

# **Determination of Photolytic Degradation of Melixol (Flupentixol –Melitracen ) Combination Product**

A research paper is submitted to the department of pharmacy, East West University is conformity with the requirements for the degree of Bachelor of pharmacy.

## **Submitted by**

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*The research paper is dedicated to my parents, my brother*

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Above all, I express my gratitude to Almighty Allah for giving me the strength, energy and patients to carry out this research work.

## **Certificate**

This is to certify that the thesis “Determination of photolytic degradation of Melixol(Flupentixol-Melitracen) combination product” is submitted to the department of pharmacy, East West University, Aftabnagar, Dhaka-1212, In partial fulfillment of the requirements for the degree of bachelor of pharmacy (B.Pharm) was carried out by Mishkut Shukrana (ID: 2008-1-70-079) under my guidance and supervision and that no part of the thesis has been submitted for any other degree. I further certify that all the sources of information and laboratory facilities availed of this connection is duly acknowledged.

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## **Certificate**

This research paper is submitted to the department, East West University in conformity with the requirements for the degree of bachelor of pharmacy ( B.Pharm) was carried out by Mishkut Shukrana(ID: 2008-1-70-079).

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**Dr. Sufia Islam**

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## **Abstract**

The aim of this study is to identify the photolytic degradation of the Melixol, Square pharmaceutical, Bangladesh, combination product Flupentixol-Melitracin. Each tablet contains Flupentixol INN 0.5 mg (as di-hydrochloride) and Melitracen INN 10 mg (as hydrochloride). It is well known that light or other electromagnetic radiation can change the properties of some drug compounds. The most obvious way to identifying the responds is to measure the potency degradation of the drug, which I have conducted in my research project. Here the loss of potency is measured by UV-spectrometry. Beside the potency observation physical parameters were also determine to observed change of the physical characteristic like color, thickness, weight variation, hardness etc. of the tablets. At the end of the study, it was proved that Melixol drug is not photo stable and should have some protection in the final dosage form to save it from degradation.

**Key words:** Melixol, Flupentixol-Melitracen, Photolytic degradation, Potency

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When drug interact with light it leads to photosensitivity responses in susceptible patients. Adverse photosensitivity responses to drugs occur as a phototoxic reaction, and it can be reversed by withdrawal or substitution of the drug. Photosensitizing chemicals usually have low molecular weight (200 to 500 Daltons) and these are planar, tricyclic, or polycyclic configurations. A characteristic that is essential for the chemical to be regarded as a photosensitiser is, all absorb ultraviolet (UV) and/or visible radiation. The photochemical and photo biological adverse reactions caused by the more photoactive drugs are mainly free radical in nature, but reactive oxygen species are also involved.

In the past, discoloration of the material was the only evidence of light induced decomposition. At that time sensitive preparations were kept in dark bottles to preserve their 'pharmaceutical elegance. But now the modern chromatographic techniques allow the separation of decomposition products and provide clear evidence of instability. In recent years, chromatographic isolation of pure derivatives is done by spectrometric analyses has also allowed the identification of some of the photo degradation product.

(Macor, 2011).

The drug Melixol shows photolytic degradation because of the presence of thioxanthene group in flupentixol. The structure of the photo degradation product of flupentixol was determined by ultra high performance liquid-chromatography linked to mass spectrometry. The main photoproduct is generated because of the addition of a hydroxyl group on the double bond which is adjacent to the thioxanthene ring. A high-performance liquid chromatography (HPLC) method was developed for quantification of the thioxanthene which is present in neuroleptic flupentixol. In the structure of flupentixol

there also present fluoride ion. This fluoride ion enhanced the generation of free radical  $\text{OH}\cdot$ , which reduces recombination rate (Hashimoto, 2012)

Melixol tablet contains two ingredients. Flupentixol INN 0.5 mg (as di hydrochloride) and Melitracin INN 10 mg (as hydrochloride).

### 1.1 Pharmacology:

Flupentixol is a neuroleptic with anxiolytic and antidepressant properties when given in small doses, and Melitracin is a bipolar thymoleptic with activating properties in low doses. In combination the compound renders a preparation with antidepressant, anxiolytic and activating properties and mutually neutralizes side effects. Flupentixol acts by blocking the Dopamine (a neurotransmitter) receptors in the brain cells. Excess amount of dopamine receptors normally act to modify behavior and over-stimulation resulting in psychotic illness. Flupentixol blocks these receptors to control psychotic illness. Thus it is neuroleptic with anxiolytic and antidepressant properties. Melitracin acts by decreasing reuptake of norepinephrine and serotonin at the synapse resulting in high concentration of these neurotransmitters at the post-synaptic end. Thus it is antidepressant.

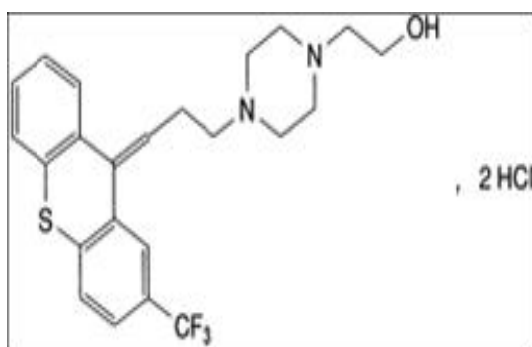


Figure 1.1: Flupentixol

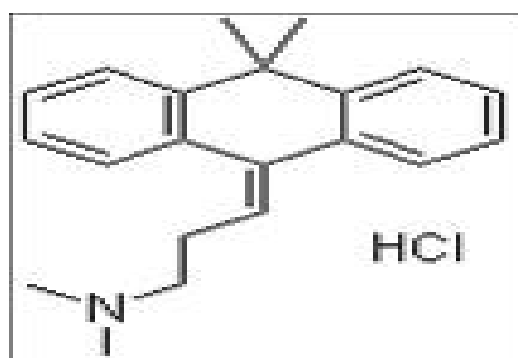


Figure 1.2: Melitracin

### 1.2 Characters of flupentixol:

Chemical name : (Z)-4-[3-[2-(Trifluoromethyl)-9Hthioxanthen-9-ylidene] propyl]-

1- piperazin ethanol dihydrochloride

Molecular formula :  $C_{23}H_{27}Cl_2F_3N_2OS$

Molecular weight : 507.44

Appearance : White Solid

Melting point : 209-216°C

Solubility : Soluble in DMSO, Methanol and Water

### 1.3 Characters of melitracen:

Chemical name : 3-(10, 10-dimethylanthracen-9-ylidene)-N, Ndimethylpropan-  
1-amine hydrochloride

Molecular formula :  $C_{21}H_{25}N$

Molecular weight : 291.43g/mol

Appearance : Crystalline Solid

Melting point : 245-248°C

Boiling point : 399.1 °C at 760

#### **1.4 Pharmacokinetics: Flupentixol**

Absorption: Flupentixol is readily absorbed from the GI tract. Peak plasma concentrations after 3-8 hr (oral); slowly absorbed from the injection site, peak plasma concentrations after 4-7 days (IM).

Distribution: It crosses the blood-brain barrier and placenta; enters breast milk. >95% bound to Plasma.

Metabolism: It is extensively hepatic via sulfoxidation, side-chain N-dealkylation and glucuronic acid conjugation.

Excretion: The elimination half-life ( $T_{1/2\beta}$ ) of flupentixol is about 35 hours and the mean systemic clearance (Cl<sub>s</sub>) is about 0.29 l/min.

Flupentixol is excreted mainly with faeces, but also to some degree with the urine. When tritium labelled flupentixol is administered to man the excretion pattern showed the excretion via faeces and it is about 4 times the urinary excretion.

In nursing mothers flupentixol is excreted in small amounts with the breast milk. The ratio milk serum concentration in women is on an average 1.3.

#### **1.5 Pharmacokinetics Melitracen:**

Absorption: It is rapidly absorbed after oral administration and bind strongly to plasma albumin, 90–95% at therapeutic plasma concentrations.

Distribution: It has a large volume of distribution, extensive protein binding.

**Metabolism:** Metabolism of melitracenis is especially their hydroxylation, results in the formation of active metabolites, which contribute to both the therapeutic and the adverse effects of these compounds.

**Excretion:** It has an elimination half-life averaging about 1 day (up to 3 days for protriptyline)

**1.6 Route of Administration:** Melixol is administered orally.

**1.7 Indications and Clinical Uses:** Melixol is indicated in anxiety along with depression and apathy. These includes:

- ✓ Psychogenic depression
- ✓ Depressive neuroses
- ✓ Masked depression
- ✓ Psychosomatic affections accompanied by anxiety and apathy
- ✓ Menopausal depression
- ✓ Dysphoria and depression in alcoholics and drug addicts

**1.8 Contra-Indications:** Melixol tablet is contra-indicated at the time of depression of the CNS, of state of coma. The administration of this is not advised in the phase of immediately consecutive recovery to a myocardial infarction, at the time of a cardiac block of any rank, disorders of cardiac condition as well as coronary insufficiency .The concomitant administration of inhibitors of the MAO is contra-indicated.

**1.9 Commercial Pack:**

Melixol® tablet: Each film coated tablet contains Flupentixol Hydrochloride BP equivalent to 0.5 mg Flupentixol & Melitracen Hydrochloride INN equivalent to 10 mg Melitracen. Each box contains 5X10 tablets in blister pack.

## Method and material

Sample collection and quantity: 500 tablets of Melixol, manufactured by Square Pharmaceuticals (contains Flupentixol INN 0.5mg and Melitracen INN 10mg) of same same batch, were collected from the local pharmacy shop in Dhaka as a sample. Among them 100 tablet was kept for the control test and remaining 400 tablet were subjected to various photo exposure or sample test.

### 2.1 Raw Materials:

**Table 1.1: Raw Materials used in the experiment including source**

Materials Name	Source (Supplier Name)
Melixol tablets	Square pharmaceutical ltd.

### 2.2 Reagents:

**Table 1. 2: Reagents used in the experiment including source**

Reagents Name	Source (Supplier Name)
Concentrated Sulfuric acid	MERK, Germany
Distilled Water	Laboratory (East West University)

### 2.3 Equipments & Instruments:

**Table 1.3: Equipments & Instruments used in the experiment including source**

Serial No	Equipments Name
1	Tablet Hardness tester
2	Friabilator
3	Electronic balance
4	Vernier caliper
5	UV- Vis spectrometer

**Table1. 4: List of Apparatus/ Glasswares used throughout this project**

Serial No.	Name	Serial No.	Name
1.	Several Plastic Containers	9.	Forceps
2.	Mortar & Pastels	10.	Fanel
3.	Test tubes	11.	Beakers
4.	Volumetric Flasks (50 ml & 100 ml)	12.	Saptula
5.	Pipette pumper	13.	Glass Rod



6.	Pipette	14.	Filter Papers
7.	Volumetric Pipette	15.	Alluminium foil paper
8.	Thermometer		

## 2.4 Methods:

**2.4.1 Preparation of the solvent:** The solvent was prepared by diluting 5ml of concentrated H<sub>2</sub>SO<sub>4</sub> in a 1000ml volumetric flask with distilled water.

**2.4.2 Scanning and determination of the maximum wavelength ( $\lambda_{max}$ ):** In order to measure the maximum wavelength of the drug, a qualitative solution of the drug was made in 0.1N H<sub>2</sub>SO<sub>4</sub> and was scanned by using a UV- spectrophotometer within the region of 200-400 nm, where 0.1 N H<sub>2</sub>SO<sub>4</sub> was used as blank.

An absorption curve was obtained showing the characteristic maximum absorption. It was found that the  $\lambda_{max}$  flupentixol was 229 nm and  $\lambda_{max}$  for melitracen was 258 nm

### 2.4.3 Preparation of calibration standard curve and equation derivation:

The standard curve was prepared to compare the test result with it to determine the degradation of the drug. For standard curve preparation the average weight of 10 tablets were taken and all the 10 tablets were crushed by using mortar and pestle.

The average weight of the 10 tablets which was previously measured was weight from the crashed powder tablets. After measuring the powder drugs by the help of a balance, it was left to dissolve in 100ml of 0.1N H<sub>2</sub>SO<sub>4</sub> solvent.

Series of dilution was carried out with the standard stock solution by pipetting 2 ml of the stock solution in test tube (1) and adding 8 ml of solvent to it. Then again pipetting 2 ml solution from test tube (1) to test tube (2) and adding 8 ml solvent to it. This was continued for more 3 times. Thus producing a known concentration ranging from 0.2, 0.04, 0.008, 0.0016, 0.00032 for melitracen and 0.01, 0.002, 0.0004, 0.00008, 0.000016 for flupentixol . Then the solutions where scanned ranging from 400-200 nm wavelength against the blank, and we got 229nm wavelength for flupentixol and 258nm wavelength for melitracen.

After identifying the wavelength of flupentixol and melitracen, absorbance of the above solutions was taken for both 229nm for flupentixol and 258nm for melitracen. The observed value was plotted against concentration and a linear regression equation was obtained.

### **2.5 Sample collection:**

The UV and partially the visible range of solar radiation have some major influence on the photolytic degradation of flupentixol and melitracen. To determine the photostability of the drug the tablets were subjected to various types of photo exposure, which are:

- Sunlight exposure(winter and summer)
- Exposure to normal room temperature (2 weeks, 1 month,2 month)
- Bulp light exposure (25 watt, 40 watt)

**2.5.1 Sunlight exposure:** The sunlight exposed sample was collected by dividing the collection process in two segments, one in winter season and another in summer. In winter season, 30 tablets were kept on a solid surface and was place to the roof for the sun exposure. A thermometer was also kept aside the solid surface containing the tablets which submerge in glass of water. After 3 hour 10 tablets was collected exposed in a temperature of 99°F. Then, again 3 hour later 10 tablets was collected and the exposed temperature was 108°F. Finally, the remaining 10 tablets were collected exposed for total 9 hour falling the temperature from 108-100°F.

In the summer the sample was collected in similar strategy as the winter sample. But the temperature of the sunlight was much higher than the winter sunlight, which was 100°F, 108°F, and 108-106°F accordingly for 3 hour, 6 hour, and 9 hour exposed samples.

