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Research Article

QUANTITATIVE DEGRADATION MONITORING IN CORE AND ENTERIC COATED ASPIRIN TABLETS

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ABSTRACT

Aspirin is used as antipyretic, anti-inflammatory and analgesic drug. Core tablet is regular form of aspirin while enteric coated is designed to resist against gastric fluids thus, it gets dissolve in lower intestine without dissolving in stomach. In present report, comparative degradation in core and enteric coated aspirin tablets were monitored under specific conditions. They were exposed in both unpacked and packed forms to UV rays of shorter and longer wavelengths, kept in environment of relative humidity 35, 50 and 75 % and at temperature of 40, 50 and 60 ºC respectively. The exposition time was 24, 48 and 72 hours as to investigate the degradation pattern as a function of exposed time. Minimum degradation of 1.97% observed is for packed enteric coated tablets in 24hrs when exposed to longer wavelength and maximum degradation of 28.26% is observed for unpacked core tablet when exposed to shorter wave length. More pronounced effect on degradation was observed due to exposure to radiation and humidity as compared to temperature.

Keywords*:* Aspirin, UV-spectroscopy, Enteric coating, Degradation

INTRODUCTION

Aspirin or acetylsalicylic acid is a derivative of salicylic acid that is analgesic, antipyretic, and anti-inflammatory which is used in the relief of headache, muscle and joint pain. It works by restricting the production of prostaglandins and can be found in single-ingredient oral pain relievers, fever reducers or in medicines which contain more than one active ingredient [1]. Moreover, it is also available in medicines which are used to treat additional symptoms, such as occasional sleeplessness, stomach upset, heartburn, and the multiple common cold symptoms [2-5]. Core aspirin is usually taken and easy to dissolve is the regular and conventional form of aspirin. The other one "enteric coated" form is the coated form which is also known as "delayed release tablet". The enteric coated allows the aspirin to pass through the stomach without getting dissolve in it. Aspirin causes some gastric problem or irritation in stomach of many people, therefore, enteric coated is developed to circumvent this problem. The enteric coating prevents the release of drug until it has passed through the stomach, and then releases to the intestine and get dissolve there [6,7]. Aspirin is a substituted phenyl ester and it has good leaving group due to an aromatic ester since it is unstable in moist conditions therefore, it get easily hydrolyzed in weakly alkaline medium. Since pH is maintained to control the stability and composition of aspirin drug [8]. In moist conditions, aspirin undergoes autocatalytic degradation [9] forming salicylic acid. Increase in temperature may also leads to the degradation of that product. The aim of present project is to measure the comparative degradation rate of core and enteric coated aspirin tablets under different environmental conditions. It includes exposure to UV radiation of shorter and longer wavelength, temperature at 40, 50 and 60 ˚C and relative humidity ranging from 35, 50 and 75 % accordingly. The degradation of drug was monitored after 24, 48 and 72 hrs in both packed and un-packed forms carried out through UV spectrophotometer. The results indicate a distinct degradation pattern under the above mentioned conditions explaining the drug stability in core and enteric coated forms.

EXPERIMENTAL

Chemical and Reagents

All the chemical and reagents were purchased from Sigma Aldrich of analytical grade and used without any prior treatment. Core and enteric coated tablets were gifted by local pharmaceutical laboratory for proposed study.

Procedure

All standard solutions of core and enteric coated aspirin tablets were prepared in 0.1N H_2SO_4 due to its higher absorption coefficient as compared to methanol and 0.1N HCl. Since different tablets have different weight even in same batch therefore, the average weight is considered by taking weight of 20 tablets. As these tablets also contain excipients, so by the filtration of standard solution, excipients were filtered out. This excipient free standard solution was scanned on visible spectrophotometer at 228nm to measure their absorbance.

UV Exposure

Enteric coated and core tablets were exposed to UV radiations under UV lamp at longer (365 nm) and shorter (254nm) wavelengths in both covered and un-covered forms. Sample was taken out after 24, 48 and 72 hours for analysis.

Temperature Effect

Effect of temperature on the degradation of both types of tablets was studied at 40, 50 and 60 ˚C in covered and un-covered forms. The degradation rate was analyzed after 24, 48 and 72 hours through UV-visible spectrophotometer.

Humidity Exposure

Relative humidity effect on the degradation of drugs was evaluated by using different humidity levels i.e. 35, 50 and 75 % at constant temperature. Samples were analyzed after 24, 48 and 72 hours.

