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RESEARCH ARTICLE

Evaluation of Photo-degradation of Paracetamol Tablet in Various Packaging Modes in Bangladesh

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ABSTRACT

Experiments were conducted on two local brands of paracetamol available in Bangladeshi pharmaceutical market, one is Napa (manufactured by Beximco Pharmaceuticals Ltd) and another is Parapyrol (manufactured by Glaxosmithkline). Though, these two brands are available in blister-transparent and strip packages respectively, blister-opaque (Alu-PVDC) was also used for these two brands along with two existing packaging systems to assess that which one provides better protection from photo degradation in comparison with others. Napa and Parapyrol both were brought on same environmental exposure and they were packaged in three packaging systems - blister-transparent, blister-opaque and strip. Half of the total tablets were kept in control condition at room temperature and another half were subjected to sunlight for the specific period of time. And it was ensured that both of these brands of paracetamol were equally exposed to sunlight. Then certain quality control tests (e.g. hardness, friability, and disintegration) were carried out to measure the changes due to sunlight exposure. Effect of sunlight on the potency of these two brands of three packaging systems was also measured. The assay of paracetamol content of the stored samples was carried out according to the BP (1993) method by extraction with 0.1M sodium hydroxide and measurement of absorbance at the maximum at 257 nm. The contents of paracetamol were calculated taking 715 as the value of A (1% 1cm) at 257 nm. It was observed that minute changes have been occurred both in physical quality and potency of the paracetamol of all aforementioned packaging systems due to the photo degradation.

KEYWORDS

Paracetamol, Photo-degradation, Blister and Stability

INTRODUCTION

The stability of a product may be defined as the extent to which a product retains, within specified limits, through its period of storage and use, the same properties and characteristics possessed at the time of its packaging. The characteristics include physical, chemical, microbiological, therapeutic and toxic properties, and all are required to remain acceptable limits till the time of use of the product by a patient. Stability testing provides evidence on how the quality of a drug substance or drug products varies with time under the influence of a variety of environmental factors, such as temperature, humidity and light. It measures and documents the ability of a product to retain its potency prior to its predicted

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expiration date. These data are used to determine acceptable shelf-life, proper storage conditions and suitable packaging.

Packaging is the process by which the pharmaceuticals are suitably packed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. Packaging is the science, which involves preparing the articles for transport, storage, display, and use. Packaging is a means of presenting products to the customers protecting its quality. In the pharmaceutical industry, it is vital that the package selected adequately preserve the integrity of the product. The selection of a package therefore begins with a determination of the products physical and chemical characteristics, its protective needs and its marketing requirements. Faulty packaging of pharmaceutical dosage forms can invalidate the most stable formulation. Consequently, it is essential that the choice of container materials for any particular product be made only after a thorough evaluation has been made of the influence of these materials on the stability of the product and of the effectiveness of the container in protecting the product during extended storage under varying environmental conditions of temperature, humidity and light. The materials most commonly employed as container components for pharmaceutical preparations include glass, metal, plastic and rubber. Pharmaceutical products differ considerably in their composition, so naturally they are subject to different forms of chemical degradation such as Hydrolysis, Oxidation, Isomerzation, Optical isomerization, Geometrical isomerization, Decarboxylation, and Polymerization. There are some Physical factors influencing chemical degradation such as Temperature, Moisture, and light etc. Among the factors influencing drug degradation the photostability or photosensibility of pharmaceuticals is an area of growing concern as the number of drugs found to be photosensitive is increasing. Already in 2005 the United States Pharmacopeia listed over 250 drugs that require protection from ultraviolet (UV) and/or visible light. Photo degradation is the degradation of a photodegradable molecule caused by the absorption of photons, particularly those wavelengths found in sunlight, such as infrared radiation, visible light, and ultraviolet light. However, other forms of electromagnetic radiation can cause photo degradation. Photo degradation includes photo dissociation, the breakup of molecules into smaller pieces by photons. It also includes the change of a molecule's shape to make it irreversibly altered, such as the denaturing of proteins, and the addition of other atoms or molecules. A common photo degradation reaction is oxidation. This type of photo degradation is used by some drinking water and wastewater facilities to destroy pollutants. Photo degradation in the environment is part of the process by which ambergris evolves from its fatty precursor.