**2.5.2 Exposure to normal room temperature:**

The exposure of the tablets was done in normal room temperature. The tablets were kept in the normal room temperature in 3 plastic transparent box 20 tablets in each of the box. The box was labeled as 2 week, 1 month, and 2 month.

**2.5.6 Bulb light exposure (25 watt, 40 watt):** The photostability of the drug can be altered by the effect of some artificial light.

Two power ranges of bulb, 25 watt and 40 watt were used as the artificial light source. Thirty tablets were kept on a solid surface and were placed under 25 watt containing lamp. A thermometer was kept behind the tablets submerge in a glass of water to measure the temperature. After three hour 10 tablet were collected

**2.6 Sample analysis:** After the collection of the sample it was time to proceed to the analysis step. At first the average weight of the three sample tablets were taken by the electronic balance. Then the tablets were crashed to fine powder by the help of mortar and pestle. The average weight that was previously accounted was then weighted from the crashed powdered sample and was allowed to dissolve into 100ml of 0.1N H<sub>2</sub>SO<sub>4</sub> in a 100 ml volumetric flask. The solution of the volumetric flask was then filtered thought a filter paper.10 ml of the filtrate was pipetted to a 100ml volumetric flask and 0.1 N H<sub>2</sub>SO<sub>4</sub> was then added to the filtrate.

After all that, the sample solution was prepared for the potency test using UV-vis spectroscopy. For that, each of the tests was run against a blank, and for the test the test solution was poured into the quartz cell. The quartz cell was then placed into the holder situated inside the machine. Using a specified software technology the absorbance of the sample solution was established in the computer.

Physical parameters determination:For determination of the physical parameters of the tablets, some set of test was carried out. The parameters are:

- Color
- Weight variation test
- Thickness
- Friability test

- Hardness test

**2.6.1 Color:** Color of the tablet was observed to determine the bleaching of the color compound of the tablet, which shows the change of the properties of the tablets. To run this experiment a digital camera was used with having a fixed resolution and without flash. The pictures of the sample tablets were always taken in fixed placed having constant lighting condition.

### **2.6.2 Weight Variation Test of Tablets:**

Weight variation test is most significant because it has a relationship with content uniformity of a solid dosage forms. A small weight variation does not ensure good content uniformity between dosage units; a large weight variation precludes good content uniformity. Any of the following factors, can produce excessive tablet variations:

1. Poor granulation flow properties, resulting in uneven die fill.
2. A wide variation in granulation particle size, which result in a variation in die fill density as a function of particle size and particle size distribution at different points in the production run, differences in lower punch length, which result in different size die cavities

Procedure:

1. 10 tablets were taken and weighed all the tablets
2. The average was taken and it was considered as the standard weight of an individual tablet
3. All the tablets were weighed individually and observed whether the individual tablets are within the range or not.

The variation from the average weight in the weights not more than two tablets must not differ more than the percentage listed below:

Average weight	Percentage difference
130 mg or less	± 10
More than 130 to 324 mg	±7.5
More than 324 mg	±5

**Calculation:**

$$\text{Weight variation} = \frac{\text{Tablet weight} - \text{Average Weight}}{\text{Average Weight}} \times 100$$

**2.6.3 Thickness test:**

The thickness test was carried out to measure the thickness of the sample tablet. To determine if there is any deviation of the tablet due to the exposure of the light. It was done by using a Vernier caliper.

**Procedure:**

1. First placing the tablet between the two jaws of the vernier caliper.
2. Then, the main scale reading was taken.
3. The vernier scale was taken also.

The two reading was added together by multiplying with the vernier constant



Figure 1.3 : Vernier caliper

**Calculation:**

Main scale reading + (vernier scale reading \*vernier constant)

**2.6.4 Hardness Test of Tablets:**

Tablet hardness is usually expressed as the load required crushing a tablet placed on its edge. Hardness is thus sometimes termed the tablet crushing strength. The suitability of a tablet in regard to mechanical stability during packaging and shipment can usually be predicted on the basis of hardness. Tablet hardness, in turn, influences tablet density and porosity. It may affect tablet friability and disintegration time. It usually affects drug dissolution and release and it may affect bioavailability.

**Procedure:**

1. The slide scale of the hardness tester was made zero
2. One tablet was placed vertically between two jaws.
3. Force was applied with a screw thread and spring until the tablet fractured.
4. Reading in Kg was taken from the sliding scale.

**2.6.5 Friability Test of Tablets:**

Friction and shock are the forces that most often cause tablets to chip, cap or break. The friability test is closely related to tablet hardness and is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping. The value is expressed as a percentage. A maximum weight loss of not more than 1% of the weight of the tablets being tested during the friability test is considered generally acceptable and any broken or smashed tablets are not picked up. Normally, when capping occurs, friability values are not calculated. A thick tablet may have less tendency to cap whereas thin tablets of large diameter often show extensive capping, thus indicating that tablets with greater thickness have reduced internal stress.

**Procedure:**

1. 10 tablets were weighted. It was considered as an initial reading
2. The tablet were placed in the section 1 of the drum of the friability tester and rotated 100 times.
3. The tablets were re-weighted. It was considered as a final reading.
4. The percent loss was calculated.
5. According to the U.S.P the tablets should not lose more than 1% of their total weight

**Calculation%:**

$$\text{Percent of friability} = (M1 - M2) / M1 \times 100\%$$

Where, M1 = weight of the tablets before the rotation

M2 = weight of the tablets after the rotation

$$\% \text{ Loss} = \left( \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \right) \times 100$$



**3.1 Weight variation:** The percentage weight variation of all the sample tablets are within the range, which is  $\pm 10$  for 130 mg or less dosage form according to the United States Pharmacopeia. There was no major deviation of the content uniformity by the exposure of the light or radiation.

### 3.1.1 Sunlight Exposure Winter:

Table 1.1, table 1.2 and table 1.33 showing the percentage weight variation of the 3 hour, 6 hour and 9 hour exposed tablet sample in winter season. Figure 1.1, 1.2 and 1.3 is just representing the graph of the statistical data of the weight variation of each sample.

**Table 2.1: The percentage weight variation 3 hour exposed tablet sample in winter season**

No	Initial wt	Avg. wt	wt. variation	% Weight Variation; $(A-I/I) \times 100$
1	0.1454		0.00426	0.4264
2	0.149		-0.02	2
3	0.1475		-0.01	1.003
4	0.1486		-0.0174	1.7362
5	0.1409	$1.4602/10=0.1460$	0.0363	3.63
6	0.1409		0.0363	3.03
7	0.1492		-0.0213	2.131
8	0.141		0.0356	3.56
9	0.1461		-0.0054	0.0547
10	0.1445		0.0105	1.051

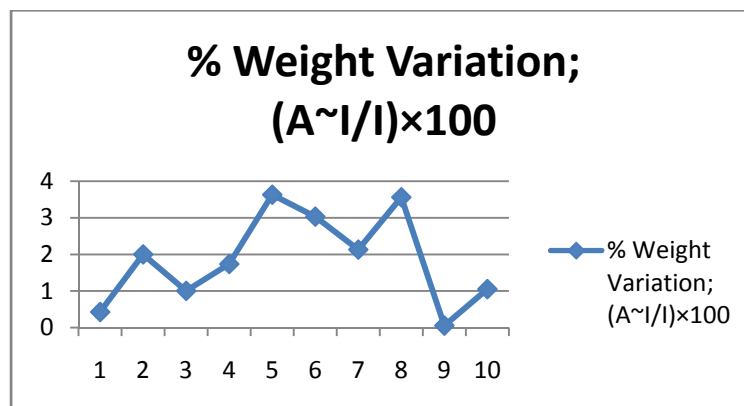


Figure 2.1: Graph of the percentage weight variation of 3 hour exposed tablet

**Table 2.2: The percentage weight variation of 6 hour exposed tablet sample in winter season**

No	Initial wt	Avg. wt	Wt. Variation	% Weight Variation; $(A \sim I/I) \times 100$
1	0.1464		-0.015	1.502
2	0.1423		0.01335	1.3352
3	0.1426		0.01122	1.122
4	0.1476		-0.023	2.303
5	0.1452	$1.4420/10=0.144$	-0.0069	0.6887
6	0.1403		0.0277	2.7797
7	0.1388		0.0389	3.89
8	0.1523		-0.0532	5.318
9	0.1472		-0.0203	2.038
10	0.148		-0.0256	2.567

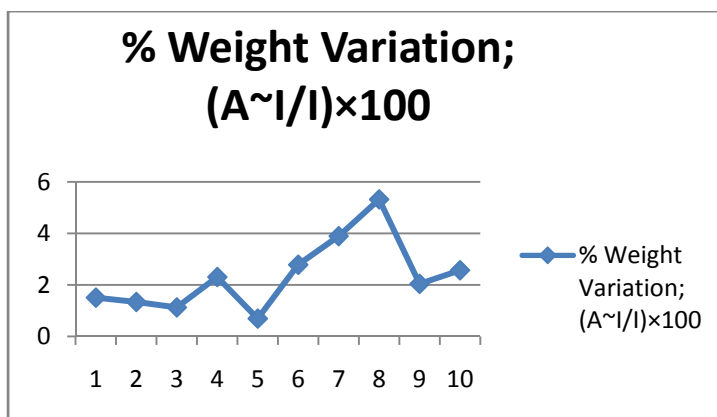


Figure 2.2 : Graph of the percentage weight variation of 6 hour exposed tablet

**Table 2.3: The percentage weight variation of 9 hour exposed tablet sample in winter season**

No	initial wt.	Avg. wt	Wt. variation	% Weight Variation; (A~I/I)×100
1	0.1444		-0.0053	0.5263
2	0.1434		0.00167	0.1673
3	0.144		-0.0025	0.25
4	0.1432		0.00307	0.30726
5	0.1436	1.4364/10=0.1436	0.0027	0.0278
6	0.1438		-0.0011	0.11126
7	0.1435		0.00098	0.09756
8	0.143		0.00447	0.4475
9	0.1433		0.00237	0.2372
10	0.1434		0.00167	0.1673

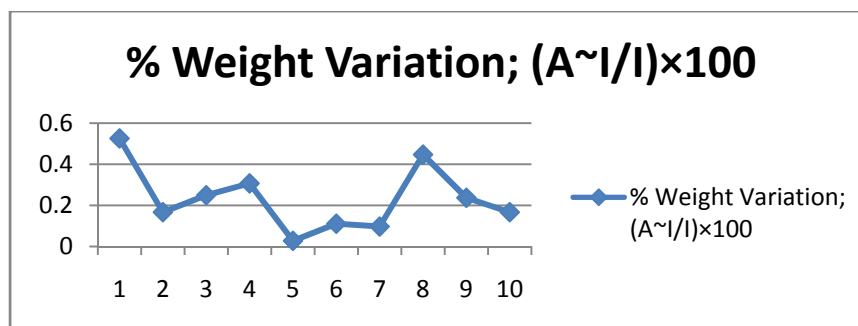


Figure 2.3 : Graph season of the percentage weight variation of 9 hour exposed tablet samples in winter

**3.1.2Sunlight Exposure Summer:**

**Table 3.1: The percentage weight variation of 3hour exposed tablet sample in summer**

No	Individual Wt.	Avg. wt	Wt. Variation	% Weight Variation; (A~I/I)×100
1	0.1464		-0.015	1.502
2	0.1423		0.01335	1.335
3	0.1426		0.01122	1.122
4	0.1476		-0.023	2.303
5	0.1452	1.4420/10=0.14	-0.0069	0.688
6	0.1403		0.0277	2.779
7	0.1388		0.0389	3.89
8	0.1523		-0.0531	5.318
9	0.1472		-0.0203	2.038
10	0.148		-0.0256	2.567

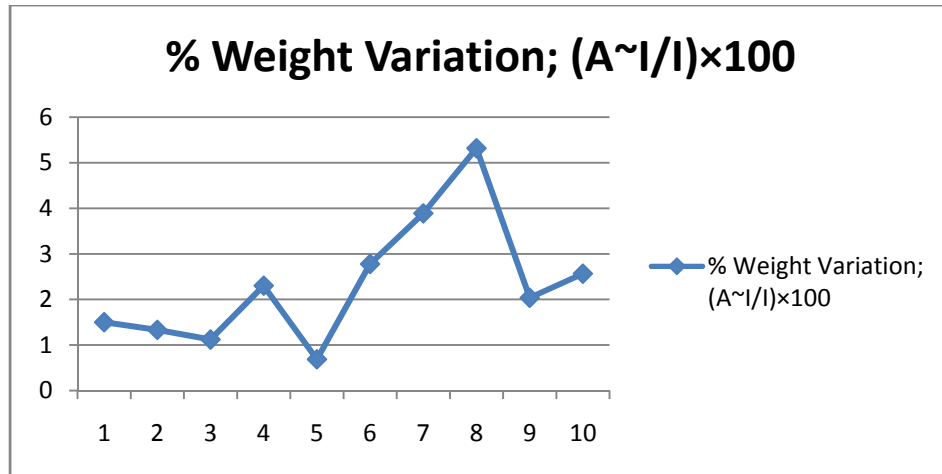


Figure3.1: Graph of the percentage weight variation of 3 hour exposed in the summer

**Table3.2: The percentage weight variation of 6 hour exposed tablet sample in season**

No	Individual Wt.	Avg. wt	Wt. Variation	% Weight Variation; (A~I/I)×100
1	0.1423		0.0021	0.2108
2	0.1435		-0.0063	0.6271
3	0.1442		-0.0111	1.1095
4	0.1348		0.0578	5.786
5	0.1427	1.4260/10=0.14	0.0007	0.07007
6	0.1428		-0.0014	0.14
7	0.1452		-0.0179	1.7906
8	0.1468		-0.0286	2.861
9	0.1438		-0.0083	0.834
10	0.1398		0.02002	2.00286

