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DEGRADATION STUDIES OF CEFUROXIME TABLET BY USING SPECTROPHOTOMETRIC TECHNIQUES

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ABSTRACT

Forced degradation is a process whereby the natural degradation rate of a product is increased by the application of additional stress. A forced oxidative degradation study of Cefuroxime in tablet form was performed. The study was conducted based on available guidelines and main reference. Cefuroxime has a cepham ring in its structure. It can easily undergo hydrolytic, oxidative, thermal & photolytic degradation and the degraded products were analyzed by using UV spectrophotometry. The assay values of degraded products in different time intervals were analyzed by using UV spectrophotometry. Forced degradation was performed in tablet form using 0.1N Sodium hydroxide, 0.1N Hydrochloric acid, 30% Hydrogen peroxide solution respectively. Cefuroxime was subjected to hydrolytic, oxidative, photolytic and thermal degradation at different time intervals based on reference. The assay value of hydrolytic degradation of sample using 0.1N Sodium hydroxide was found to be 70.44% at the end of the 90 mins and 21.88% at the end of 1st day degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. The assay value of hydrolytic degradation sample using 0.1N Hydrochloric acid was found to be 70.94% at the end of the 90 mins and 18.64% at the end of 1st day degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. The assay value of oxidative degradation sample using 30% Hydrogen peroxide was found to be 67.90% at the end of the 90 mins and 59.12% at the end of 1st day degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. In Thermal degradation only small amount of degradation was observed up to 5th

day. It shows that sample exhibit stability against thermal degradation. At the end of the 5th day the assay value of sample was found to be 75.33% respectively. In Photolytic degradation also small amount of degradation was observed up to 5th day. It shows that sample exhibit stability against sunlight. At the end of the 5th day the assay value of sample was found to be 72.88% It was concluded that Cefuroxime was found unstable under hydrolytic and oxidative condition while is stable under thermal and photolytic degradation.

KEYWORDS: Cefuroxime, Hydrolytic degradation, Oxidative degradation, Thermal and Photolytic degradation.

INTRODUCTION

Forced Degradation studies are used to identify reaction which may occur to degrade a processed product; usually conducted before final formulation, forced degradation uses external stresses to rapidly screen material stabilities. Cefuroxime is indicated for the prophylaxis and treatment of infections caused by bacteria susceptible to this particular form of antibiotic. There are very few reported methods for analysis of degradation product of Cefuroxime are selected for the study. Forced Degradation study is carried out to demonstrate the specificity when developing stability indicating method and to help identify reaction that causes degradation of pharmaceutical product.[2] Cefuroxime was found to be a ring opening degradation product because of presence of lactam and amide linkage.[7] A forced degradation study of Cefuroxime axetil has been carried out under alkali and acidic condition using 0.1N NaOH and 0.1N HCl respectively and thermal and photolytic by UV spectrophotometry.[1]

MATERIALS AND METHODS

Apparatus

Shimadzu 1800 UV visible spectrophotometer equipped with 1cm matched quartz cells was used in present study for absorbance measurements and all the determinations were carried out at room temperature.

Reagents and Materials

- Cefuroxime tablets was purchased from medical shop (Cexil 2G - 250mg).
- All chemicals and reagents used were of analytical grade and double distilled water was used throughout the investigation.
- 0.1N NaOH, 0.1N HCl and 30% H_2O_2 was prepared according to I.P.1996

METHODS

Forced Hydrolytic Degradation Using 0.1N NaOH (Intraday Study) Standard preparation

Cefuroxime was transferred to volumetric flask and dissolved in ethanol to achieve a concentration of 1mg/mL; an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm.[8]

Sample preparation (stress)

Cefuroxime was transferred to volumetric flask and dissolved in 10 mL of ethanol to dissolve the drug substance, and then 0.1N NaOH was added to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm. The same procedure was repeated for 60mins, and 90mins time interval.

Blank preparation

A blank solution of 0.1N NaOH solution was prepared in a similar manner. The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 278nm against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated.

Table 1: Results Obtained from Hydrolytic Degradation 0.1 N NaOH (Intraday studies).

Stress condition (Alkali hydrolysis)	Time (Mins)	Sample Percentage Content (%)	Remarks
0.1 N Sodium Hydroxide	30	84.40	Degradation observed
	60	75.73	Degradation observed
	90	70.44	Degradation observed

Forced Hydrolytic Degradation Using 0.1N NaOH (Interday Study) Standard preparation

The standard preparation was prepared in a similar manner which was mentioned in an intraday preparation.

Sample preparation (stress)

Same method was followed, but the final solution was scanned and absorption was recorded at the following time intervals 1st, 3rd, and 5th day.

Blank preparation

Similar to intraday preparation.

Table 2: Results Obtained from Hydrolytic Degradation 0.1 N NaOH (Interday studies).

