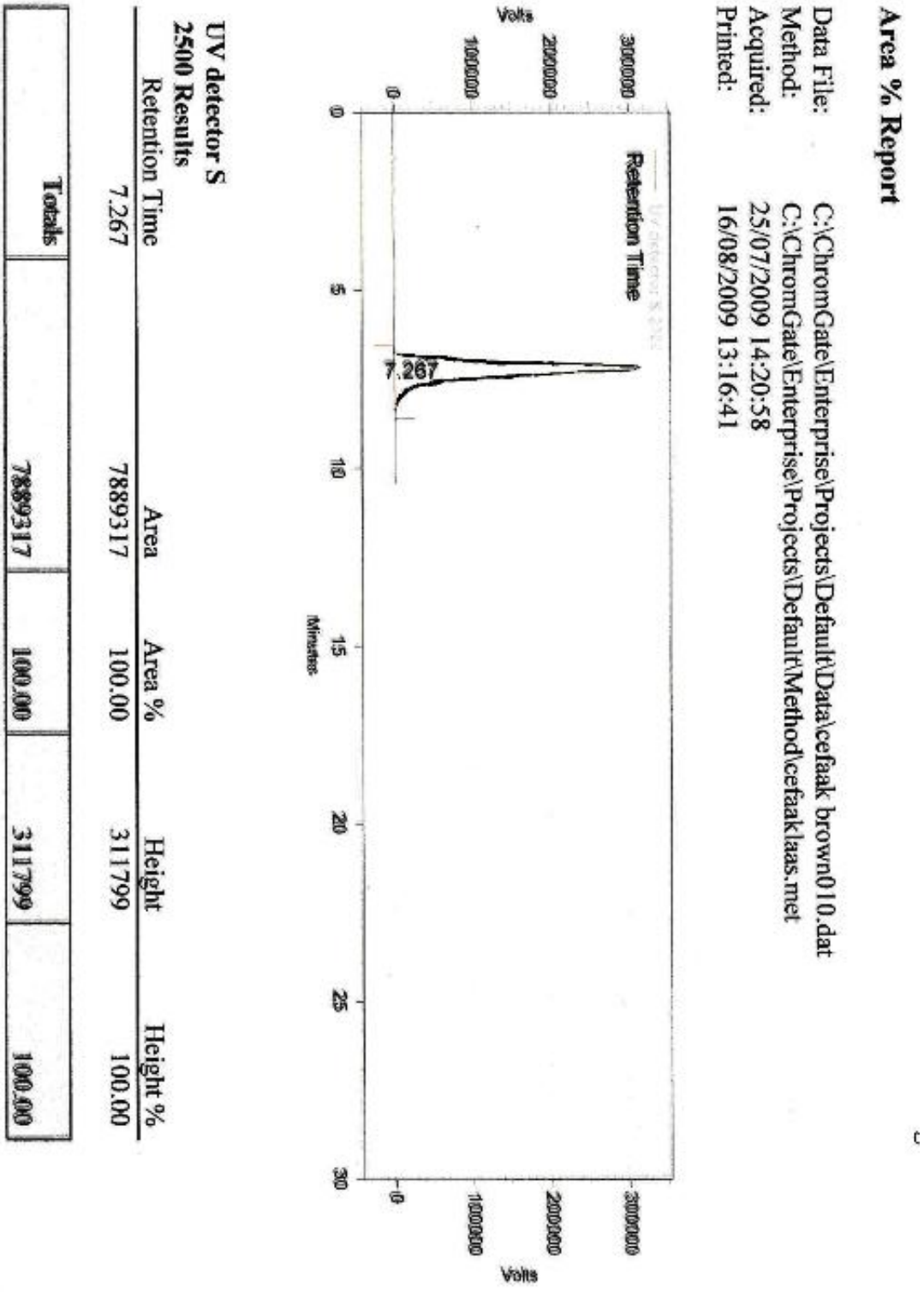

Area % Report

Data File: C:\ChromGate\Enterprise\Projects\Default\Data\cefaak brown010.dat
Method: C:\ChromGate\Enterprise\Projects\Default\Method\cefaaklaas.met
Acquired: 25/07/2009 14:20:58
Printed: 16/08/2009 13:16:41

UV detector S
2500 Results

Retention Time	Area	Area %	Height	Height %
7.267	7889317	100.00	311799	100.00
Totals	**7889317**	**100.00**	**311799**	**100.00**