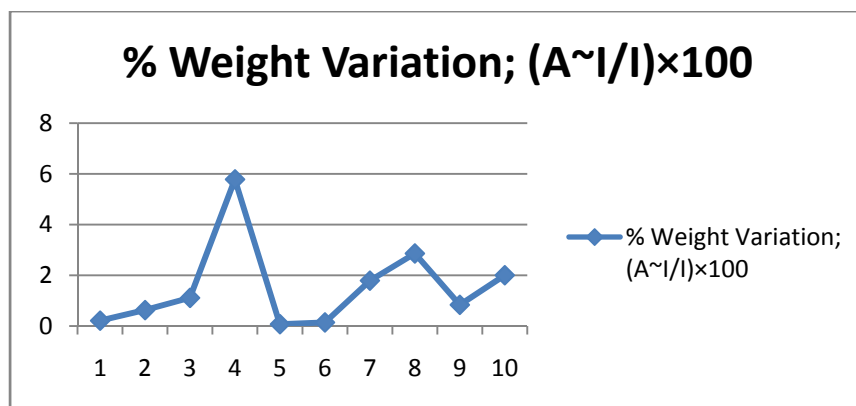


Figure 3.2 : Graph of the percentage weight variation of 6 hour exposed tablet samples in summer season

**Table 3.3: The percentage weight variation of 9 hour exposed tablet sample in summer season**

No	Initial wt.	Average wt.	Wt. Variation	% Weight Variation; (A~I/I)×100
1	0.1423		-0.0075	0.75193
2	0.1435		-0.0158	1.5818
3	0.1442		-0.0206	2.0596
4	0.1398		0.01022	1.0228
5	0.1427	1.4123/10=0.14123	-0.0103	1.0301
6	0.1428		-0.011	1.0994
7	0.1452		-0.0273	2.7341
8	0.1484		-0.0483	4.8315
9	0.1438		-0.0179	1.7872

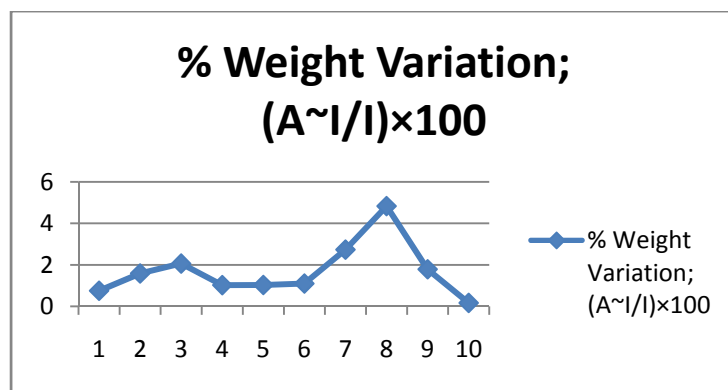


Figure 3.3: Graph of the percentage weight variation of 9 hour exposed tablet samples in summer season

**3.1.3 Bulb exposure (40 watt exposed samples):**

**Table 4.1: The percentage weight variation of 3 hour exposed tablet sample**

No	Individual wt.	Avg. wt.	Wt. variation	% Weight Variation; $(A-I/I) \times 100$
1	0.1399		0.0385	3.859
2	0.14		0.03785	3.7857
3	0.144		0.03785	3.7857
4	0.1421		0.02251	2.2519
5	0.1401	1.4530/10=0.14	-0.0055	0.5475
6	0.14		0.03785	3.7857
7	0.1448		0.00345	0.3453
8	0.1461		-0.0055	0.5475
9	0.145		0.00206	0.2068
10	0.1442		0.00762	0.7628

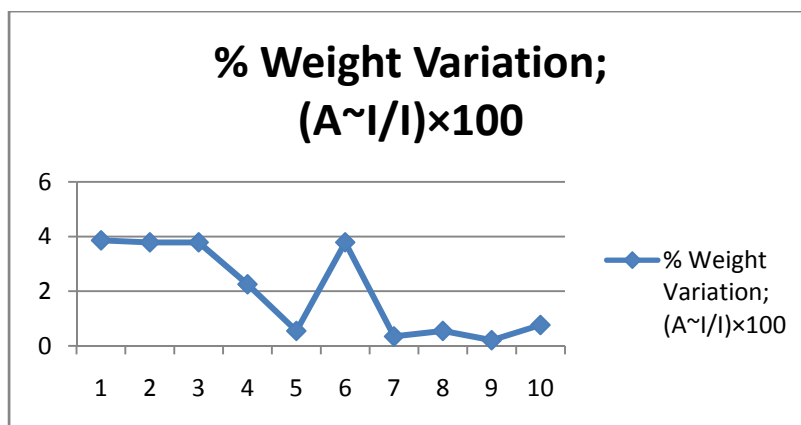


Figure 4.1: Graph of the percentage weight variation of 3 hour exposed samples.

**Table 4.2: The percentage weight variation of 6 hour exposed tablet sample**

No	Individual wt.	Avg. wt.	wt. variation	% Weight Variation; ( $A \sim I / I$ ) $\times 100$
1	0.1406		0.0278	2.788
2	0.1431		0.0093	0.9923
3	0.1451		0.0242	2.4259
4	0.145		-0.0033	0.331
5	0.1405	1.14452/10=0.14	0.0286	2.8612
6	0.1452		-0.0047	0.4683
7	0.1451		-0.004	0.39972
8	0.1442		0.0022	0.2219
9	0.1448		-0.0019	0.1933
10	0.1432		0.00921	0.92178



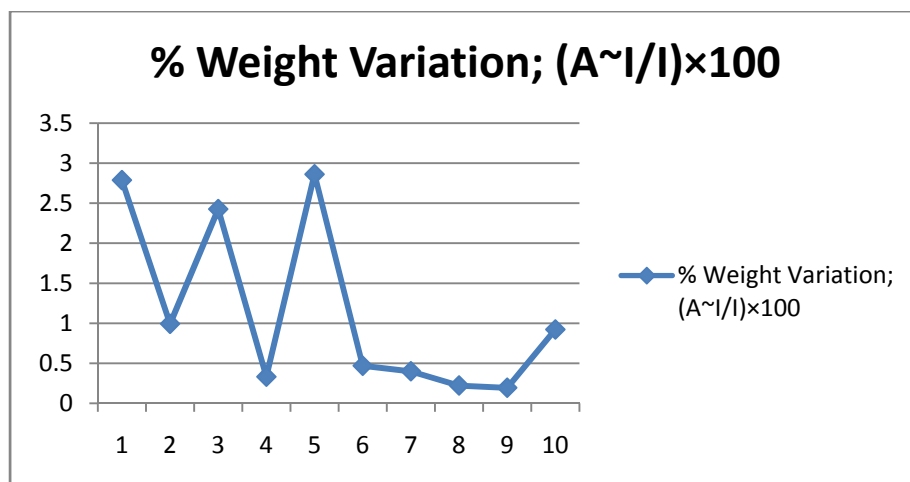


Figure 4.2 : Graph of the percentage weight variation of 6 hour exposed samples.

**Table 4.3: The percentage weight variation of 9 hour exposed tablet sample**

No	Individual wt.	Avg. wt.	Wt. variation	% Weight Variation; (A~I/I)×100
1	0.1406		0.02012	2.0128
2	0.1458		-0.0163	1.6255
3	0.1455		-0.0142	1.1226
4	0.145		-0.0108	1.6827
5	0.1452	1.4343/10=0.143	-0.0122	1.219
6	0.1444		-0.0067	0.6717
7	0.1454		-0.0135	1.3548
8	0.1408		0.01867	1.8678
9	0.141		0.01723	1.7234
10	0.1456		-0.0149	1.4903

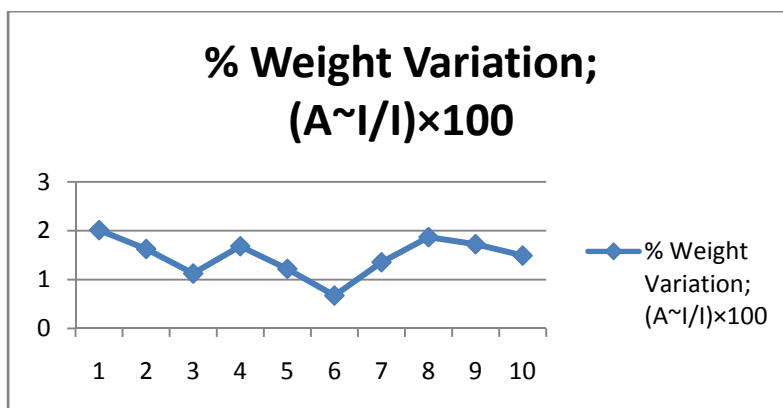


Figure 4.3 : Graph of the percentage weight variation of 9 hour exposed sample

**3.1.4Bulb exposure (25 watt bulb exposure):**

**Table 5.1: The percentage weight variation of 3 hour exposed tablet sample**

No	Initial Wt.	Avg. wt.	Wt. Variation	% Weight Variation; $(A \sim I/I) \times 100$
1	0.1434		0.01882	1.8828
2	0.1436		0.0174	1.7409
3	0.1447		0.00967	0.9675
4	0.1435		0.01811	1.8118
5	0.1437	1.4610/10=0.1461	0.0167	1.6701
6	0.1448		0.00897	0.8977
7	0.1444		0.01177	1.1772
8	0.1447		0.00967	0.9675
9	0.145		0.00758	0.7586
10	0.1449		0.00828	0.82815

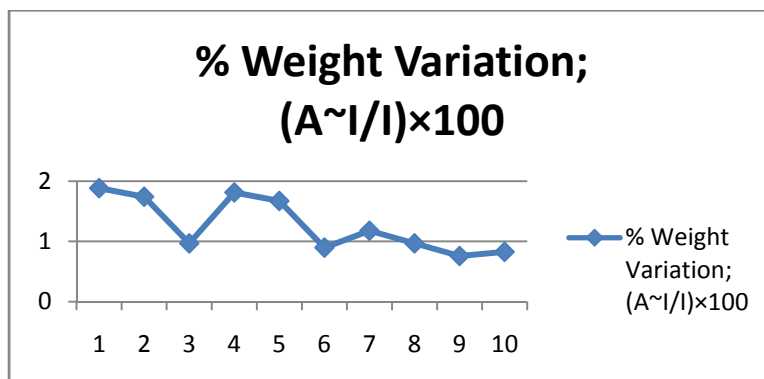


Figure 5.1 : Graph of the percentage weight variation of 3 hour exposed sample

**Table 5.2: The percentage weight variation of 6 hour exposed tablet sample**

No	initial wt.	Avg. wt	Wt. variation	% Weight Variation; ( $A \sim I/I$ ) $\times 100$
1	0.144		0.01007	1.0069
2	0.1429		0.01784	1.7844
3	0.1425		0.02071	2.0701
4	0.1425		0.0207	2.0701
5	0.143	$1.4545/10=0.1454$	0.01713	1.732
6	0.1442		0.00866	0.8668
7	0.1441		0.00936	0.9368
8	0.1435		0.0135	1.3588
9	0.143		0.0171	1.713
10	0.1437		0.0121	1.2178

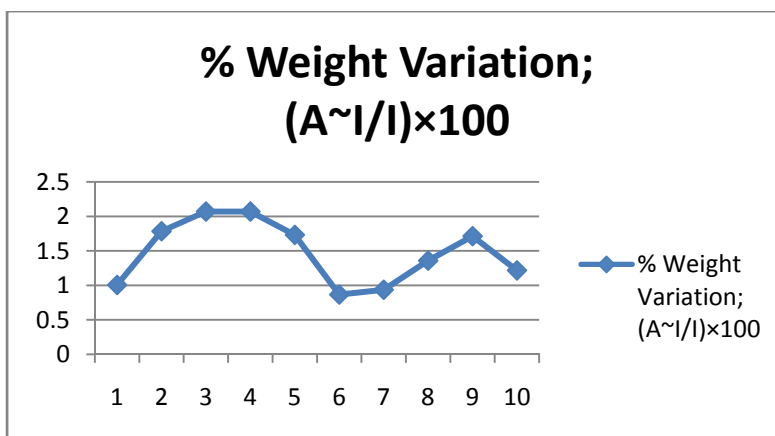


Figure 5.2 : Graph of the percentage weight variation of 6 hour exposed samples

Table 5.3: The percentage weight variation of 9 hour exposed tablet sample

No	initial wt.	Avg. wt	Wt. variation	% Weight Variation; (A~I/I)×100
1	0.1444		-0.0053	0.5263
2	0.1434		0.00167	0.1673
3	0.144		-0.0025	0.25
4	0.1432		0.00307	0.30726
5	0.1436	1.4364/10=0.14364	0.0027	0.0278
6	0.1438		-0.0011	0.11126
7	0.1435		0.00098	0.09756
8	0.143		0.00447	0.4475
9	0.1433		0.00237	0.2372
10	0.1434		0.00167	0.1673

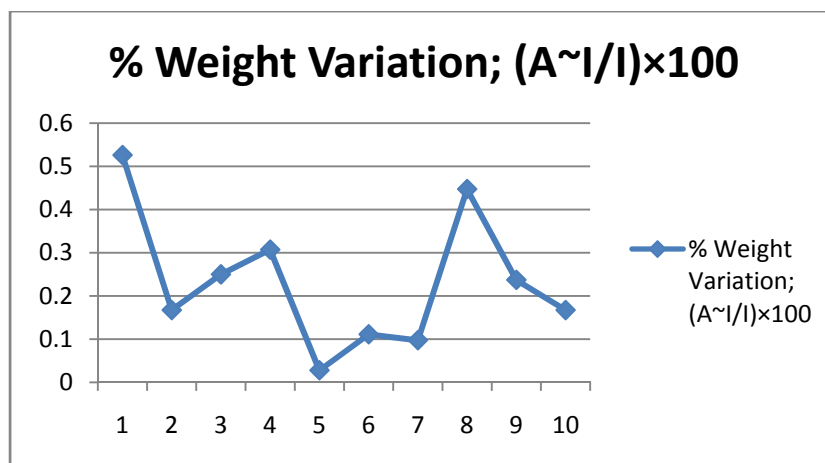


Figure 5.3 : Graph of the percentage weight variation of 9 hour exposed

samples **3.1.5 The normal room condition:**

**Table 6.1: The percentage weight variation of 2 week sample**

No	Initial Wt.	Avg. wt.	Wt. Variation	% Weight Variation; (A~I/I)×100
1	0.145		0.2064	20.641
2	0.1409		0.2415	24.151
3	0.1472			1.426
4	0.1437		0.0097	0.9742
5	0.1455	0.1451	0.00274	0.274
6	0.1432		0.01326	1.326
7	0.1456		-0.0034	0.3434
8	0.1417		0.02399	2.399
9	0.1415		0.02544	2.544
10	0.1416		0.02471	2.4717