The photochemical degradation of a sensitive material can be reduced by protecting it from light. This may be achieved by storing the product in a clear glass container, then either placing it in the dark or enclosing it in an opaque wrapper. Alternatively, light-resistant containers may be used. Since degradation is chiefly due to the absorption of light of shorter wavelength, the British Pharmaceutical Codex defines a light resistant-container as one that does not transmit more than 15 percent of incident radiation between 290 and 450.

The amount of light transmitted through a glass container depends upon the composition and thickness of the glass. The light transmission characteristics of different types of glass container have been reported that the yellow-green and amber glasses are satisfactory since they transmit very little light below 400nm. Medium green containers are less effective, while colorless and blue glass transmit high percentages of ultraviolet wavelengths.

The inspection of solutions for any sign of precipitation or discoloration is difficult in colored containers, and for this reasons many parenteral solutions are packed in clear glass containers and placed in a light-proof enclosure. Blister package and strip package is mostly

popular and established packaging systems for tablet and capsule dosage forms.

Insufficient photo stability can result in a loss of drug potency related to light-initiated reactions with excipients as well as unintended biological effects from degradation products, reactions with substrates, or with environmental oxygen. These concerns affect the handling, packing, and labelling of the drugs and vary according to the sensitivity of the compound. Determination of photo degradation is still done by visual inspection, by repeated dissolution studies, or else by chromatographic methods. Needless to say, visual inspection is not accurate while the other two techniques are time consuming.

That is why regulatory agencies require more and more information on the photo-stability of drugs. A faster and less cumbersome method for determining the presence of photo-instability and measuring the degree of degradation would be useful to help reduce costs and testing times while providing sufficient accuracy. In view of the sensitivity of pharmaceutical compounds to various stimuli. It is essential to make a thorough evaluation of the influence of packaging material on the stability of the product and of the effectiveness of the material in protecting the product during extended storage under varying environmental conditions of temperature, humidity and light. In these circumstances an effort has been made to assess the photostability of paracetamol and effectiveness of its different packaging systems against photodegradation.

MATERIALS AND METHOD

Pure paracetamol tablet is treated as raw material, two different Bangladeshi brands (Parapyrol from GSK and Napa from Beximco Pharma Ltd.), three types of packaging systems for tablet used as they are Blister-transparent, blister-opaque and strip as well as chemical reagents as they are 0.1 N HCL, 0.1 N NaOH and purified water. List of instruments used for this study is shown in the table 1. Equally 50% of each brand of packed paracetamol tablets was subjected to expose under room condition and sunlight for consecutive 30 days.

Table 1: Instruments Used for the Experiments

Sr	Name of Instrument	Brand and Country of Origin
1	UV-Spectrophoto-meter	UV-1601PC,UV-VisibleSpectrophotometer (SHIMADZU, Japan)
2	Disintegration test apparatus	Erweka, Germany
3	Roche friabilator	Thermonik, Bombay-400 025, India
4	Tablet hardness tester	Erweka, Germany
5	Blister Machine	Done from Apex Pharma Ltd.

Hardness Test

The hardness of tablet depends on the weight of the material used, space between the upper and lower punch at the time of compression and pressure applied during compression. The hardness also depends on the nature and quantity of excipient used during formulation. If the finished tablet is too hard, it may not disintegrate in the required period of time and if the tablet is too soft it may not withstand the handling during packing and transporting. Therefore it is very necessary to check hardness of tablets when they are being compressed and pressure adjusted accordingly on the tablet machine. Tablet hardness can roughly be determined by holding the tablet in between the fingers of the hand and through it lightly on the floor, if it does not break it indicates that proper hardness has been obtained. A number of hardness tasters are used for determining the tablet hardness but Monsanto hardness testers, Erweka hardness tester and Pfizer tasters are commonly used. Hardness of 4kg is considered suitable for handling the tablets hardness of 6kg or more produce tablet of highly compact nature. Hardness unit was considered as Kg/cm^2.

Friability / Abrasion Test

Friability test is performed to evaluate the ability of the tablets to withstand abrasion in packing, handling and transporting. The instrument used for this test is known as Friability Test Apparatus or Friabilator. The laboratory friability tester is known as Roche Friabilator. Friabilator consists of plastic chamber which is divided into two parts and revolves at a speed of 25 r.p.m. A number of tablets are weighed and placed in the tusubling chamber which is rotated for four minutes or for 100 revolutions. During each revolution the tablets fall from a distance of six inches to undergo shock. After 100 revolutions the tablets are again weighed and the loss in weight indicates the friability. The acceptable limits of weight loss should not be more than 0.8% -1%.

