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Degradation study of different brands of paracetamol by UV spectroscopy

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ABSTRACT

Objective: To investgate the forced degradation study for the determination of degradation of the drug substance.
Methods: Paracetamol was exposed to different conditions according to International Conference on Harmonization guideline. The amount of degradation product can be calculated with the help of UV spectrophotometer. The official test limits according to British Pharmacopoeia/United States Pharmacopoeia should not less than and should not more than lapelled amount. Forced degradation of drug substance was exposed to acidic and basic medium of panadol. Forced degradation of drug substance of panadol, disprol and calpol were also observed negligible difference in availability on exposure to UV and heat. This method can be used successfully for studying the stress degradation factors. Because this method is less time consuming and simple and cost effective also.
Results: The brands *i.e.* calpol, panadol and disprol, when they come in contact with different degradation parameters (before, acid, base, heat and UV treatments) according to statistical analysis, the result showed significant values ($P < 0.05$) which indicated that there was no degradation in any of the brand.
Conclusions: The result indicated there is no degradation found in these brands.

1. Introduction

One of the most common symptoms is pain and this is one of the most frequent reasons why people seek medical care. Therefore, it is not surprising that the analgesics are among the most widely used categories of drug. Hence, for the treatment of inflammation and pain, paracetamol is used, and chemically paracetamol (4-hydroxyacetanilide) is used. Paracetamol is a weak peripheral cycloxygenase inhibitor and from the inhibition of prostanoid synthesis in the central nervous system, analgesic effect of paracetamol may arise. Antipyretic effect of paracetamol is reported to inhibit prostaglandin synthesis at the level of the hypothalamus causing alteration in body temperature[1].

UV spectrophotometric method used for forced degradation studies have not been reported in Pakistan. In many laboratories, spectrophotometric method was used due to less equipment cost and economical maintenance advantages. By the help of this technique, the UV absorbance spectra are measured at 200–380 nm. In accordance with the International Conference on Harmonization guideline, the force degradation state of active pharmaceutical substance includes acidic, basic and photolytic conditions. For the estimation of forced degradation of a pharmaceutical ingredient, acid/base stress testing is performed. By exposure to acidic or basic medium over time to its chief degradation products, this test involves degradation of a drug substance. Acid/base hydrolysis take place in labile carbonyl functional groups which are amides (lactams), esters (lactones), aryl amines, imides, imines alcohols and carbamates. The technique is employed to recognize the raise in the degradation product and the consequent loss of pharmaceutical active component *i.e.* forced degradation is capable to indicate that the selected technique is a representative of stability[2].

The objective of this study was to analyze forced degradation studies by treating the different brands of bromazepam under hydrolytic (acidic and basic), photolytic and thermal stress

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conditions, by using spectrophotometer, as defined under International Conference on Harmonization guideline Q1A (R2). Because of economical maintenance advantage and less equipment cost, it is generally preferred over other methods.

We already performed these types of degradation studies which are useful for pharmacy profession[3-6].

Basic parameters for drug degradation studies are acid/base stress testing, humidity and with temperature, photo degradation.

Forced degradation of drug was performed with acidic and basic condition contact to its basic (monomer) degradation product. Degradation of drug product obtained by carbonyl functional groups include alcohol, carbamates, amides (lactam), aryl amine esters (lactones), imines and imides then hydrolysis of acid/base is carried out.

Forced degradation of drug substance in thermal/humidity environment was performed by exposing the drug product over long time which results in forceful degradation of drug substance to its primary components. By this process, testing of thermal/humidity stress degradation is carried out.

Forced degradation of drug substance in UV light was performed by exposing the drug substance to UV light. Drug substance which are naturally and synthetically polymer prepared become crack on exposing to UV light.

2. Materials and methods

2.1. Experimentation

Paracetamol brands used were panadol 500 mg tablets of GlaxoSmithKline Pakistan Limited, disprol 500 mg tablets of Reckitt benckiser Pakistan Limited and calpol 500 mg tablets of GlaxoSmithKline Pakistan Limited. Analytical reagent, 1 mol/L HCl and 1 mol/L NaOH, were used and water used was deionized filtered and double distilled. Pyrex type stirrer, measuring cylinder, pipette, funnel, beaker and volumetric flask were used. The glass ware after washing with chromic acid rinsed with water is freshly laboratory prepared, double distilled or deionzed. Instruments, UV lamp, weighing balance, spectrophotometer and water bath were used in this study.

2.2. Preparation of working solutions

2.2.1. Preparation of NaOH

In 100 mL volumetric flask, accurately 40 g NaOH was dissolved and to make up the volume up to 100 mL, deionized water was added.

2.2.2. Preparation of HCl

A total of 8.36 mL hydrochloric acid (37% 12 mol/L) was took accurately analytical grade in 100 mL volumetric flask to make up the volume up to 100 mL by adding deionized water.

2.2.3. Preparation of paracetamol solution

The tablets of each of the brands were weighed individually. Each brand of tablets was triturated in mortar pestle individually. Powder was equal to 20 mg of paracetamol. PDL (23.67 mg), DPL (22.90 mg), CPL (24.65 mg) were accurately weighed. In the 100 mL volumetric flask, all of 3 brands powders transferred individually. These powder samples were dissolved and shaked with water and finally more water was added to make up the volume up to 100 mL respectively for each sample. A total of 20 mg/100 mL concentration solution was preferably obtained. By using spectrophotometer at 294 nm wavelength individually all brands absorbance were determined.