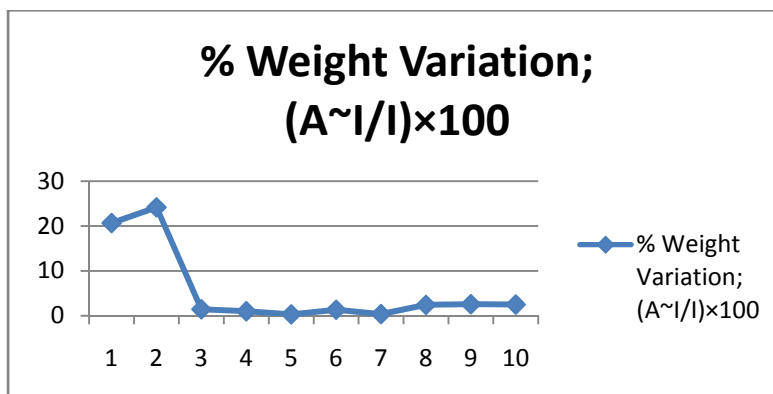


Figure 6.1: graph of % weight variation of 2 week sample

**Table 6.2: Percentage weight variation data of 1 month samples**

No	Initial Wt.	Avg. wt.	Wt. Variation	% Weight Variation; ( $A \sim I / I$ ) $\times 100$
1	0.1402		0.00114	0.1141
2	0.137		0.02452	2.4525
3	0.1394		0.00688	0.6886
4	0.1409		-0.0038	0.3832
5	0.1371	1.4036/10=0.14036	0.02377	2.3778
6	0.1417		-0.0095	0.9456
7	0.1428		-0.0171	1.7086
8	0.1413		-0.0067	0.6052
9	0.1415		-0.0081	0.8056
10	0.1417		-0.0095	0.9456

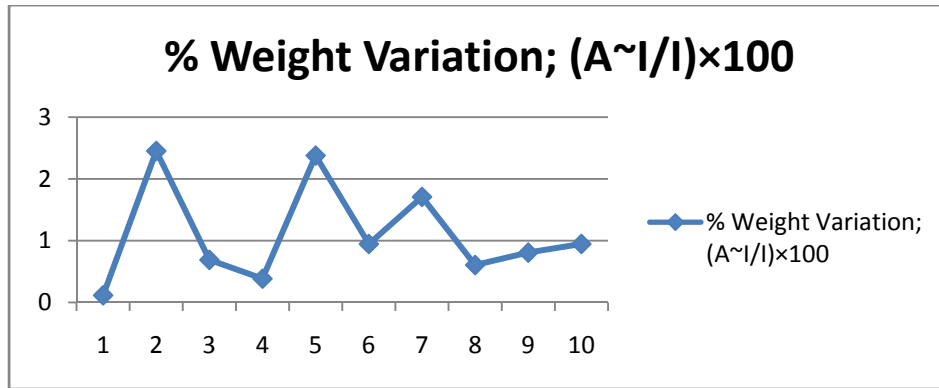


Figure:6.2: Graph of percentage weight variation of 1 month samples

**Table 6.3: percentage weight variation of 2 month samples**

No	Initial Wt.	Avg. wt.	Wt. Variation	% Weight Variation; (A~I/I)×100
1	0.1402		0.00114	0.1141
2	0.137		0.02452	2.4525
3	0.1394		0.00688	0.6886
4	0.1409		-0.0038	0.3832
5	0.1371	1.4036/10=0.1403	0.02377	2.3778
6	0.1417		-0.0095	0.9456
7	0.1428		-0.0171	1.7086
8	0.1413		-0.0067	0.6052
9	0.1415		-0.0081	0.8056
10	0.1417		-0.0095	0.9456

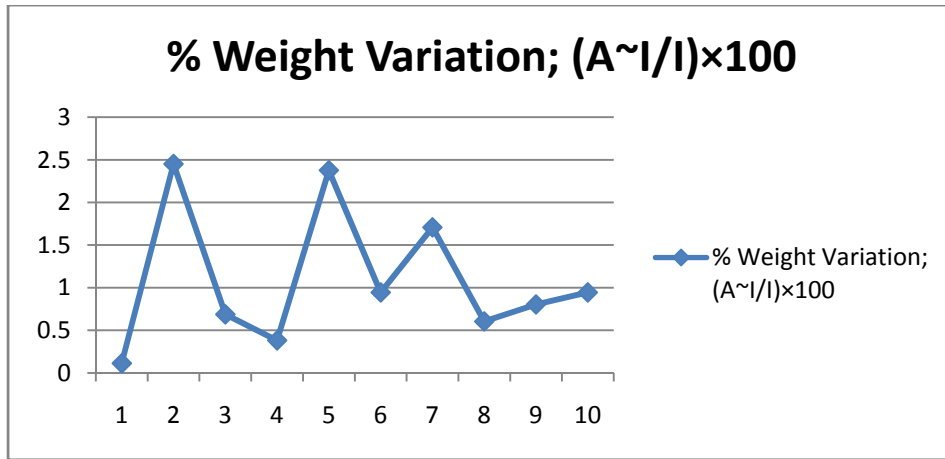


Figure 6.3: Graph of the percentage weight variation of 2 month samples.

**3.2Hardness data:** The hardness had some variation but it was within the range.

**3.2.1Sunlight Exposure Winter:**

**Table 7.1: Data of the hardness test of the 3 hour exposed tablets in the winter season.**

Tablet no.	Hardness(kg)	Hardness Average(kg)
1	5.9	
2	5.7	5.6
3	5.2	



**Table 7.2: Data of the hardness test of the 3 hour exposed tablets in the winter season.**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.2	
2	5.00	5.03
3	4.9	

**Table 7.3: Data of the hardness test of the 9 hour exposed tablets in the winter season.**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	4.9	
2	4.5	4.766
3	4.9	

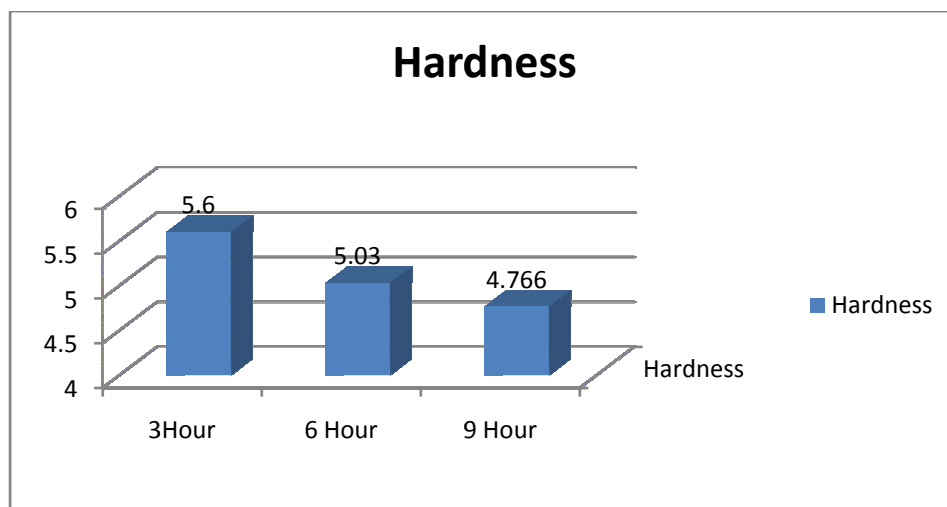


Figure 7.1 : Graphical representation of the mean hardness value of the sunlight exposure samples in winter

### 3.2.2Sunlight Exposure Summer:

**Table 8.1: Data of the hardness test of the 3 hour exposed tablets in the sunlight exposure in summer**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.7	
2	5.6	5.5
3	5.2	

**Table 8.2: Data of the hardness test of the 6 hour exposed tablets in the sunlight exposure in summer.**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.00	
2	4.9	5.03
3	4.9	

**Table 8.3: Data of the hardness test of the 6 hour exposed tablets in the sunlight exposure in summer.**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	4.8	
2	4.5	4.73
3	4.9	

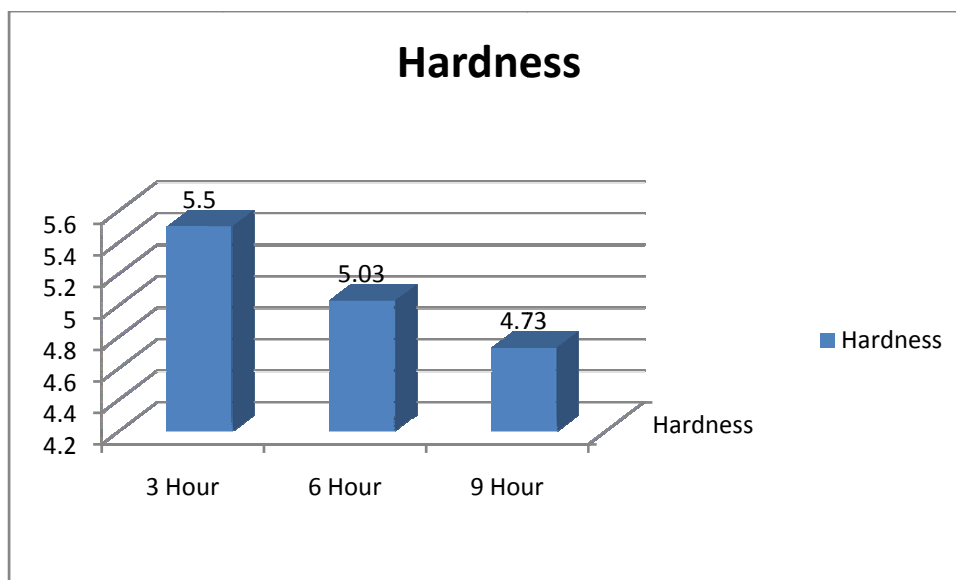


Figure 8.1 : Graphical representation of the mean hardness value of the sunlight exposure samples in summer.

**3.2.3 Normal light room condition:**

**Table 9.1: Data of the hardness test of 2 week samples**

Tablet no.	Hardness(kg)	Hardness Average(kg)
1	6.0	6.00
2	6.1	
3	5.9	

**Table 9.2: Data of the hardness test in kg of 1 month samples**

Tablet no.	Hardness(kg)	Hardness Average(kg)
1	5.8	
2	6.0	5.9
3	5.9	

**Table 9.3: Data of the hardness test in kg of 2 month samples**

Tablet no.	Hardness(kg)	Hardness Average(kg)
1	5.8	
2	5.9	5.83
3	5.8	

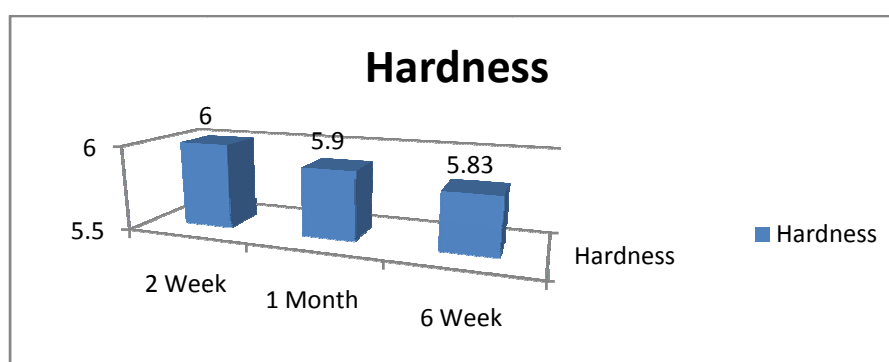


Figure 9.1: Graphical representation of the mean Hardness value of the normal room condition

**Bulb exposure (40 watt):**

**Table 10.1: Data of the hardness test of the 3 hour exposed tablet**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	6.5	
2	6.2	
3	6.3	6.1
4	5.8	
5	5.7	

**Table 10.2: Data of the hardness test of the 6 hour exposed tablets**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.9	
2	5.2	
3	5.5	5.64
4	6.2	
5	5.4	

**Table 10.3: Data of the hardness test of the 9 hour exposed tablets**

Tablet no.	Hardness(kg)	Hardness Average(kg)
1	5.0	
2	4.5	5.16
3	5.1	
4	6.0	
5	5.2	

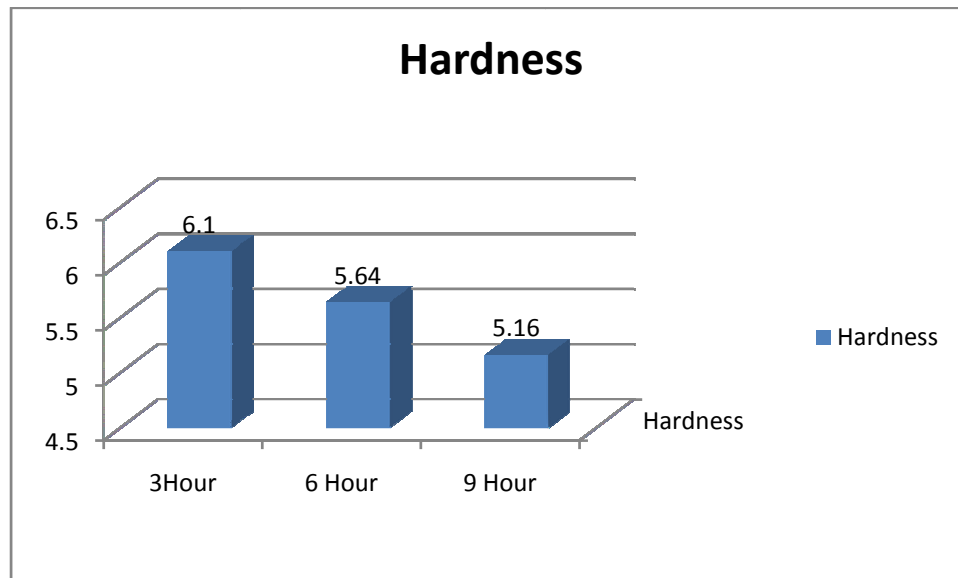


Figure 10.1: Graphical representation of the mean hardness value of the 40 watt exposed tablets