% Friability = [{(Wi-Wf) / Wi}× 100], Wi= Initial weight, Wf=Final weight

Disintegration Time

The disintegration test is performed to find out that within how much time the tablet disintegrates. This test is very important and necessary for all the tablets, coated or uncoated to be swallowed because the dissolution rate depends upon the time of disintegration which ultimately affects the rate of absorption of drugs. The apparatus used for this test is known as disintegration test apparatus. This apparatus consists of a glass or plastic tube which is open at one end and the other end is fitted with a rust proof No. 10 mesh.

The tube is suspended in a bath of water or suitable liquid equivalent to gastric juice (0.1 N HCL) which is thermostically maintained at a temperature of 37^0C. The tube is allowed to move up and down at a constant rate i.e. 29 – 32 times per minute through a distance of 75 mm. The volume of the liquid and distance of movement adjusted in such a way that at the highest point the mesh screen just breaks the surface of the liquid to give a turbulent movement to the tablets and at the lowest point the mesh screen remains about 25mm above the bottom of the container. About five tablets are placed in the tube along with a plastic disk over the tablets unless otherwise stated in the monograph. The plastic disk does not allow the tablets to float and imparts a slight pressure on the tablets. The tube is allowed to move up and down and disintegration time noted when all the tablets have passed through the sieve.

This time should comply with the time stated in the monograph for that tablet. The test fails if all the tablets do not pass through the sieve within specified time. Generally the disintegration time for uncoated tablets is 30 min. and for coated tablets one hour.

Potency Determination by UV-Visible Spectrophotometric Method

For sample preparation, 20 tablets were weighed and their average weight was determined. Then these tablets were crushed into fine powders and the powder equivalent to 150 mg of paracetamol was weighed and transferred into a 200ml volumetric flask. 50 ml 0.1 M NaOH was added and diluted with 100 ml water and shaken for about 15 minutes.

This mixture was mixed well and filtered through whatmann-1 filter paper. 10 ml of the filtrate was transferred to a 100 ml volumetric flask and volume was made with water and mixed well. Then 10 ml of the resulting solution was transferred into a 100 ml volumetric flask and 10 ml 0.1 M NAOH was added. Then the final volume was made with water and mixed well. Absorbance of the resulting solution was measured at maximum 257 nm wavelength. And the content of paracetamol was calculated taking 715 as the value of A (1%, 1cm) at the maximum 257 nm wavelength. Calculation was done as per following formula.

The amount of Paracetamol in mg per tablet was calculated by following formula:

$$= \frac{\text{Sample absorbance} \times 1000 \times 200 \times 100 \times 100 \times \text{Average weight in mg}}{715 \times 100 \times \text{Weight of sample in mg} \times 10 \times 10}$$

and the amount in % of labeled amount was calculated in following formula:

$$= \frac{\text{Amount observed}}{\text{Label claim (mg/tab)}} \times 100$$

RESULTS AND DISCUSSION

Hardness and Friability

The highest hardness value was recorded by no. 8 tablet but the average tablet hardness was below the standard.

According to the British Pharmacopoeia maximum loss of 1% of the mass of tablets tested (for friability) is considered acceptable. Under room temperature Parapyrol of blister-transparent package met the friability requirement. The result is shown in table 2.

Table 2: Hardness and Friability of Parapyrol of blister-transparent package under room condition

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 3.0 kg/cm^2	3.8 ± 0.790	Initial weight (Wi) = 599mg Final weight (Wf) = 593mg % Friability= $\frac{(Wi-Wf)}{Wi}\times 100$ $= \frac{599-593}{599}\times 100$ = 1 %
2) 3.7 kg/cm^2		
3) 3.0 kg/cm^2		
4) 3.0 kg/cm^2		
5) 4.8 kg/cm^2		
6) 4.5 kg/cm^2		
7) 3.0 kg/cm^2		
8) 5.0 kg/cm^2		
9) 4.1 kg/cm^2		
10) 4.0kg/cm^2		

Under sunlight the highest hardness value for the Parapyrol of blister-transparent package was recorded by no. 4 tablet and the average hardness value met the standard.

Mean tablet friability was within the acceptable limit specified by BP. The result is given in table 3.