RESULTS AND DISCUSSION

Effect of UV exposure

These tablets were exposed to UV radiations at longer and shorter wavelengths in their packed (blister in case of enteric coated and tin foil in case of core tablet) and uncovered form. Exposure to shorter and longer wavelengths for extended times leads to the serious degradation of core tablet. Due to higher energy of shorter wavelength, aspirin drugs show more degradation at shorter wavelength as compared to at longer wavelength. At initial stages, less pronounced degradation was observed at longer wavelength however, with increase in time of exposure, degradation rate enhances. The higher degradation rate was noticed in core than in enteric coated since the core drug degrades more as compared to enteric coated drug. The enteric coated tablets were covered in

coated material which acts as barrier between UV rays and tablet powder and therefore, do not allow UV rays to pass through. While in core form, UV rays are directly interacting with drug and therefore, leading to enhanced degradation. The uncovered drugs degrade rapidly as compare to the covered ones due to the direct exposure of UV rays. Interestingly, degradation trend is almost the same in their packing and without the packing, however, the degradation rate is entirely different in core and enteric coated drugs. It also reveals that even blister packing is not suitable for complete protection from UV radiations. Complete results of degradation at longer and shorter wavelengths are presented as follow.

Table 1: Degradation pattern in core and enteric coated aspirin tablets in packed and un-packed forms when exposed to UV radiation of longer wavelength.

Drugs	**Core Aspirin Initial Absorbance = 0.598**		**Enteric Coated Aspirin Initial Absorbance = 0.609**	
	Un-packed			
Duration	**Abs.**	**Degradation**	**Abs.**	**Degradation**
After 24 hours	0.565	5.52 %	0.596	2.13 %
After 48 hours	0.535	10.53 %	0.579	4.92 %
After 72 hours	0.498	16.72 %	0.560	8.04 %
	Packed			
Duration	**Abs.**	**Degradation**	**Abs.**	**Degradation**
After 24 hours	0.571	4.51 %	0.597	1.97 %
After 48 hours	0.544	9.03 %	0.581	4.59 %
After 72 hours	0.512	14.38 %	0.568	6.73 %

Table 2: Degradation pattern in core and enteric coated tablets in packed and un-packed forms when exposed to UV radiation of shorter wavelength.

Drugs	**Core Aspirin Initial Absorbance = 0.598**		**Enteric Coated Aspirin Initial Absorbance = 0.609**	
	Un-packed			
Duration	**Abs.**	**Degradation**	**Abs.**	**Degradation**
After 24 hours	0.549	8.19 %	0.582	4.43 %
After 48 hours	0.489	18.23 %	0.554	9.03 %
After 72 hours	0.429	28.26 %	0.543	10.83 %
	Packed			
Duration	**Abs.**	**Degradation**	**Abs.**	**Degradation**
After 24 hours	0.560	6.35 %	0.587	3.61 %
After 48 hours	0.513	14.21 %	0.559	8.21 %
After 72 hours	0.476	20.40 %	0.548	10.01 %

Effect of Humidity

Humidity is the most important factor that plays critical role in deterioration of aspirin. As in humid environments, acetyl salicylic acid degrades rapidly into salicylic acid. At a relative humidity level of 35, 50 and 75 %, the enteric coated drug enteric coated tablets degrade less as compared to core aspirin tablet. Since salicylic acid could have serious effects on stomach of some people as if it gets in contact with stomach linings then it may cause severe reaction in stomach such as vomiting, allergic reactions, swelling and stomach bleeding. This is why enteric coated aspirin was designed to reduce these reactions as it does not get dissolve in stomach immediately. Enteric coating prevents tablets from hydrolysis while core being in uncoated form immediately degrades into salicylic acid. For both type of aspirin tablets the extent of degradation depend upon humidity level and time. The results of humidity studies are as follows.