**3.2.4Bulb exposure (25 watt):****Table 11.1: Data of the hardness test of the 3 hour exposed tablets**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	6.0	
2	5.8	6
3	6.2	

**Table 11.2: Data of the hardness test of the 3 hour exposed tablets**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.2	
2	5.8	5.6
3	5.8	



**Table 11.3: Data of the hardness test of the 3 hour exposed tablets**

Tablet no.	Hardness(kg)	Hardness Averege(kg)
1	5.2	
2	5.8	5.6
3	5.8	

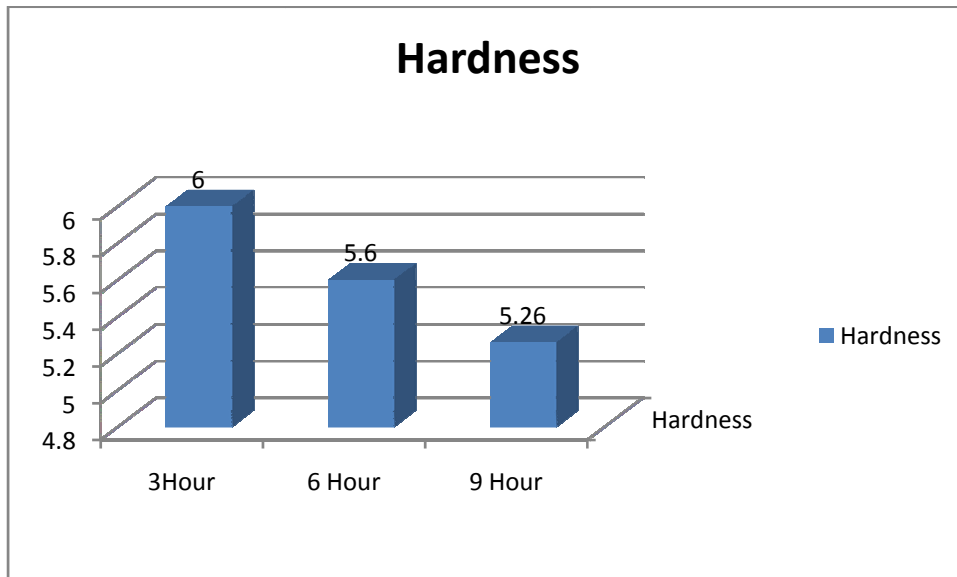


Figure 11.1: Graphical representation of the mean hardness value of the 25 watt exposed tablets

**3.3 Friability data:** The friability was good and impressive as it was not above 1 %.

Below the data table and the bar diagram of the data can explain it more easily.

**3.3.1 Sunlight Exposure Summer:**

**Table 12.1: data for the friability test of the 3 hour exposed tablets in summer season**

Initial weight	Weight after rotation	Friability
1.442	1.4320	0.00786

**Table 12.2: data for the friability test of the 6 hour exposed tablets in summer season**

Initial weight	Weight after rotation	Friability
1.4260	1.4231	0.0069

**Table 12.3: data for the friability test of the 9 hour exposed tablets in summer season**

Initial weight	Weight after rotation	Friability
1.4123	1.4012	0.00505

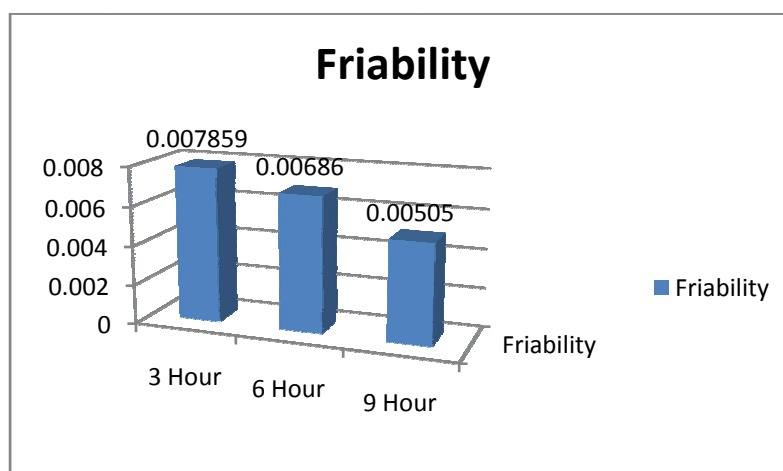


Figure 12.1 : Graphical representation of the friability

### 3.3.2Sunlight Exposure Winter:

**Table 13.1: data for the friability test of the 3 hour exposed tablets in winter season**

Initial weight	Weight after rotation	Friability
1.4602	1.4586	0.0069

**Table 13.2: data for the friability test of the 6 hour exposed tablets in winter season**

Initial weight	Weight after rotation	Friability
1.442	1.432	0.00109

**Table 13.3: data for the friability test of the 9hour exposed tablets in winter season**

Initial weight	Weight after rotation	Friability
1.4276	1.4264	0.0008

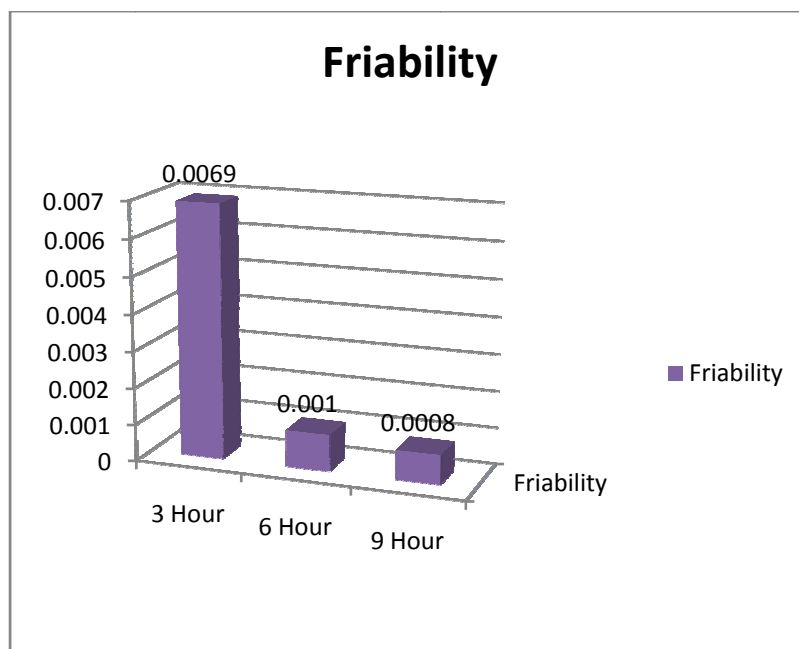


Figure 13.1 : Graphical representation of the friabilty

**3.3.3 Normal light(2 week):**

**Table14.1 : Friability data of 2 week sample tablets**

Initial weight	Weight after rotation	Friability
1.4560	1.4434	0.01382

**Table14.2 : Friability data of 1 month sample tablets**

Initial weight	Weight after rotation	Friability
1.4467	1.4067	0.00865

**Table14.3 : Friability data of 2 month sample tablets**

Initial weight	Weight after rotation	Friability
1.4380	1.4365	0.001043

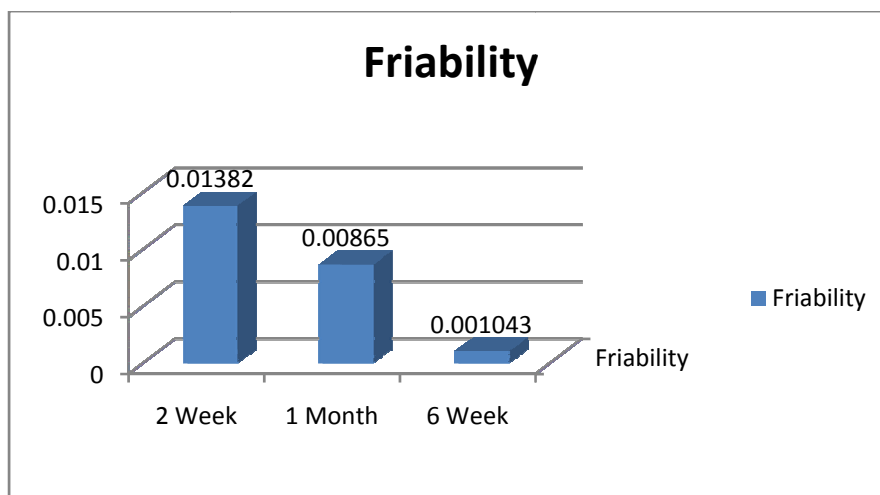


Figure 14.1 : Graphical representation of the friability

**3.3.4Bulb exposure(40 watt):**

**Table 15.1: data for the friability test of the 3 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.461	1.54	0.0068

**Table 15.2: data for the friability test of the 6 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.4545	1.4541	0.0043

**Table 15.3: data for the friability test of the 9 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.4364	1.4362	0.00364

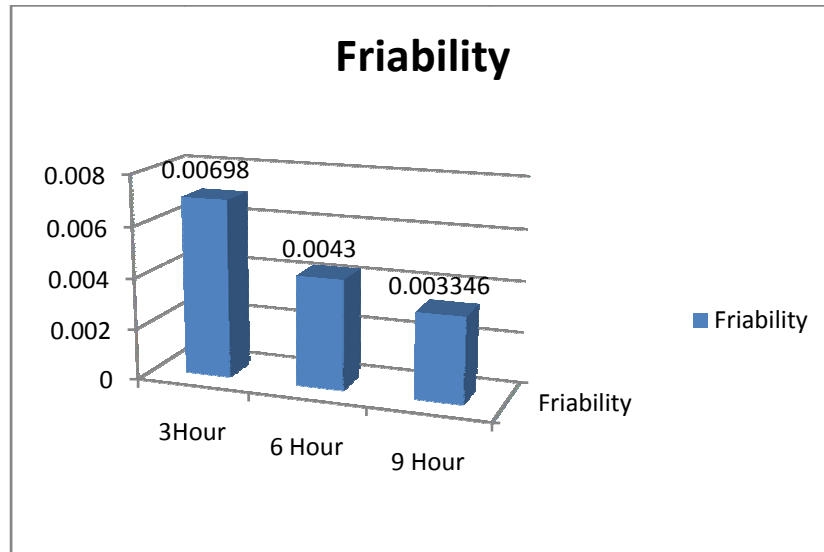


Figure 15.1 : Graphical representation of the friability



**3.3.5Bulb exposure(25 watt):**

**Table 16.1: data for the friability test of the 3 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.462	1.543	0.0068

**Table 16.2: data for the friability test of the 3 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.4487	1.43	0.000275

**Table 16.3: data for the friability test of the 3 hour exposed tablets**

Initial weight	Weight after rotation	Friability
1.442	1.4165	0.000139

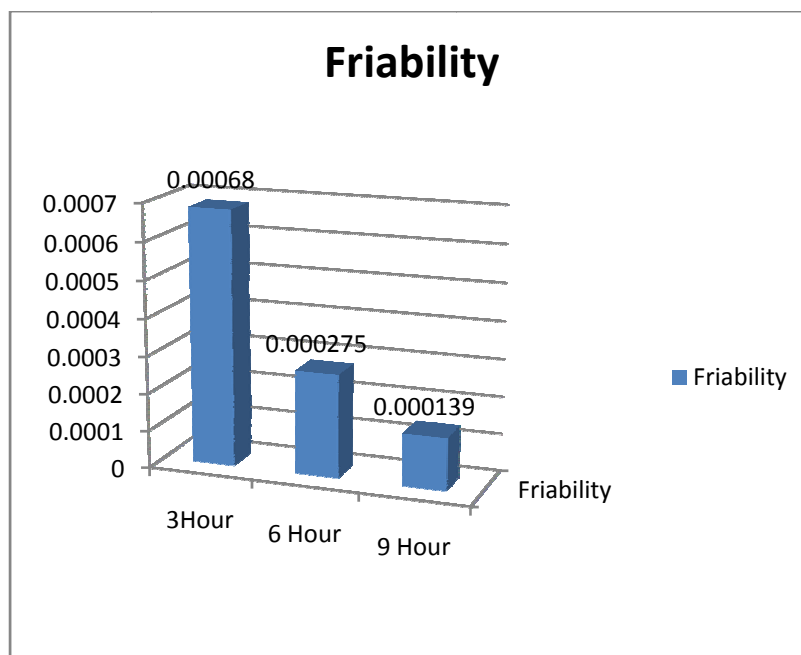


Figure 16.1 : Graphical representation of the friability

**3.6 Thickness test:** In the overall experiment I have found the same data of thickness

**Table 18.1: data for the thickness test of the tablets**

Tablet no.	Main scale reading(cm), M	Vernier scale reading(cm), V	Thickness of the tablets (cm),i.e.(M+V) cm
1	0.4	0.4	0.8
2	0.4	0.4	0.8
3	0.4	0.4	0.8
4	0.4	0.4	0.8
5	0.4	0.4	0.8
6	0.4	0.4	0.8
7	0.4	0.4	0.8
8	0.4	0.4	0.8
9	0.4	0.4	0.8
10	0.4	0.4	0.8

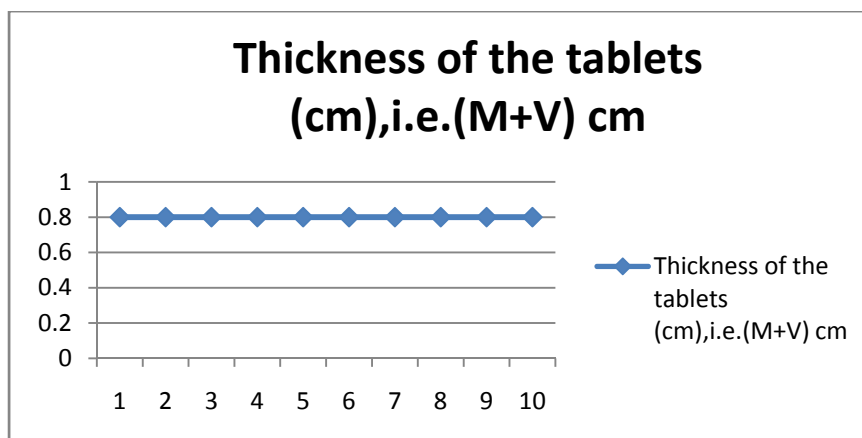


Figure 17.1: Graphical representation of the thickness

**3.7 Potency determination:** The potency determination proved that there is an occurrence of photodegradation of the drug.