Table 3: Hardness and Friability of Parapyrol of blister-transparent package under sunlight

Tablet Hardness (kg/cm^2)	Tablet Hardness (kg/cm^2)	Mean tablet friability (%)
1) 2.9 kg/cm^2	4.0 ± 0.988	Initial weight (Wi) = 598mg Final weight (Wf) = 594mg % Friability= $\frac{(Wi-Wf)}{Wi}\times 100$ $= \frac{598-594}{594}\times 100$ = 0.7 %
2) 3.0 kg/cm^2		
3) 5.0 kg/cm^2		
4) 5.8 kg/cm^2		
5) 4.8 kg/cm^2		
6) 3.7 kg/cm^2		
7) 3.9 kg/cm^2		
8) 4.0 kg/cm^2		
9) 4.1 kg/cm^2		
10) 3.0kg/cm^2		

The highest hardness value of Parapyrol of blister-opaque package under room condition was recorded by no.1 tablet and most of the tablets have least hardness value of 4.0 kg/ cm^2. Average hardness value and tablet friability rate both met the BP requirement. The result is given in table 4.

Table 4: Hardness and Friability of Parapyrol of blister-opaque package under room condition

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 5.1 kg/cm^2	4.4 ± 0.389	Initial weight (Wi) = 599mg Final weight (Wf) = 593mg % Friability= $\frac{(Wi-Wf)}{Wi}\times 100$ $= \frac{599-593}{599}\times 100$ = 1 %
2) 4.1 kg/cm^2		
3) 4.1 kg/cm^2		
4) 4.8 kg/cm^2		
5) 4.0 kg/cm^2		
6) 4.2 kg/cm^2		
7) 4.7 kg/cm^2		
8) 4.8 kg/cm^2		
9) 4.2 kg/cm^2		
10) 4.0kg/cm^2		

In contrast, under sunlight the highest hardness value for the Parapyrol of blister-opaque package was recorded by no. 4 tablet and the average hardness value met the standard. Mean tablet friability was within the acceptable limit specified by BP. The result is given in table 5.

Table 5: Hardness and Friability of Parapyrol of blister-opaque package under sunlight

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 4.0 kg/cm^2	4.23 ± 0.301	Initial weight (Wi) = 599mg Final weight (Wf) = 595mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ $=\frac{599-595}{599}\times100$ = 0.7 %
2) 4.6 kg/cm^2		
3) 4.0 kg/cm^2		
4) 5.0 kg/cm^2		
5) 4.5 kg/cm^2		
6) 4.0 kg/cm^2		
7) 4.1 kg/cm^2		
8) 4.0 kg/cm^2		
9) 4.0 kg/cm^2		
10) 4.1kg/cm^2		

The highest hardness value of Parapyrol of strip package under room condition was recorded by no.2, 3 and 7 tablet and most of the tablets have least hardness value of 4.0 kg/ cm^2. Average hardness value and tablet friability rate both met the BP requirement. The result is given in table 6.

Table 6: Hardness and Friability of Parapyrol of strip package under room condition

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 4.1 kg/cm^2	4.4 ± 0.495	Initial weight (Wi) = 601mg Final weight (Wf) = 596mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ $=\frac{601-596}{601}\times100$ = 0.8 %
2) 5.0 kg/cm^2		
3) 5.0 kg/cm^2		
4) 4.9 kg/cm^2		
5) 4.2 kg/cm^2		
6) 3.6 kg/cm^2		
7) 5.0 kg/cm^2		
8) 4.2 kg/cm^2		
9) 4.1 kg/cm^2		
10)4.2kg/cm^2		

In contrast, under sunlight the highest hardness value for the Parapyrol of strip package was recorded by no. 3 tablet and most of the tablets have the standard hardness value. The average hardness value and the mean tablet friability were within the acceptable limit specified by BP. The result is given in table 7.

Table 7: Hardness and Friability of Parapyrol of strip package under sunlight

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 4.0 kg/cm^2	4.17 ± 0.134	Initial weight (Wi) = 600mg Final weight (Wf) = 594mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ $=\frac{600-594}{600}\times100$ = 1 %
2) 4.1 kg/cm^2		
3) 5.0 kg/cm^2		
4) 4.0 kg/cm^2		
5) 4.0 kg/cm^2		
6) 4.0 kg/cm^2		
7) 4.2 kg/cm^2		
8) 4.0 kg/cm^2		
9) 4.4 kg/cm^2		
10) 4.0 kg/cm^2		

The highest hardness value of Napa of blister-transparent package under room condition was recorded by no. 1 tablet and most of the tablets have least hardness value of 4.0 kg/cm^2. Mean tablet hardness was within the acceptable range.