Stress condition (Alkali hydrolysis)	Time (Mins)	Sample Percentage Content (%)	Remarks
0.1 N Sodium Hydroxide	1st day	21.88	Degradation observed
	3rd day	0	Complete Degradation
	5st day	0	Complete Degradation

Forced Hydrolytic Degradation Using 0.1N HCl (Intraday Study) Standard preparation

Cefuroxime was transferred to volumetric flask and dissolved in ethanol to achieve a concentration of 1mg/mL; an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm.[8]

Sample preparation (stress)

Cefuroxime was transferred to volumetric flask and dissolved in 10 mL of ethanol to dissolve the drug substance, and then 0.1N HCl was added to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm. The same procedure was repeated for 60mins, and 90mins time interval.

Blank preparation

A blank solution of 0.1N HCl solution was prepared in a similar manner. The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 278nm against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated.

Table 3: Results Obtained from Hydrolytic Degradation 0.1N HCl (Intraday studies).

Stress condition (Acid hydrolysis)	Time (Mins)	Sample Percentage Content (%)	Remarks
	30	87.24	Degradation observed
0.1 N Hydrochloric acid	60	80.06	Degradation observed
	90	70.94	Degradation observed

Forced Hydrolytic Degradation Using 0.1N HCl (Interday Study) Standard preparation

The standard preparation was prepared in a similar manner which was mentioned in an intraday preparation.

Sample preparation (stress)

Same method was followed, but the final solution was scanned and absorption was recorded at the following time intervals 1st, 3rd, and 5th day.

Blank preparation

Similar to intraday preparation.

Table 4: Results Obtained from Hydrolytic Degradation 0.1N HCl (Interday studies).

Stress condition (Acid hydrolysis)	Time (days)	Sample Percentage Content (%)	Remarks
	1st day	18.64	Degradation observed
0.1 N Hydrochloric acid	3rd day	0	Complete Degradation
	5st day	0	Complete Degradation

Forced Oxidative Degradation using 30% H2O2 (Intraday Study) Standard preparation

Cefuroxime was transferred to volumetric flask and dissolved in ethanol to achieve a concentration of 1mg/mL; an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm.[8]

Sample preparation (stress)

Cefuroxime was transferred to volumetric flask and dissolved in 10 mL of ethanol to dissolve the drug substance, and then 30% Hydrogen peroxide was added to achieve a concentration of 1mg/mL. After 30mins, an aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The solution was scanned in the UV region and the maximum absorbance was recorded at 278nm. The same procedure was repeated for 60mins, and 90mins time interval

Blank preparation

A blank solution of 30% H2O2 solution was prepared in a similar manner. The procedure was repeated thrice. After the stipulated time, the absorption of the resulting solution showed maxima 278nm against reagent blank treated in the same way. Three such determinations were made and the assay value was estimated.

Table 5: Results Obtained from Oxidative Degradation using 30% H2O2 (Intraday studies).

Stress condition (Oxidation)	Time (Mins)	Sample Percentage Content (%)	Remarks
	30	86.19	Degradation observed
30% Hydrogen peroxide	60	74.74	Degradation observed
	90	67.90	Degradation observed

Forced Oxidative Degradation Using 30% H2O2 (Interday Study) Standard preparation

The standard preparation was prepared in a similar manner which was mentioned in an intraday preparation.

Sample preparation (stress)

Same method was followed, but the final solution was scanned and absorption was recorded at the following time intervals 1st, 3rd, and 5th day.

Blank preparation

Similar to intraday preparation.

Table 6: Results Obtained from Oxidative Degradation using 30% H2O2 (Interday studies).

Stress condition (Oxidation)	Time (days)	Sample Percentage Content (%)	Remarks
	1st day	59.12	Degradation observed
30% Hydrogen peroxide	3rd day	0	Complete Degradation
	5st day	0	Complete Degradation

Forced Thermal Degradation at 50^0C (Interday Study) Sample preparation (stress)

Cefuroxime tablets were crushed weighed and transferred to a petri dish. This petri dish was placed in a hot air over at the temperature of 50ºC. The next day 50mg equivalent of Cefuroxime tablet powder was weighed from a petri dish and transferred to 50mL volumetric flask. It was dissolved in ethanol and the volume made up to 50mL. An aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The same procedure was repeated for 3rd and 5th day.

Blank preparation

Distilled water was used as a blank.

Table 7: Results Obtained from Thermal Degradation at 50^{0}C (Interday studies).

Stress condition (Thermal)	Time (days)	Sample Percentage Content (%)	Remarks
	1st day	95.59	Degradation observed
50^{0}C	3rd day	83.78	Degradation observed
	5st day	75.33	Degradation observed

Photolytic degradation using sunlight

Cefuroxime tablets were crushed weighed and transferred to a petri dish. This petri dish was placed under a sun light. The next day 50mg equivalent of Cefuroxime was taken from the petri dish and transferred to 50mL volumetric flask. It was dissolved in ethanol and the volume made up to 50mL. An aliquot solution was diluted with distilled water to get a final concentration of 10µg/mL. The same procedure was repeated for 3rd and 5th day.