The linear regression equation was derived from the calibration curve which was  $y = 104.1x - 0.005$  and  $R^2 = 0.999$  for flupentixol and for melitracen it was  $y = 4.513x + 0.003$  :  $R^2 = 1$ , where  $y$  is the absorbance and  $x$  is the concentration. The equation shows that a linear line has been obtained.

**Table 18.1: Standard curve for Flupentixol**

Concentration(mg)	Absorbance
0.01	1.038
0.002	0.194
0.0004	0.03
0.00008	0.007
0.000016	0.004

**Table 18.2: Standard curve for Melitracen**

Concentration(mg)	Absorbance
0.2	0.906
0.04	0.186
0.008	0.043
0.0016	0.009
0.00032	0.003

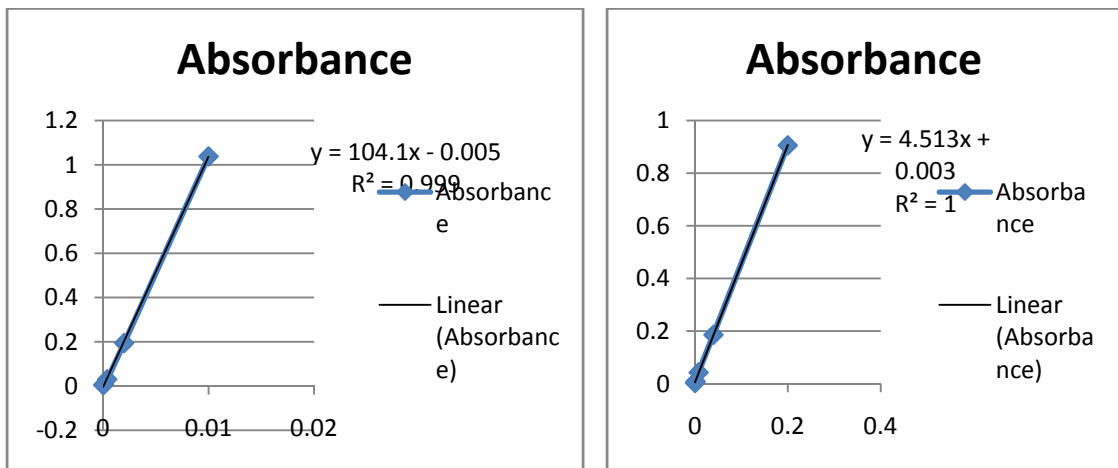


Figure 19.1: Standard curve for Flupentixol and melitracen

The result include the potency determination and estimating some physical parameters of the test samples.

When the tablets are kept under sunlight there occur photolytic degradation as the potency was measured by the absorbance of the two compounds. It was less than the control tablets, which proving the degradation of the potency due to the photolytic exposure.

The degradation was bit higher in the summer season as the temperature increases. The winter sample was degrading less than the summer samples as the temperature was not that much as the summer season. For the three hour exposed tablets in winter the temperature was 99° F but in summer the temperature was 100°, and for the 6 hr exposed samples the temperature in winter was 108°F and in summer it was more than 108°F. But for the 9 hr sample the temperature was dropping as the sun was starting to set.

It was estimate that the degradation was dropping according to the temperature of the environment of the sample.

### **3.7.1 Sunlight exposed sample summer:**

The potency analysis has being conducted and Table 29 and 30 showing the photo degradation of the drug components. It showing that the 6 hour exposed sample degrade the most as the temperature of the 6 hour exposed tablets was high than others. And the 9 hour sample degrade than the 3 hour but not more than the 6 hour because the temperature was falling and so the degrade was less.

**Table 19.1: The absorbance and concentration data for Flupentixol under sunlight exposure in summer samples**

UV analysis for flupentixol		
condition	Concentration	Absorbance
Blank	0	0
3 hour	0.00556	0.574
6 hour	0.00534	0.551
9 hour	0.00435	0.448

**Table 19.2 The potency of Flupentixol under sunlight exposure in summer samples**

Condition	Hour	Potency
Sunlight(summer)	3 hour	0.556
	6 hour	0.534
	9 hour	0.435

**Table 19.3: The absorbance and concentration data for Melitracen of sunlight exposure in summer samples.**

UV analysis for melitracen		
Condition	concentration	Absorbance
Blank	0.00000	0
3 hour	0.1072	0.487
6 hour	0.1052	0.478
9 hour	0.0842	0.383

**Table 19.4: the potency of Melitracen under sunlight exposure in summer samples is**

Condition	Hour	Potency
Sunlight(summer)	3 hour	10.72
	6 hour	10.52
	9 hour	8.42



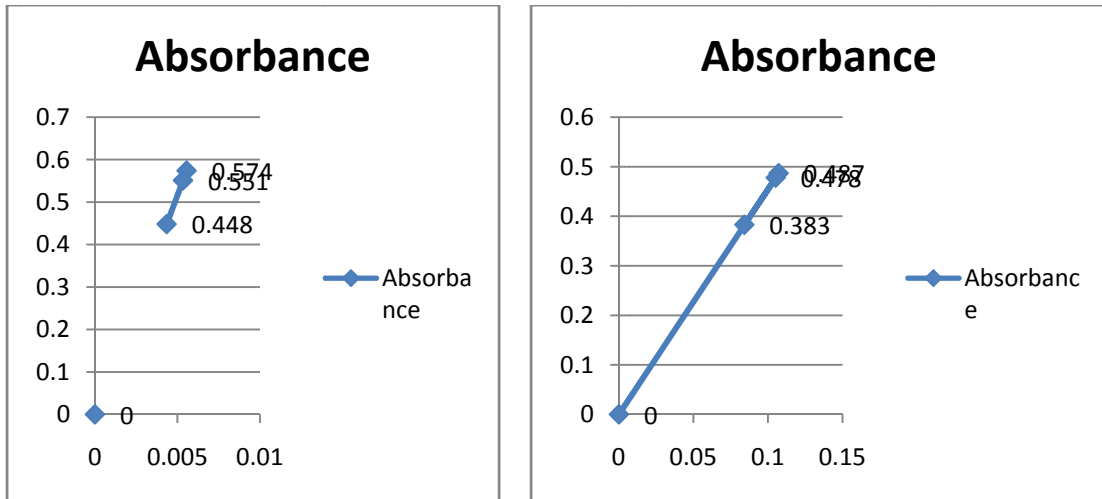


Figure 20.1: UV spectrophotometry analysis for flupentixol and melitracen absorbance Vs concentration graph.(a) flupentixol (b) Melitracen

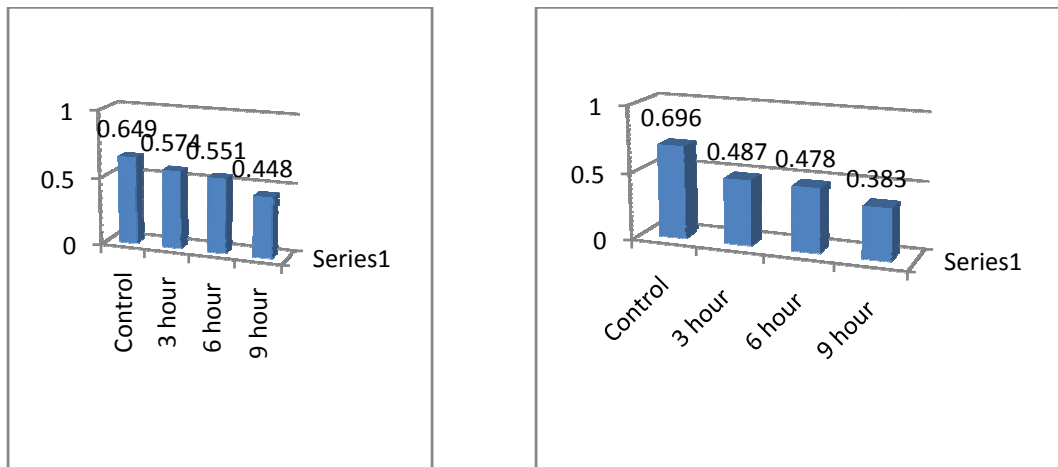


Figure 20.2: bar diagram of the absorbance of the three conditions 1 denote the 3 hour, 2 denote the 6 hour sample and 3 denote the 9 hour sample. (a) is for flupentixol and (b) is for Melitracen.

**3.7.2 Sunlight exposure winter:** The potency determination shows on the table 43 and 44 that the exposure did reveal the photo degradation of the exposed samples. here blank is used as 0 absorbance and concentration

**Table 20.1: The absorbance and concentration data for Flupentixol of sunlight exposure in winter samples**

UV analysis for flupentixol		
condition	Concentration	Absorbance
Blank	0	0
3 hour	0.00549	0.567
6 hour	0.005542	0.572
9 hour	0.005523	0.57

**Table 20.2 the potency of Flupentixol under sunlight exposure in winter samples is:**

Condition	Hour	Potency
Sunlight(winter)	3 hour	0.549
	6 hour	0.5542
	9 hour	0.5523

**Table 20.3: The absorbance and concentration data for Melitracen of sunlight exposure in winter samples**

UV analysis for melitracen		
Duration	concentration	Absorbance
Blank	0.00000	0
3 hour	0.115	0.552
6 hour	0.1061	0.482
9 hour	0.107	0.486

**Table 20.4: the potency of Melitracen under sunlight exposure in winter samples is:**

Condition	Hour	Potency
Sunlight(summer)	3 hour	11.5
	6 hour	10.61
	9 hour	10.7

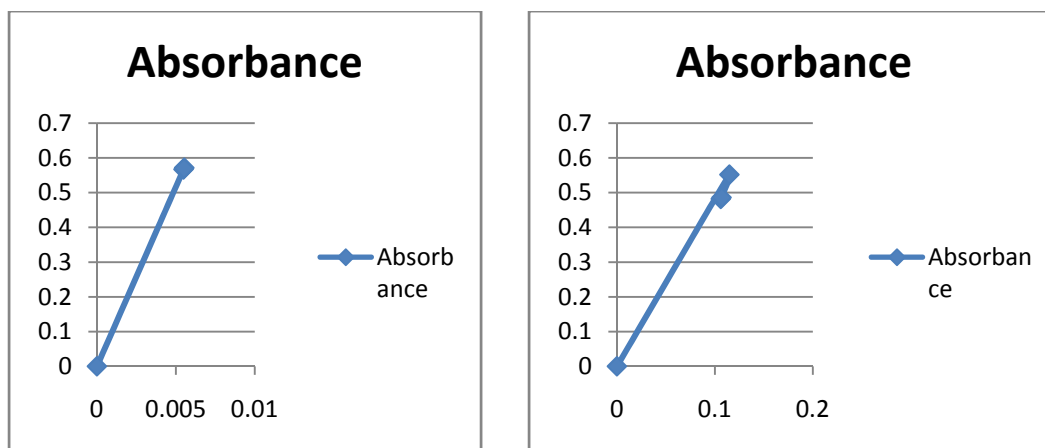


Figure 21.1 : UV spectrophotometry analysis for flupentixol and melitracen absorbance Vs concentration graph.(a) flupentixol (b) Melitracen

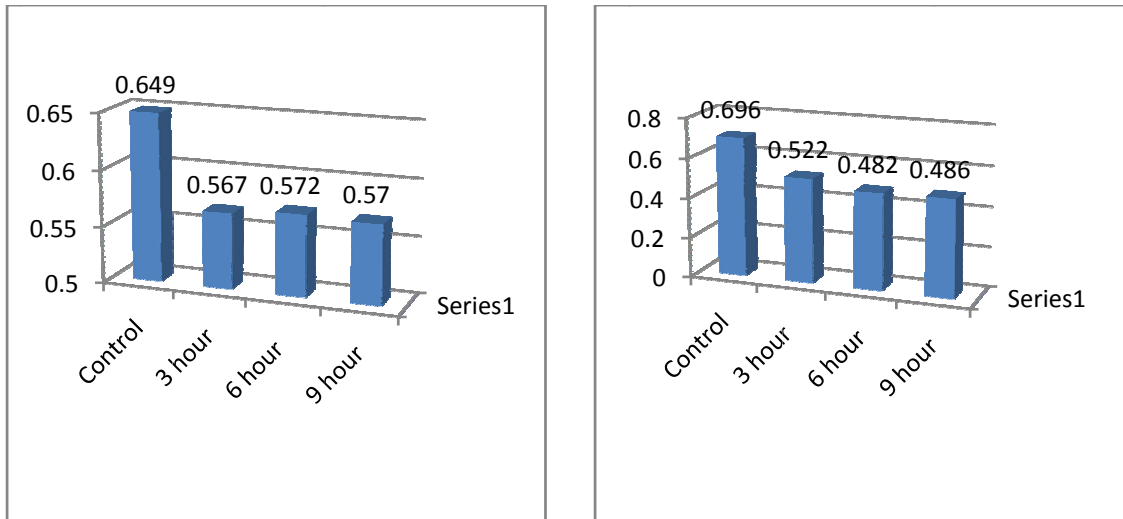


Figure 21.2: Figure 13.3: bar diagram of the absorbance of the three conditions 1 denote the 3 hour, 2 denote the 6 hour sample and 3 denote the 9 hour sample.(a) is for flupentixol and (b) is for Melitracen.

**3.7.3The normal room condition:**

The potency determination of the samples was conducted for the normal room temperature; the potency did losses with the time being kept. The potency did degrade in a good and impressive way eventually with the duration of the exposure time.