Under room temperature Napa of blister-transparent package did not meet the friability requirement. The result is given in table 8.

Table 8: Hardness and Friability of Napa of blister-transparent package under room condition

Tablet Hardness (kg/cm^2)	Mean tablet hardness (kg/cm^2) $\pm SD$	Mean tablet friability (%)
1) 5.0 kg/cm^2	4.4 ± 0.425	Initial weight (Wi) = 582mg Final weight (Wf) = 575mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ = $\frac{582-575}{582}\times100$ = 1.2 %
2) 4.5 kg/cm^2		
3) 4.0 kg/cm^2		
4) 4.9 kg/cm^2		
5) 4.0 kg/cm^2		
6) 4.1 kg/cm^2		
7) 4.2 kg/cm^2		
8) 4.0 kg/cm^2		
9) 4.9 kg/cm^2		
10) 4.7kg/cm^2		

Under sunlight the highest hardness value for the Napa of blister-transparent package was recorded by no. 2 tablet. But the mean hardness value and mean tablet friability was not within the acceptable limit specified by BP. The result is given in table 9.

Table 9: Hardness and Friability of Napa of blister-transparent package under sunlight

Tablet Hardness (kg/c^{m^2})	Mean tablet hardness (kg/c^{m^2}) $\pm SD$	Mean tablet friability (%)
1) 3.8 kg/cm^2	3.9 ± 0.338	Initial weight (Wi) = 580mg Final weight (Wf) = 570mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ = $\frac{580-570}{580}\times100$ = 1.7 %
2) 4.2 kg/cm^2		
3) 4.1 kg/cm^2		
4) 4.0 kg/cm^2		
5) 4.0 kg/cm^2		
6) 4.0 kg/cm^2		
7) 3.2 kg/cm^2		
8) 3.9 kg/cm^2		
9) 4.0 kg/cm^2		
10) 3.9 kg/cm^2		

The highest hardness value of Napa of blister-opaque package under room condition was recorded by no. 4, 6, and 10 tablet and mean hardness value was within the acceptable range. But tablet friability rate did not meet the BP requirement. The result is given in table 10.

Table 10: Hardness and Friability of Napa of blister-opaque package under room condition

Tablet Hardness (kg/c^{m^2})	Mean tablet hardness (kg/c^{m^2}) $\pm SD$	Mean tablet friability (%)
1) 4.2 kg/cm^2	4.12 ± 0.287	Initial weight (Wi) = 583mg Final weight (Wf) = 574mg % Friability= $\frac{(Wi-Wf)}{Wi}\times100$ = $\frac{583-574}{583}\times100$ = 1.5 %
2) 4.0 kg/cm^2		
3) 4.0 kg/cm^2		
4) 4.5 kg/cm^2		
5) 3.6 kg/cm^2		
6) 4.5 kg/cm^2		
7) 3.8 kg/cm^2		
8) 4.2 kg/cm^2		
9) 3.9 kg/cm^2		
10) 4.5 kg/cm^2		

In contrast, under sunlight the highest hardness value for the Parapyrol of blister-opaque package was recorded by no. 2 tablet and most of the tablets have least hardness value of 4.0 kg/cm^2. The mean hardness value met the standard, but the mean tablet friability was not within the acceptable limit specified by BP. The result is given in table 11.

Table 11: Hardness and Friability of Napa of blister-opaque package under sunlight

Tablet Hardness (kg/c^{m^2})	**Mean tablet hardness (kg/c^{m^2}) $\pm SD$**	**Mean tablet friability (%)**
1) 4.9 kg/ cm^2	4.32 ± 0.469	Initial weight (Wi) = 583mg Final weight (Wf) = 574mg % Friability = $\frac{(Wi-Wf)}{Wi} \times 100$ $= \frac{582-575}{582} \times 100$ = 1.2 %
2) 5.2 kg/ cm^2		
3) 4.0 kg/cm^2		
4) 4.5 kg/cm^2		
5) 4.0 kg/cm^2		
6) 4.8 kg/cm^2		
7) 3.5 kg/cm^2		
8) 4.2 kg/cm^2		
9) 4.1 kg/cm^2		
10)4.0 kg/cm^2		

The highest hardness value of Napa of strip package under room condition was recorded by no. 7 tablet and most of the tablets have least hardness value of 4.0 kg/cm^2.