2.3. Procedure for forced degradation studies

2.3.1. For acid

Forced degradation of drug substance in acidic media was performed by taking 5 mL of 20 mg/100 mL of PDL, DPL and CPL in 3 separated test tubes, then 5 mL of 1 mol/L HCl was added in each test tube. The sample was left for 30 min. Solution was transferred to a separated cuvette after the time period completion and UV absorbance of the solution was measured at the 294 nm wavelength.

2.3.2. For base

Forced degradation of drug substance in basic media was performed by taking 5 mL of 20 mg/100 mL solution of PDL, DPL and CPL in 3 separated test tubes, then 5 mL of water was added in each test tube and the sample was left for 30 min, and then UV absorbance of solution was measured at 294 nm wavelength.

2.3.3. For UV light

Forced degradation of drug substance in UV light was performed by taking the 5 mL of 20 mg/100 mL solution of PDL, DPL and CPL, then 5 mL of water was added in each test tube and these test tubes were exposed to UV light for 30 min, and then UV absorbance of solution was measured at 294 nm wavelength.

2.3.4. For heat

Forced degradation of drug substance in thermal/humidity environment was performed by taking 5mL of 20 mg/100 mL solution of PDL, DPL and CPL, then in each test tube, 5 mL of water was added and UV absorbance of solution was measured at 294 nm wavelength

2.4. Statistical analysis

The SPSS 19.0 version software was used for statistical analysis

of degradation of paracetamol and the Two-way ANOVA test was applied.

3. Results

We have conducted the degradation study on three brands of paracetamol using disprol 500 mg tablets of Reckitt benckiser Pakistan Limited, panadol 500 mg tablets of GlaxoSmithKline Pakistan Limited and calpol 500 mg tablet of GlaxoSmithKline Pakistan Limited. When paracetamol brands were treated with the 1 mol/L HCL, it showed availability of different brands. When paracetamol brands were treated with the 1 mol/L NaOH drugs, it showed the increased availability and absorbance respectively. When subjected to heat for 30 min, paracetamol showed no changes. When exposed to UV light, negligible changes had been observed respectively. Table 1 represents the UV absorption of different brands of the paracetamol before and after exposing to the degradation environment. We concluded according to our results that when the PDL introduced into acidic medium 1 mol/L HCL, it showed degradation to minor extension that is 99.543%; DPL showed degradation to moderate extension that is 99.672%; CPL also gave greater results on exposure to acidic medium (100%) respectively. Similarly on exposure to 1 mol/L NaOH basic medium, the PDL showed the moderate (100.388%) degradation whereas DPL showed degradation to minor extension that is 99.871% while CPL gave moderate results on exposure to basic medium (100.094%) respectively. When PDL (99.457%), DPL (993.389%) and CPL (99.934%) heated for 30 min and evaluated for degradation studies, it showed negligible changes in concentration respectively for degradation studies. When PDL (99.809%), DPL (99.587%) and CPL (99.680%) exposed to UV light for 30 min and evaluated for degradation studies, it also showed minor changes in concentration respectively for degradation studies. Results of degradation studies are given in Tables 1 and 2.

Table 1
Absorbance of different brands of paracetamol in percentage. %.

Treatments		1	2	3	Average
PDL	Before	99.669	99.834	100.497	100
	Acid treatment	99.544	100.228	100.293	100
	Base treatment	100.388	100.032	99.644	100
	Heat treatment	99.457	99.330	101.213	100
	UV treatment	99.809	100.032	100.222	100
CPL	Before	99.671	100.033	100.330	100
	Acid treatment	100.000	100.131	99.869	100
	Base treatment	100.095	99.779	100.126	100
	Heat treatment	99.935	100.195	99.870	100
	UV treatment	99.681	100.223	100.160	100
DPL	Before	99.672	100.033	100.295	100
	Acid treatment	99.673	100.393	100.000	100
	Base treatment	99.872	100.449	99.680	100
	Heat treatment	99.389	100.129	100.482	100
	UV treatment	99.588	100.349	100.095	100

Table 2
Absorbance of different brands of paracetamol.

Treatments		1	2	3	Average
PDL	Before	3.010	3.015	3.035	3.020
	After acid	3.055	3.076	3.078	3.069
	After base	3.102	3.091	3.079	3.090
	After heat	3.115	3.111	3.17	3.132
	After UV	3.143	3.150	3.156	3.149
CPL	Before	3.025	3.036	3.045	3.035
	After acid	3.065	3.069	3.061	3.065
	After base	3.167	3.157	3.168	3.164
	After heat	3.074	3.082	3.072	3.076
	After UV	3.124	3.141	3.139	3.134
DPL	Before	3.042	3.053	3.061	3.052
	After acid	3.044	3.066	3.054	3.054
	After base	3.117	3.135	3.111	3.121
	After heat	3.093	3.116	3.127	3.112
	After UV	3.139	3.163	3.155	3.152

4. Discussion

Our hypothesis was that when all the brands of paracetamol were exposed to different degradation parameters, there will be no degradation in the active ingredient of the brands of paracetamol. The brands *i.e.* CPL, PDL and DPL when they come in contact with different degradation parameters (before, acid, base, heat and UV) according to statistical analysis showed significant values $P < 0.05$, which indicated that there was no degradation in any of the brand.

According to specification of United State Pharmacopoeia, the content official limit of not less than (98%) and not more than (101%) the labeled amount. We have concluded from our studies that paracetamol more degrades in acidic and basic medium. Whereas little degradation also arises with time. While in UV and heat paracetamol, it shows negligible degradation effect.

Conflict of interest statement

We declare that we have no conflict of interest.

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