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"COMPARATIVE STABILITY OF MARKET SAMPLE OF CEFIXIME ORAL SUSPENSION"

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Abstract: *Stability testing is now the key procedural component in the pharmaceutical development program for a new drug as well as new formulation. Stability tests have been carried out so that recommended storage conditions and shelf life can be included on the label to ensure that the medicine is safe and effective throughout its shelf life. Stability of a material or product to maintain a stated property value within specified period of time when stored under specific conditions is very significant for drug products. Cefixime $C_{16}H_{15}N_5O_7S_2$ for oral suspension (50 mg/5ml) a third generation cephalosporin (Cefixime) used for the treatment of various types of infections. Using HPLC method, the concentrations of Cefixime trihydrate brands, X, Y and Z at zero time were within the pharmacopial limit when reconstituted with distilled, decreases gradually with time and the reaction followed first order kinetics.*

Keywords: Cefixime trihydrate, suspension, stability, market.

1. INTRODUCTION

Stability testing of pharmaceutical products is a complex set of procedures involving considerable cost, time consumption and scientific expertise in order to build in quality, efficacy and safety in a drug formulation. Stability testing thus evaluates the effect of environmental factors on the quality of the a drug substance or a formulated product which is utilized for prediction of its shelf life, determine proper storage conditions and suggest labelling instructions used for packaging[1-4] . In oral suspension the reconstituted drug substances is very critical, because within the stability period drug can be utilized, so fixation of durability of reconstituted sample is very important[5,].

Cefixime oral suspension contain the equivalent of not less than 80 % and not more than 120 % of labelled amount of Cefixime after 5 days of reconstitution when stored in Refrigerator (2 to 8 °C) and 40°C ± 2°C &75 % RH ± 5% and 25°C ± 2°C & 60 % RH ± 5%.

The chemical reactions like solvolysis, oxidation, reduction, racemization etc. that occur in the pharmaceutical products may lead to the formation of degradation product, loss of potency of activepharmaceutical ingredient (API), loss of excipient activity like antimicrobial preservative action and antioxidants etc.[7-10].

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2. MATERIALS AND METHODS:

2.1.Chemicals: Tetrabutylammonium hydroxide (10% aqueous solution), Acetonitrile (HPLC Grade), HPLC grade water (Milli Q or equivalent), Orthophosphoric acid (AR grade).

2.2. Mobile Phase Preparation: 6.5 pH Buffer: Tetrabutylammonium hydroxide solution: Dilute 25 ml 10% Tetrabutylammonium hydroxide solution with water to obtain 1000 ml of solution and adjust the pH to 6.5 with 1.5 M phosphoric acid.

Mobile Phase:Prepare a mixture of Acetonitrile, Buffer and Water in the ratio 40: 10: 50. Filter and degas. Adjust the pH to 5.0 ± 0.1 using 1 M phosphoric acid.

2.3. Experimental Methods: The Three Brands (X, Y & Z) of Market Sample Were Reconstituted With Distilled Water and Stored at 25°C and 40°C for Seven Days Period and simultaneously the same sample has kept at 2 to 8°C in refrigerator and the result illustrated in table 1 & 2. The analytical method were same for all the brand and storage condition.

Instrumentation:	
Column C-18 DB)	**: 250 mm x 4.6 mm x 5 µm, ODS (preferably Supelco 516)**
Flow rate	**: 1.5 ml/min**
Detector	**: UV-VIS**
Wavelength	**: 220 nm**
Injection Volume	**: 20 µl.**
Column Temperature	**: 30°C**

3.0 RESULT AND DISCUSSION:

The results of stability study show that the concentration of Cefixime trihydrate for three brand X,Y and Z collected from market at zero time were found within the pharmacopoeial limit and when reconstituted with distilled water and stored at different storage conditions decreases gradually with time.As illustrated in Table -1 , the concentration of Cefixime of reconstituted oral suspension stored at 40°C decreases gradually from 108.0 % to 68.3 %, 103.5 % to 58.9 % and 109.6 % to 52.9 % of brand X,Y and Z respectively and become out of pharmacopoeial specification limit on day 3. Similarly the concentration of Cefixime at 25°C or normal room conditionbecome out of specification limit on day 5 for brand X,Y and Z as % assay decreasing and become out of specification at day 6 below 80 % of cefixime content. The same reconstituted sample when stored at temperature below 25°C and keep for seven days in refrigerator at temperature 2 to 8°C the % assay found satisfactory and within specification limit up to seven days illustrated in table 2.

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Table 1: Assay % Result of Cefixime Oral Suspension (Reconstituted)

Test Interval	Brand X 40 °C	Brand Y 40 °C	Brand Z 40 °C	Brand X 25 °C	Brand Y 25°C	Brand Z 25 °C
0 Day	108.0 %	103.5 %	109.6 %	108.0 %	103.5 %	109.6 %
Day 1	99.0 %	99.6 %	99.8 %	105.2 %	108.6 %	105.9 %
Day 2	90.3 %	86.9 %	85.3 %	99.6 %	97.8 %	101.3 %
Day 3	78.6 %	76.9 %	73.8 %	97.8 %	98.5 %	99.7 %
Day 4	76.9 %	81.9 %	76.2 %	96.3 %	96.3 %	95.8 %
Day 5	83.6 %	75.2 %	71.6 %	83.5 %	81.8 %	86.9 %
Day 6	73.5 %	71.8 %	64.3 %	79.6 %	78.9 %	74.7 %
Day 7	68.3 %	58.9 %	52.9 %	69.8 %	70.7 %	68.6 %

Table 2: Assay % Result of Cefixime Oral Suspension (Reconstituted)

Test Interval	Brand X 2 to 8 °C	Brand Y 2 to 8 °C	Brand Z 2 to 8 °C
0 Day	108.0 %	103.5 %	109.6 %
Day 1	107.9 %	103.0 %	108.9 %
Day 2	106.5 %	103.9 %	107.5 %
Day 3	103.0 %	102.4 %	105.9 %
Day 4	101.9 %	101.2 %	104.3 %
Day 5	102.3 %	100.9 %	103.6 %
Day 6	101.7 %	101.9 %	102.9 %
Day 7	100.9 %	101.2 %	101.3 %

4. CONCLUSION:

Usually the temperature has a pronounced effect on drug stability and a rise in temperature increases the frequency of collision of the reactants molecules and hence increase the degradation, while a decrease in temperature reduce collision and reduce degradation with confirm results within specification obtain. We can conclude that the Cefixime suspension reconstituted with distilled water are affected by an increase in temperature, so it should be store below the room temperature and at best and longer time for use at 2 to 8°C in refrigerator.

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