Figure 14. ***(3-8): Brawn capsule*** *area report*

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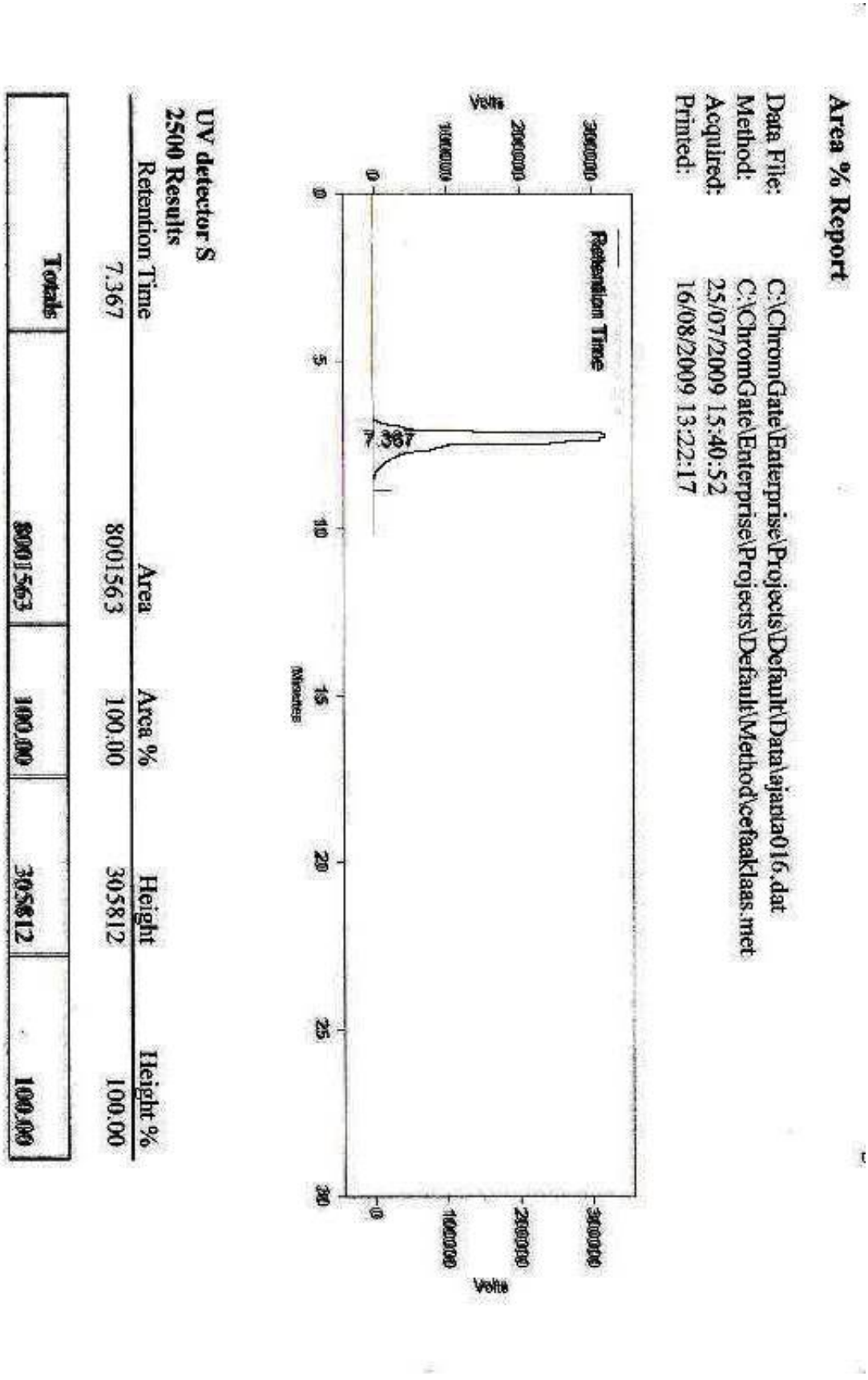

Figure 15. ***(3-9): capsule*** *area report*

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Discussion

The calibration curve was the first thing we accomplished in this investigation, and the outcome, as shown in Figure (2-4), showed a highly substantial linear correlation of the area under the peak (AUP) on the conc. The high values of r2 and r, which are near the maximum value of perfect correlation and guarantee the precision of the job and the HPLC device's qualification, show this. The study's constant factors are the strength, cost, and storage condition of each sample. The conc is the variable that was measured. cephalexin. The results, which are displayed in Table (3-2), demonstrate that all samples have recovery rates of more than 100%, and the samples with the highest recovery rates have the most recent E.D., as indicated in Table (2-3). From this table, we can see that the companies from Mission, Hovid, and Brown have lower recovery rates and an expiration date of 2011, while the companies from Iraq have higher recovery rates and an expiration date of 2012. These findings may be related to the storage conditions in our nation, as some summer days can reach up to 50˚C. The prescribed storage temperature for these drugs is typically between 8˚C and 15˚C.

Conclusion

We may describe the results of our HPLC analysis of the various cephalexin capsule kinds that were purchased from the Iraqi market as follows:

1-According to B.P., every tested capsule fell between the 7.5% and 7.5% "Maximum allowed difference" range.

2-The recoveries were about 100% with respectable accuracy and precision, according to the quantitative analysis carried out by HPLC using an external standard method.

3-Based on the USP's typical range of 90% to 120%, the results show that cephalexin capsules are acceptable.

4-The findings of the nine samples were compared, and it was discovered that, as the table illustrates, BRULEXIN is the one that is closest to 100% recovery.

Rercommendations

1. For cephalexin analysis, the HPLC quantitative analytical method is quick and accurate, and it may be applied to regular tasks.
2. Due to its great speed, simplicity, and sensitivity, the HPLC is a good methodology for pharmaceutical monitoring, making it suited for studying medications other than Cephalexin.

Future Work :

1. This approach offers the advantage of allowing for the comparison research of the various medications while also examining their bioavailability and bioequivalency.
2. Investigation of the effects of medicine storage conditions in our nation.

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