The mean hardness value was also within the acceptable range. But tablet friability rate did not meet the BP requirement. The result is given in table 12.

Table 12: Hardness and Friability of Napa of strip package under room condition

Tablet Hardness (kg/cm^2)	**Mean tablet hardness (kg/cm^2) $\pm SD$**	**Mean tablet friability (%)**
1) 4.1 kg/cm^2	4.3 ± 0.697	Initial weight (Wi) = 589mg Final weight (Wf) = 582mg % Friability= $\frac{(Wi-Wf)}{Wi} \times 100$ $= \frac{589-582}{589} \times 100$ = 1.2 %
2) 4.0 kg/cm^2		
3) 4.0 kg/cm^2		
4) 3.1 kg/cm^2		
5) 5.1 kg/cm^2		
6) 5.2 kg/cm^2		
7) 5.3 kg/cm^2		
8) 4.1 kg/cm^2		
9) 3.9 kg/cm^2		
10) 4.0 kg/cm^2		

In contrast, under sunlight the highest hardness value for the Napa of blister-opaque package was recorded by no. 2 tablet and most of the tablets have least hardness value of 4.0 kg/cm^2.

The mean hardness value met the standard, but the mean tablet friability was not within the acceptable limit specified by BP. The result is given in table 13.

Table 13: Hardness and Friability of Napa of strip package under sunlight

Tablet Hardness (kg/cm^2)	**Mean tablet hardness (kg/cm^2) $\pm SD$**	**Mean tablet friability (%)**
1) 4.0 kg/cm^2	4.06 ± 0.157	Initial weight (Wi) = 579mg Final weight (Wf) = 571mg % Friability= $\frac{(Wi-Wf)}{Wi} \times 100$ $= \frac{579-571}{579} \times 100$ = 1.4 %
2) 4.4 kg/cm^2		
3) 4.0 kg/cm^2		
4) 4.0 kg/cm^2		
5) 4.0 kg/cm^2		
6) 3.9 kg/cm^2		
7) 4.0 kg/cm^2		
8) 4.0 kg/cm^2		
9) 4.0 kg/cm^2		
10) 4.3kg/cm^2		