Blank preparation

Distilled water was used as a blank.

Table 8: Results Obtained from Photolytic Degradation using Sunlight (Interday studies).

Stress condition (Photolytic)	Time (days)	Sample Percentage Content (%)	Remarks
	1st day	94.91	Degradation observed
Sunlight	3rd day	88.17	Degradation observed
	5st day	72.88	Degradation observed

RESULTS AND DISCUSSION

- **Hydrolytic Degradation using 0.1N NaOH (Intraday and Interday)**

In intraday and interday hydrolytic degradation drug sample showed extensive degradation. The assay value of hydrolytic degradation of sample using 0.1N Sodium hydroxide was found to be 70.44% at the end of the 90 mins (Intraday) and 21.88% at the end of 1st day (Interday) degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. The study results indicated that Cefuroxime was unstable under alkali hydrolysis condition.

- **Hydrolytic Degradation using 0.1N HCl (Intraday and Interday)**

In intraday and interday hydrolytic degradation drug sample showed extensive degradation. The assay value of hydrolytic degradation of sample using 0.1N Hydrochloric acid was found to be 70.94% at the end of the 90 mins (Intraday) and 18.64% at the end of 1st day (Interday)

degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. The study results indicated that Cefuroxime was unstable under acid hydrolysis condition.

- **Oxidative Degradation using 30% H2O2 (Intraday and Interday)**

In intraday and interday hydrolytic degradation drug sample showed extensive degradation. The assay value of oxidative degradation sample using 30% Hydrogen peroxide was found to be 67.90% at the end of the 90 mins (Intraday) and 59.12% at the end of 1st day (Interday) degradation. Complete degradation of Cefuroxime was observed at the end of 3rd day onwards. The study results indicated that Cefuroxime was unstable under oxidative condition.

Thermal Degradation at 50^0C

In Thermal degradation only small amount of degradation was observed up to 5th day. At the end of the 5th day the assay value of sample was found to be 75.33% respectively. It shows that sample exhibit stability against thermal degradation.

- **Photolytic Degradation using Sunlight**

In Photolytic degradation also small amount of degradation was observed up to 5th day. At the end of the 5th day the assay value of sample was found to be 72.88%. It shows that sample exhibit stability against sunlight.

CONCLUSION

The forced degradation studies (Hydrolytic, Oxidative, Thermal and Photolytic) of Cefuroxime tablets was studied by UV visible spectroscopy at various time intervals 30mins, 60mins, 90mins (Intraday) and 1st, 3rd, 5th day (Interday). Finally, it was concluded that Cefuroxime was found to be unstable under hydrolytic and oxidative condition while it is stable under thermal and photolytic degradation.

REFERENCES

1. Jain Pritam, Patel Manish, Surana Sanjay Development and validation of UV Spectrophotometric method for determination of Cefuroxime axetil in bulk and in Formulation International Journal of Drug Development & Research, October-December 2011; 3(4): 0975-9344.
2. Deepti Jain a, Pawan Kumar Basniwa, Forced degradation and impurity profiling: Recent trends in analytical perspectives, Journal of Pharmaceutical and Biomedical Analysis,

2013; 86: 11–35.

3. M Blessy, Ruchi D Patel, Prajesh N Prajapati, Y.K. Agrawal, Development of forced degradation and stability indicating studies of drugs, Journal of Pharmaceutical Analysis.
4. Game.M.D. D*, D.M. Sakarkar, K.B. Gabhane and K.K. Tapar, Validated Spectrophotometric Methods for the Determination of Cefuroxime Axetil in Bulk Drug and Tablets, Indian Journal Chemical Technology, 2010; 2(2).
5. Shinde M V, Pishawikar S A, More H N. Spectrophotometric Determination of Cefuroxime Axetil From Bulk and in Its Tablet Dosage Form. Indian Journal of Pharmaceutical Sciences, 2008; 70249-51.
6. Saranjit Singh, Mahendra Junwal, Gajanan Modhe, Harsita Tiwari, Moolchand Kurmi, Neha Parashar, Padmaja Sidduri, Forced degradation studies to assess the stability of drugs and products, Trends in Analytical chemistry, 2013; 49: 71–88.
7. Saranjit Singh and Monika Bakshi; Guidance on Conduct of Stress Tests to Determine Inherent Stability of Drugs Pharmaceutical Technology On-Line, April 2000; 1-14.
8. Dr. Hildegard Brummer: How to approach a forced degradation study, Life science Technical Bulletin Issue No 31/ January 2011.
9. Indian Pharmacopoeia, 2010; 1026-1028.
10. Sharma BK. Instrumental methods of chemical analysis, Meerut: Goel Publishing House, 2000; 19: 1-4.
11. Connors KA. A Textbook of Pharmaceutical Analysis, Delhi: Wiley Intersciences Inc, 1994; 3: 1-3.