**Table 21.1: The absorbance and concentration data for Flupentixol of normal room condition samples.**

Condition	uv analysis room temperature for flupentixol	
	Concentration	Absorbance
Blank	0	0
2 week	0.0059	0.613
1 month	0.0055	0.57
2 month	0.00545	0.563

**Table 22.1 The potency of Flupentixol under sunlight exposure in winter samples is:**

Condition	Time	Potency
Normal room condition	2week	0.59
	1 month	0.55
	2 month	0.545

**Table 22.2: The absorbance and concentration data for Melitracen of normal room condition samples.**

Condition	UV analysis room temperature for Melitracen	
	Concentration	Absorbance
Blank	0	0
2 week	0.11101	0.504
1 month	0.10901	0.495
2 month	0.1084	0.491

**Table 22.3 the potency of Melitracen under sunlight exposure in winter samples is:**

Condition	Time	Potency
Normal room condition	2week	11.1
	1 month	10.9
	2 month	10.84

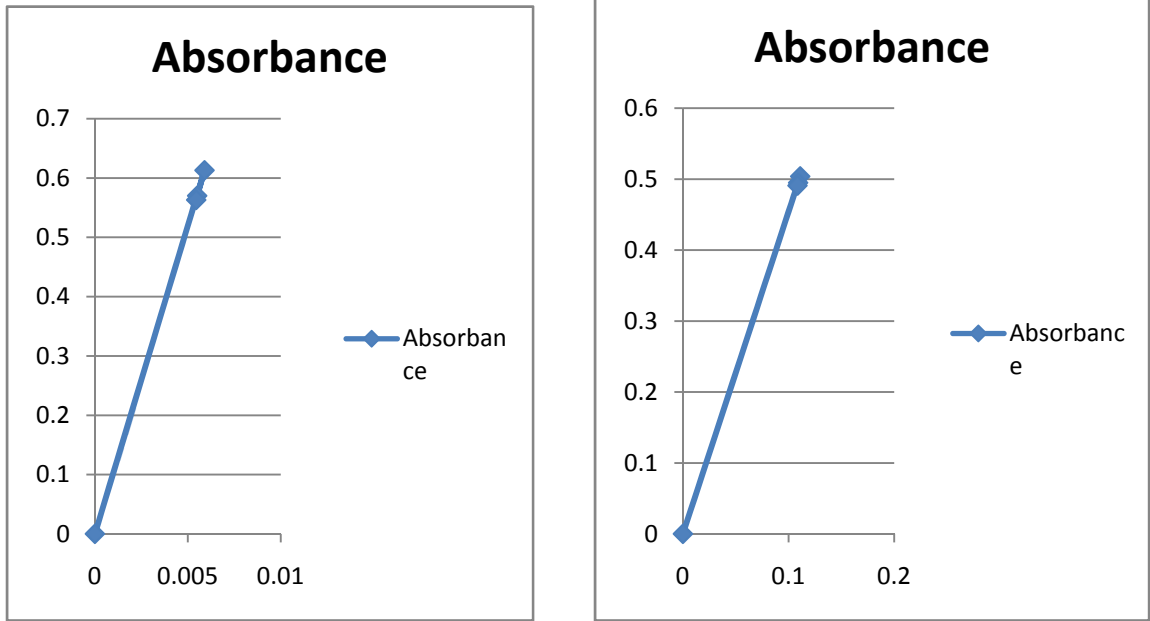


Figure 23.1 : UV analysis for flupentixol and melitracen absorbance Vs concentration graph. (a) Flupentixol (b) Melitracen



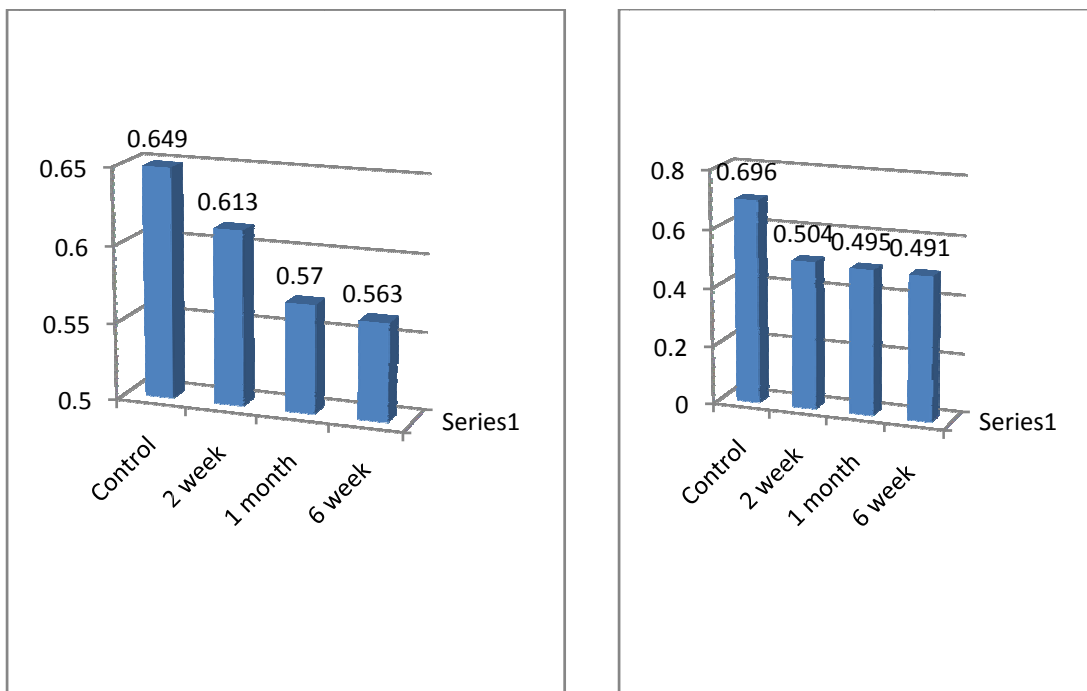


Figure 23.2: Bar diagram of the absorbance of the three conditions 1 denote the 2 week sample, 2 denote the 1 month sample and 3 denote the 2 month sample.(a) is for flupentixol and (b) is for Melitracen.

**3.7.4Bulb exposure (25 watt):Table 23.1: The absorbance and concentration data for Flupentixol of 25 watt bulb exposure.**

Uv analysis for flupentixol		
condition	Concentration	Absorbance
Blank	0.00000	0
3 hour	0.0058	0.604
6 hour	0.0046	0.475
9 hour	0.00527	0.544

**Table 23.2 the potency of Flupentixol under 25 watt bulb exposure:**

Condition	Hour	Potency
Bulb exposure(25 watt)	3 hour	0.58
	6 hour	0.46
	9 hour	0.527

**Table 24.1: The absorbance and concentration data for Melitracen of 25 watt bulb exposure.**

Uv analysis for melitracen		
condition	Concentration	Absorbance
Blank	0.00000	0
3 hour	0.0682	0.311
6 hour	0.07489	0.341
9 hour	0.0638	0.291

**Table 24.2 the potency of Melitracen under 25 watt bulb exposure**

Condition	Hour	Potency
Bulb exposure(25 watt)	3 hour	6.8
	6 hour	7.489
	9 hour	6.38

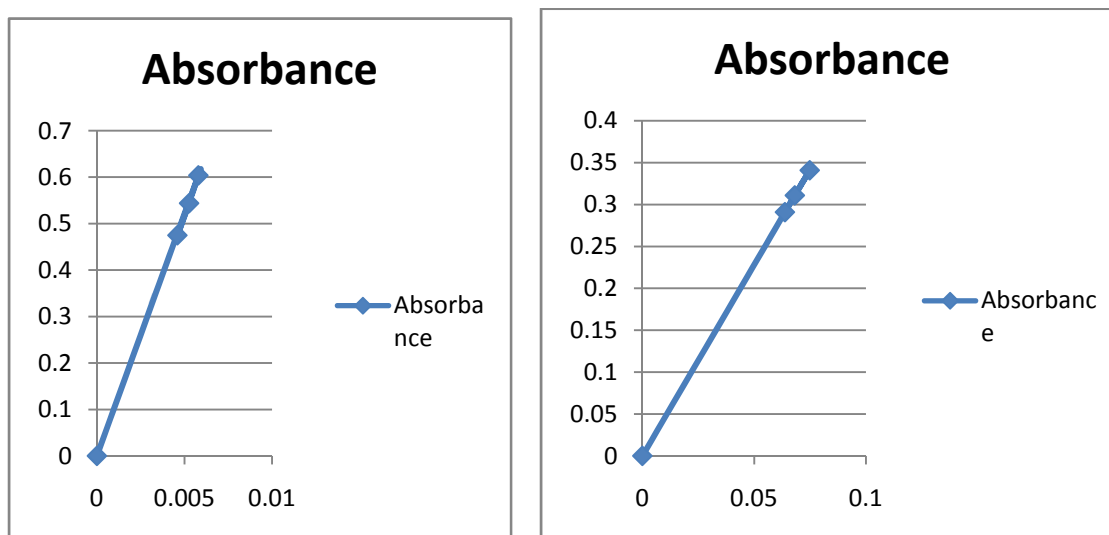


Figure 24.1 : UV spectrophotometry analysis for flupentixol and melitracen absorbance Vs concentration graph. (a) flupentixol (b) Melitracen

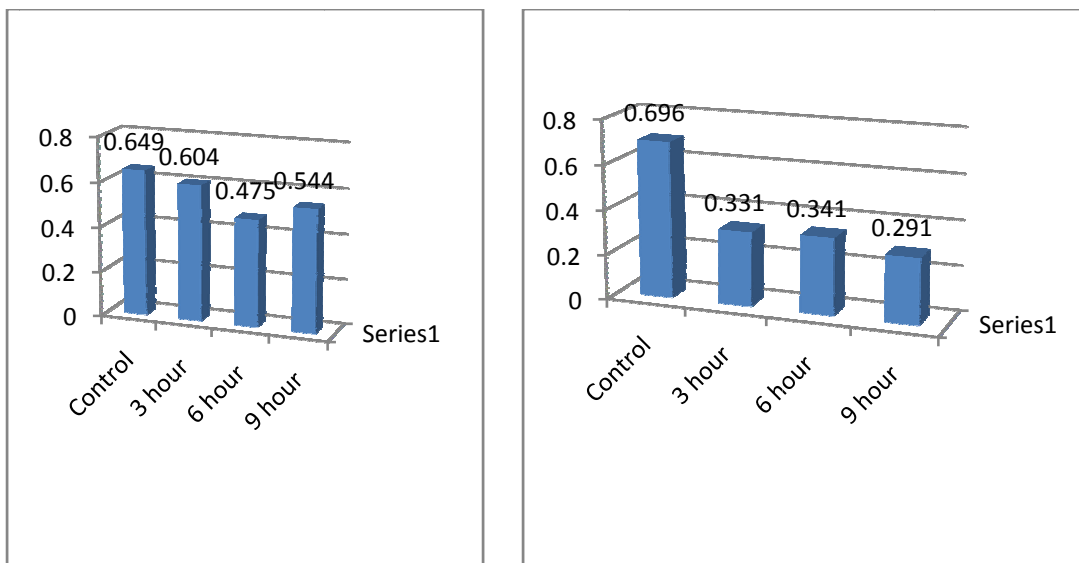


Figure 24.2: Figure 15.3: bar diagram of the absorbance of the three conditions 1 denote the 3 hour, 2 denote the 6 hour sample and 3 denote the 9 hour sample. (a) is for flupentixol and (b) is for Melitracen

**3.7.5 Bulb exposure 40 watt:**

**Table 25.1: The absorbance and concentration data for Flupentixol of 40 watt bulb exposure**

UV analysis of 40 watt for flupentixol		
Condition	Concentration	Absorbance
Blank	0	0
3 hour	0.00448	0.462
6 hour	0.00509	0.525
9 hour	0.006	0.62

**Table 25.2 the potency of Flupentixol under 40 watt bulb exposure:**

Condition	Hour	Potency
Bulb exposure(25 watt)	3 hour	0.448
	6 hour	0.509
	9 hour	0.6

**Table 25.3: The absorbance and concentration data for Melitracen of 40 watt bulb exposure**

Uv analysis of 40 watt for melitracen		
condition	Concentration	Absorbance
Blank	0	0
3 hour	0.0901	0.41
6 hour	0.1238	0.562
9 hour	0.1194	0.542

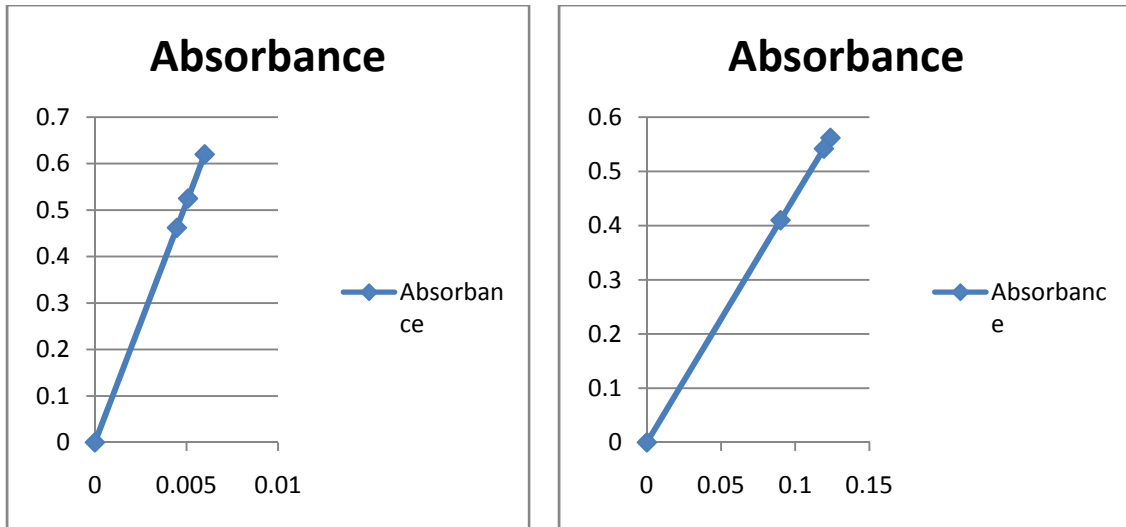


Figure 25.1: UV spectrophotometry analysis for flupentixol and melitracen absorbance Vs concentration graph. (a) flupentixol (b) Melitracen