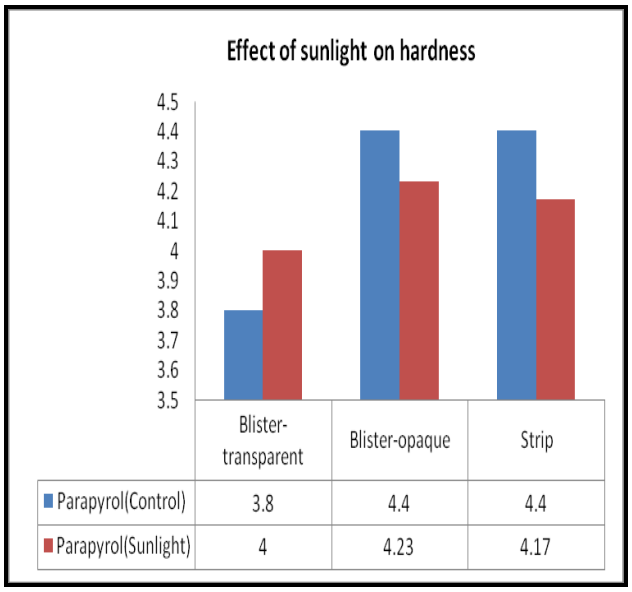

Figure 1: Effect of sunlight on mean hardness of Parapyrol

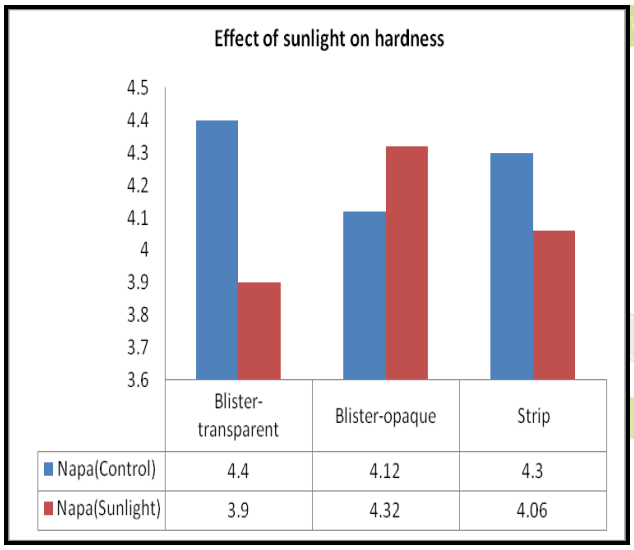

Figure 2: Effect of sunlight on mean hardness of Napa

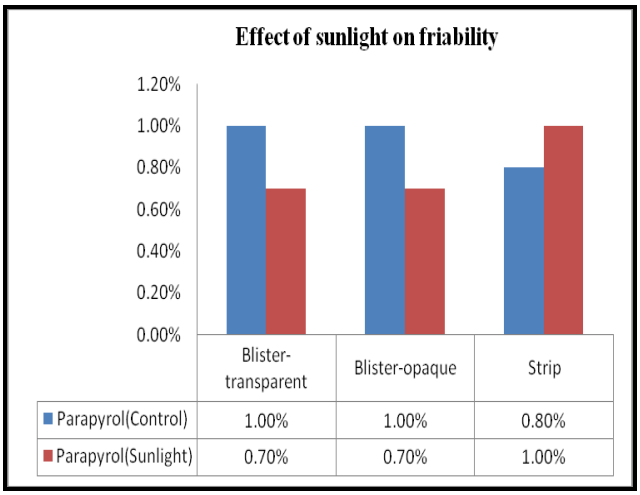

Figure 3: Effect of sunlight on friability of Parapyrol

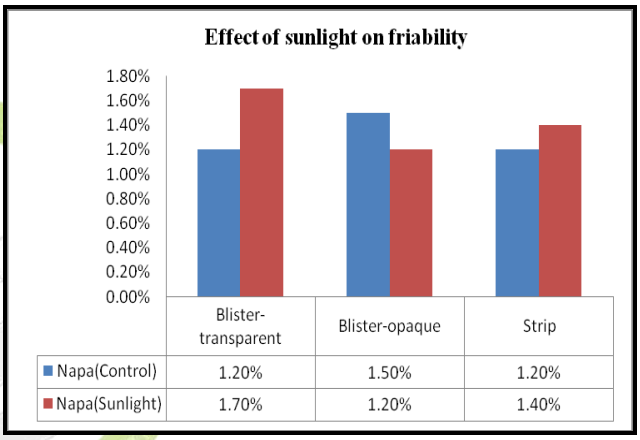

Figure 4: Effect of sunlight on friability of Napa

Disintegration Time

Disintegration time of both brands is almost same for blister-transparent, blister-opaque and strip packages under both control and sunlight condition. The result is shown in table 14.

Table 14: Disintegration time of both brands under control and sunlight

Brand	Blister-Transparent		Blister-Opaque		Strip	
	DT (mins)		DT (mins)		DT (mins)	
	Control	Sunlight	Control	Sunlight	Control	Sunlight
Parapyrol	2.6	2.5	2.5	2.5	2.4	2.5
Napa	1.2	1	1	1.2	1	59 Seconds

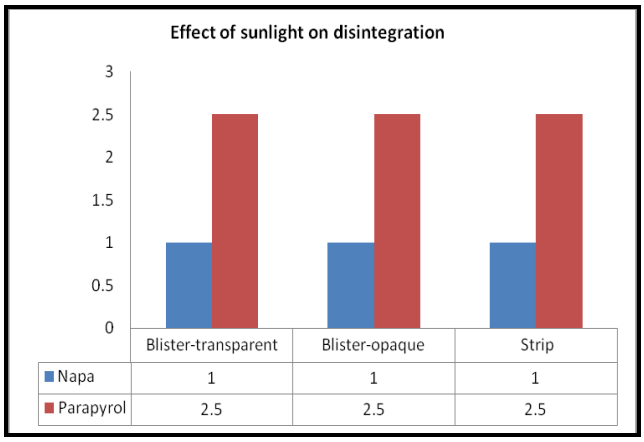

Figure 5: Effect of sunlight on disintegration of Parapyrol and Napa

Potency

Potency was determined by UV-Visible Spectrophotometric method. But according to the British Pharmacopoeia, the result of both brands was not varied significantly under both control and sunlight condition. Result is shown in below table 15.