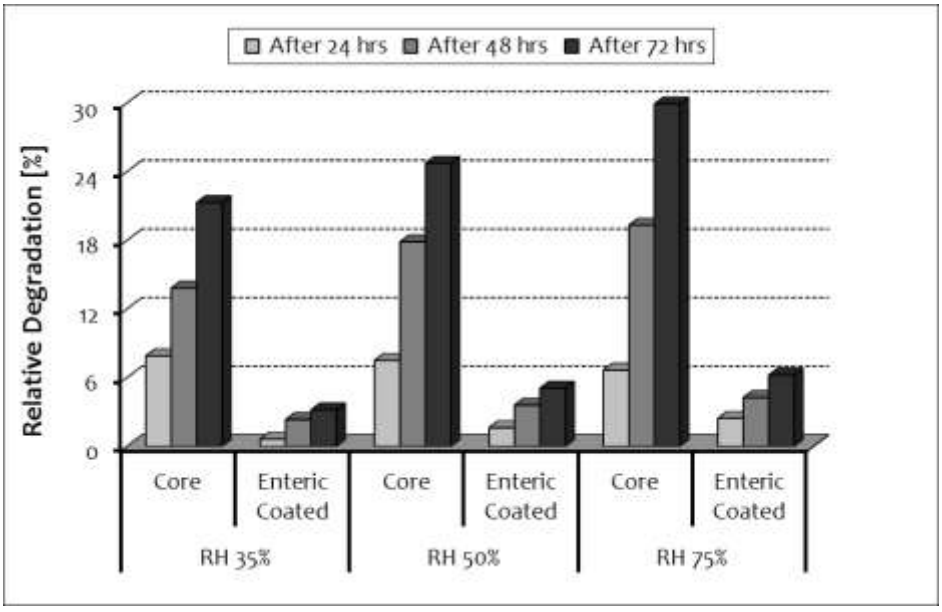

Fig. 1: Degradation rate in core and enteric coated tablets in covered and un-covered forms at 35, 50 and 75 % relative humidity.

Effect of temperature

Temperature has shown very minute effect on the degradation of aspirin in both core and enteric coated tablets. Maximum degradation about 8% in core was observed at 60 °C in unpacked form, while only 3% was noted in case of enteric coated. However this rate of degradation is negligible which indicates that aspirin in both form is stable against temperature. The complete results are presented in figure 2.

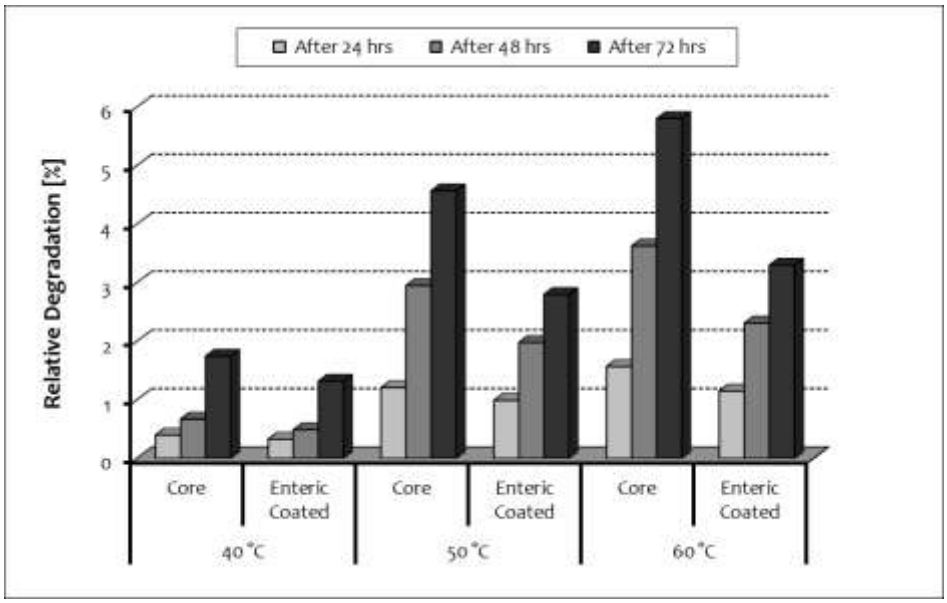

Fig. 2: Degradation rate in core and enteric coated aspirin tablets in covered and un-covered forms at 40, 50 and 60°C.

CONCLUSION

The stability of core and enteric coated aspirin tablet was investigated in this study. The results showed a distinct degradation pattern on exposing to UV radiations including shorter and longer wavelengths, and in humid environments. Higher degradation of aspirin was observed on exposure to shorter wavelength as compared to longer wavelength. Temperature above than the room temperature also contributes towards degradation of aspirin up to small effect. But keeping drugs above the room temperature for weeks may cause serious damage to aspirin. Enteric coated material protects aspirin from degradation since in all the cases core aspirin degrades more rapidly. Therefore, based upon this report, we can conclude that enteric coated aspirin is safer than core aspirin in all storage conditions and therefore, becomes first choice in place of simple core tablet.

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