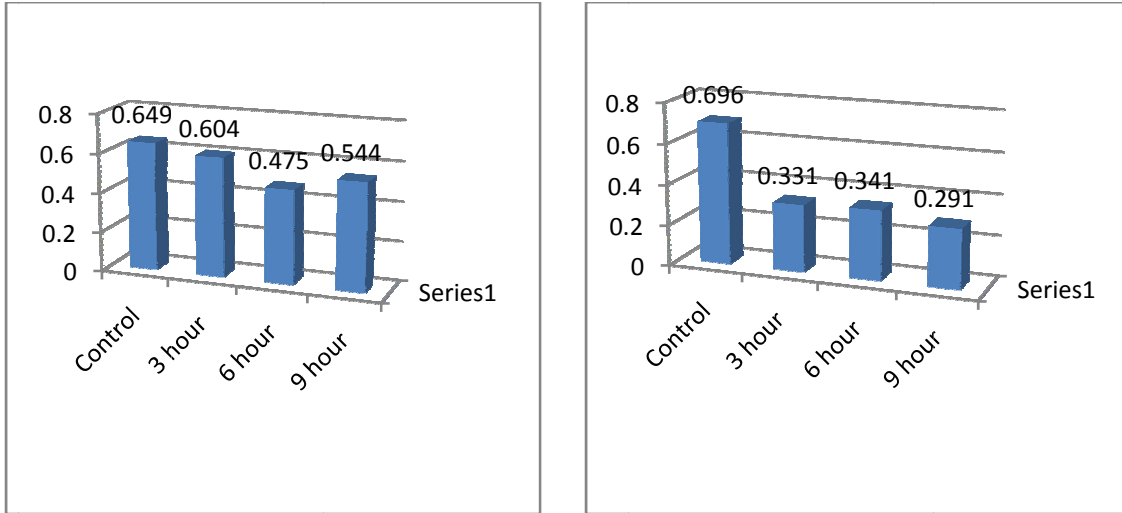


Figure 25.2: Bar diagram of the absorbance of the three conditions 1 denote the 3 hour, 2 denote the 6 hour sample and 3 denote the 9 hour sample.(a) is for flupentixol and (b) is for Melitracen

### 3.8 IR determination of the flupentixol and melitracen:

Infrared spectroscopy (IR spectroscopy) is the spectroscopy that deals with the infrared region of the electromagnetic spectrum that is light with a longer wavelength and lower frequency than visible light. Figure 23.1 is representing the IR spectrum of the control drug and figure 23.2 is showing the IR spectrum of the sample of 4 week in normal room temperature condition. From the spectrum of figure 3.44 the red circle is denoting the deviation of the structural compound of the control drug.

The deviation was occurred on the wavenumber of 3566.38 (cm<sup>-1</sup>) which was not present on the control spectrum. The wave number is denoting that a new compound might be interrupting the original structure. The unusual wavenumber of 3566.38 (cm<sup>-1</sup>) denoting that an alcohol or phenol group may be present on the sample that was not present in the original compound.

Beside the wavenumber of 3566.38 (cm<sup>-1</sup>) other two unusual peak was obtained from the IR determination which are 808.17(cm<sup>-1</sup>) and 534.28 (cm<sup>-1</sup>) , by which it shows that alkene and aromatic hydrocarbon like C-H bend (trisubstituted) and C-H bend (para) respectively may be present. From the 534.28 (cm<sup>-1</sup>) ,wavenumber it can be expressed that alkyl halides like C-Br stretch, C-I stretch etc may be present on the sample.

Moreover, three minor deviations on the spectrum also was appeared on the 4 week spectrum which was on the wavenumber on 3838.34 (cm<sup>-1</sup>), 38320.98 (cm<sup>-1</sup>) and on 3408.22 (cm<sup>-1</sup>).

The wavenumber thus explaining that O-H stretch motion compound may be present as alcohol or as carboxylic acid group.



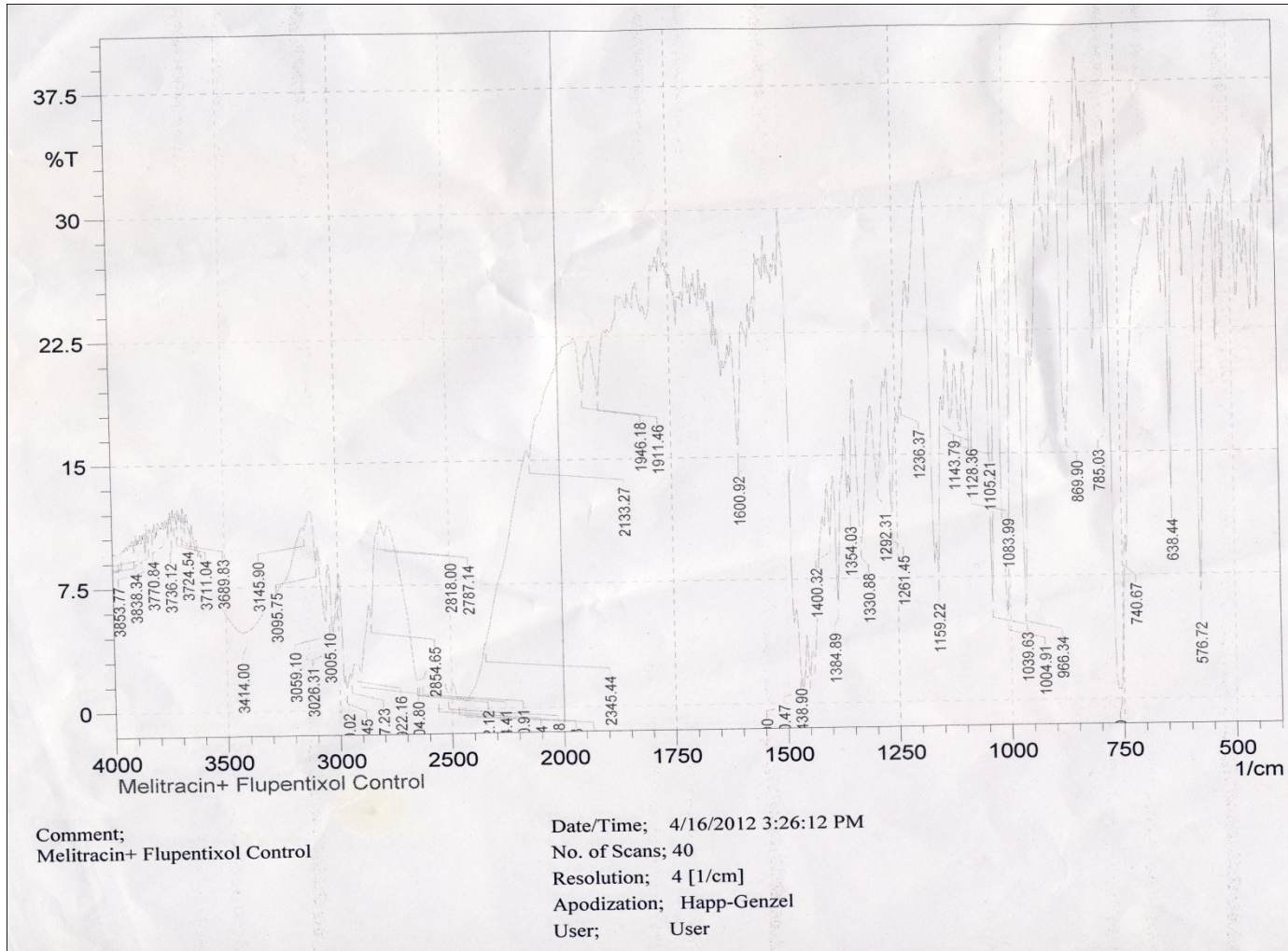


Figure 26.1: IR spectrum of Flupentixol + Melitracin of control compound.

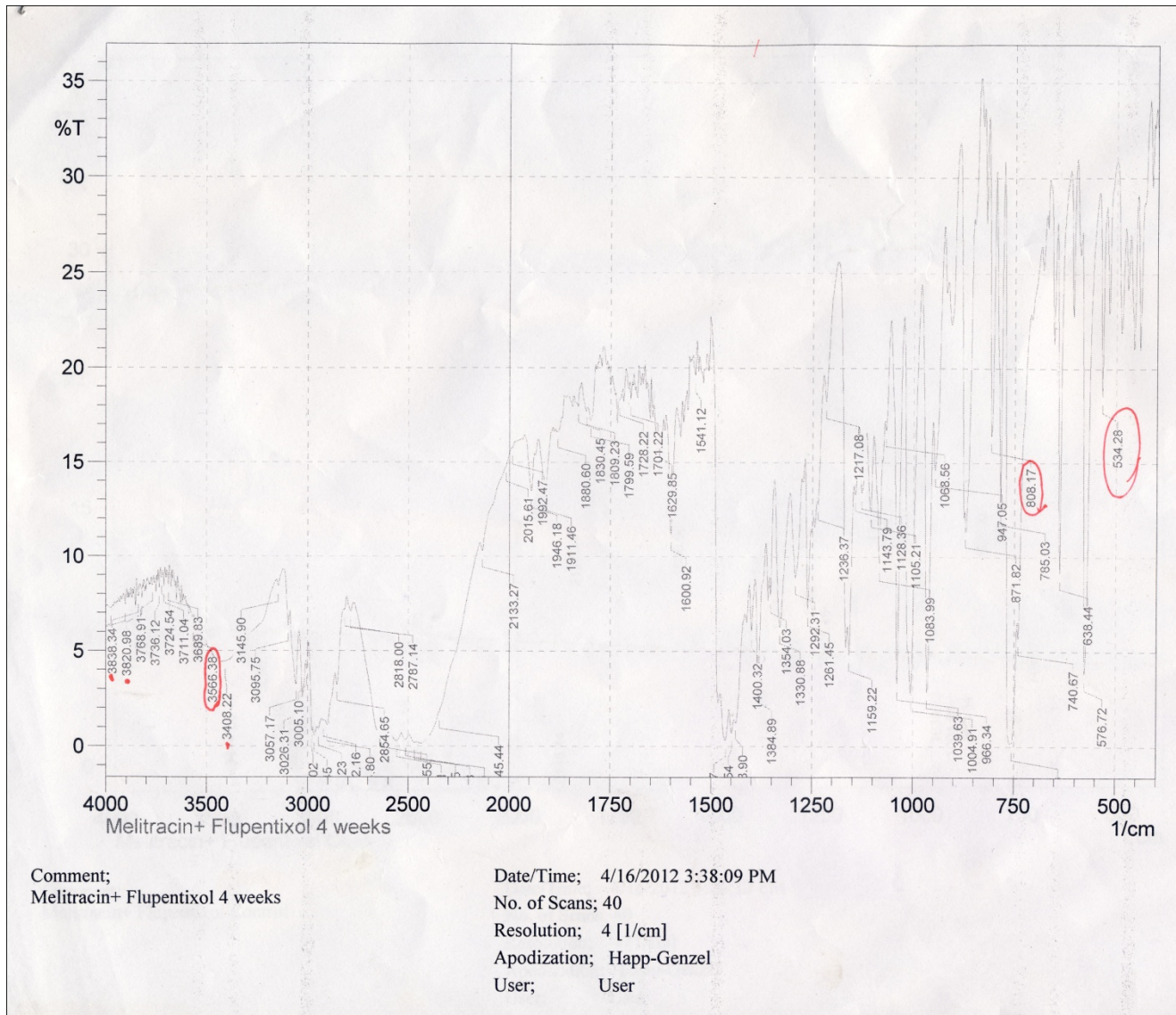


Figure 23.2 : IR spectrum of Flupentixol + Melitracen of 4 week in normal room condition.

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**4.1 Discussion:** In this study the photolytic degradation of Melixol (Flupentixol and Melitracen combination drug) is determined. For this purpose some physical parameters test such as color variation, weight variation, hardness, thickness, friability was done. Again the potency of the Melixol tablets are measured by UV spectroscopy.

From the color variation test, it was observed that the color of Melixol tablets are changed under various conditions like (sunlight exposure, normal light condition, bulb exposure) due to the photolytic effect.

Weight variation test is also done on the tablets which are kept under sunlight exposure (summer, winter), normal light condition (2 week, 1 month, 6 week), bulb exposure (40 watt, 25 watt). In all cases, the weight of the tablets are observed after 3 hour, 6 hour, 9 hour interval. The weight of the Melixol tablets which are observed after 9 hour duration are largely reduced. The weight of the tablets which are observed after 3 hour interval are less reduced than 9 hour interval. The weight of the tablets are reduced because of the moisture loss due to the photolytic degradation. But the percentage weight variation of all the sample tablets are within the range, which is  $\pm 10$  for 130 mg or less dosage form.

From the thickness test, no major change is observed due to photolytic effect. This test is done on the tablets which are kept under sunlight exposure (summer, winter), normal light condition (2 week, 1 month, 6 week), bulb exposure (40 watt, 25 watt). In all cases, the weight of the tablets are observed after 3 hour, 6 hour, 9 hour interval.

## Photolytic Degradation of Melixol 80

Hardness and friability test is also done on the tablets which are kept under the same condition like weight variation and thickness test. There was a little effect on the hardness and the friability of the tablets due to the exposure of the light and radiation.

The potency determination proved that there is a great effect of light on the Melixol tablets. Because it was found that the potency of the tablets are degraded which are kept under different condition same as during the weight variation test.

From the IR spectrum of the control drug and the sample of 4 week in normal room temperature condition it was found that there is derivation of the structural compound of the control drug. It was observed that a new compound might be interrupting the original structure.

**4.2 Conclusion:** From this study, there was found various important data which indicates that the light has a great effect on the degradation of the antipsychotic drug, Melixol, a combination product of (Flupentixol and Melitracen). In this study, the photodegradation study is mainly done by measuring the potency of the tablets by the help of UV spectrophotometer and it is proved that the drug is not photo stable and should have some protection in the final dosage form to save it from degradation.

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