Table 15: Effect of sunlight on different packaging systems of Parapyrol

Packaging system	Control	Sunlight
	Potency	Potency
Blister transparent	102 %	109.5 %
Blister opaque	109.6 %	110.7 %
Strip	103.7 %	109.8 %

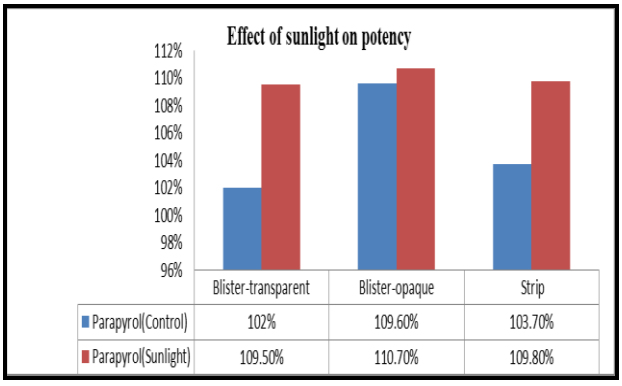

Figure 6: Effect of sunlight on potency of Parapyrol

Table 16: Effect of sunlight on different packaging systems of Napa

Packaging system	Control	Sunlight
	Potency	Potency
Blister transparent	109.3 %	107.7 %
Blister opaque	104.2 %	105 %
Strip	111.3 %	105.8 %

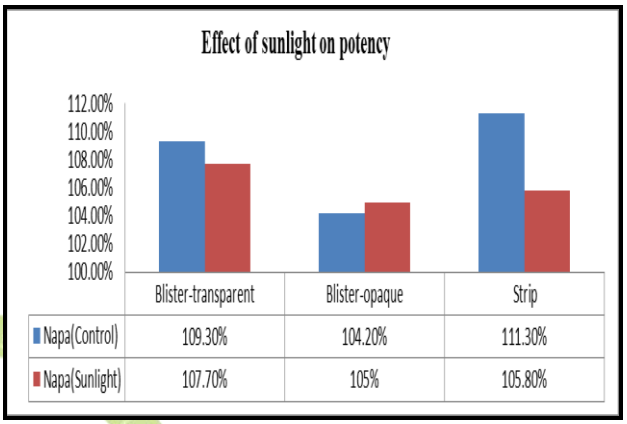

Figure 7: Effect of sunlight on potency of Napa

From the above result it is observed that no significant changes of physic-chemical properties of paracetamol occurred due to exposure of sunlight. In some cases, the result showed little change under exposure of sunlight as well as controlled condition. The assay of parapyrol brand was increased slightly under sunlight exposure than that of room condition whereas potency of Napa brand was reduced slightly under sunlight exposure than that of room condition. Although it was minute change, the reason may be due to we used separate set of sample for separate tests under room condition as well as sunlight exposure. The tablets were exposed under sunlight might have greater potency than that of the tablets under room condition because the potency changes under all conditions is very insignificant and within the specification. Another reason may be infinitesimal chemical interaction with the excipients used to stable the formulations of these different brands. This explanation can be presented both tests of hardness, disintegration time and friability.

The result would be more practical if we considered the same batch of each brand of paracetamol were subjected to tests which was not possible due to requirement of high quantity against the availability in the chemist shop. Another limitation can be mentionable that we exposed tablets under sunlight for day time for consecutive 30 days only not continuous exposure of 24 hours due to lack of sunlight at night.

If tablets were exposed under an electric lamp with the similar intensity of sunlight at the earth surface, the result could show the more empirical data of photodegradation.

CONCLUSION

Photodegradation of paracetamol was studied in the present work to investigate that whether the paracetamol is susceptible to photodegradation or not. The result of this investigation indicates that paracetamol is almost stable against photodegradation. Experiments found that minute changes occur in the physio-chemical property of paracetamol when it is subjected to direct sunlight.

These changes are negligible for both brands of paracetamol. It is also observed that paracetamol is photostable when it is packaged in blister-transparent (Alu-PVC), blister-opaque (Alu-PVDC) or strip (Alu-Alu) packages. From the findings of this investigation it can be clearly stated that there is no significant effect of sunlight on paracetamol of different packaging systems and this study declares paracetamol as a photostable drug.

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