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QUALITY EVALUATION AND COMPARATIVE STUDY ON TABLET FORMULATIONS OF DIFFERENT PHARMACEUTICAL COMPANIES

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ABSTRACT

Tablet design and post-formulation quality monitoring requires quantitative evaluations and assessments of tablet's chemical, physical and bioavailability properties. The present work reports the comparative study and quality evaluation of tablets formulated by two different pharmaceutical companies. Niacinamide, ferrous fumerate, paracetamol in combination with ibuprofen, nimesulide and ciprofloxacin of 'X' and 'Y' companies (renamed) were collected for quality analysis and evaluation. The tablets were subjected to various post-production tests such as hardness, friability and dissolution rate following standard Indian pharmacopeia procedures. With the experimental observations recorded, various plots have been made to correlate the test parameters. From the analysis of the results, it was observed that there was no much variation in the dissolution rates but there was a considerable variation in the pattern of hardness and friability of tablets of the two companies because of change in recipients and other drugs. From the comparative analysis, it was observed that the quality of 'Y' company formulations have good agreement with the literature and can be concluded to be more reliable.

Key words: Tablets, Hardness, Friability, Dissolution rate, Quality evaluation and recipients.

INTRODUCTION

Tablets and capsules represent unit dosage forms whereas liquid oral dosage forms such as syrups, suspensions, emulsions, solutions and elixirs usually contain one dose of medication in 5 to 30 mL. Such doses are erratic by a factor ranging from 20 to 50% when the drug is self administered by the patient[1]. The oral route of drug administration is the most important method for systemic effects. The parenteral route is routinely used in insulin therapy for self-administration of medication. The topical route of administration has only recently been employed with nitro-glycerine for the treatment of angina and scopolamine for motion sickness, but it suffers from effective drug absorption for systemic drug action[2] of drugs that are administered orally, solid oral dosage forms (tablet and capsule) are the preferred class of products of the two forms, the tablet has a number of advantages such as the tablet is an essentially tamper proof dosage form[3]. The standard quality control tests such as diameter, size and shape, uniformity of weight, thickness, hardness, friability, percentage of medicament (Assay), rate of disintegration, dissolution and solubility can be carried out on compressed tablets for their evaluation[4]. In the current work, five different drugs of tablets from each of the companies X and Y were collected and subjected for the quality control tests: hardness, friability and dissolution rate in order to study the effect of composition of formulations in drug release rate.

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Literature review

Kakkar[5] prepared discrete free flowing micro-capsules of Ibuprofen having good spherical geometry and smooth surface using sodium alginate as coating material and calcium chloride as gelling agent. Results of studies showed that mean diameter recovery, encapsulation efficiency, wall thickness, size distribution and release characteristics of micro-capsules were influenced by sodium alginate concentration. Surface characteristics of micro-capsules were investigated by Scanning Electron Microscopy. Vatsa and Marwah[6] used a method of orthogonal polynomials in estimation of ciprofloxacin in pharmaceutical dosage forms. The quadratic polynomial coefficient was computed by measuring the florescence of the drug in 0.01 N hydrochloric acid at 10 points equally spaced at 5 nm levels with an emission spectrum from 125 to 170 nm the quadratic polynomial coefficient was observed to be directly proportional to the concentration in the range 0.5 to 2.0 mcg. Nagoji and Rao[7] developed two new spectrometric methods for the estimation of Nimesulide. Nimesulide produces yellow colour with 0.2 N acetic acid and 0.2 N sodium carbonate and shows maximum absorbance at the wavelengths of 431 nm and 433 nm respectively. The drug in the formulations is estimated by two methods A and B. In the method A the drug in the formulations is directly dissolved in 0.2 N acetic acid and estimated. In method B the drug in the formulations is directly dissolved in 0.2 N sodium carbonate and estimated. The results obtained by both the methods are compared with those obtained by the reported U.V. spectrophotometric method. Both methods obey Beer's law in the concentration range of 1 to 30 micro-gram per mL. Murthy and Chowdhary[8] evaluated four commercially available brands of nimesulide (ABC & D) in the Indian market for four in vitro parameters viz. uniformity of weight, disintegration, drug assay and dissolution. The results of the investigation revealed that all though all the tablets fulfilled all official specifications including dissolution rate. Most products however differed in dissolution profile as well as disintegration time all most all the products follow first order kinetics.

Materials and methods

Materials

From each of the companies the following tablets were collected and the quality control tests were carried out.

Company X

(a) **Floriguard - B** (coated) consisting of niacinamide, (b) **Glyziron - C** (coated) consisting of ferrous Fumerate, (c) **I.P.M. forte** (uncoated) consisting of paracetamol and Ibuprofen, (d) **Nimsun** (uncoated) consisting of nimesulide and (e) **Ciprosun** (film coated) consisting of ciprofloxacin.

Company Y

(a) **Neurosol** (coated) consisting of niacinamide, (b) **Redisules** (coated) consisting of ferrous fumerate, (c) **Fencin–M.R** (uncoated) consisting of paracetamol and ibuprofen, (d) **Nimesulide** (Uncoated) consisting of nimesulide and (e) **Mitycip – 500** (Coated) consisting of ciprofloxacin.

Instruments

Monsanto Hardness tester, Disintegration apparatus B. P. standard (Campbell), Electronic balance (DHONE).

Chemicals

Phosphate buffer solution, 0.1 N Hydrochloric acid, Glacial acetic acid, Ceric Ammonium sulphate, Perchloric acid, Sodium hydroxide, 95% Ethanol.

Methods

Hardness test

Hardness can be defined as the strength of the tablet to withstand the pressure applied. The tablet to be tested was held between a fixed and a moving jaw of Monsanto Hardness Tester. The force applied to the edge of the tablet was gradually increased by moving the screw knob forward until the tablet breaks. The reading was noted from the scale which indicates the pressure required to break the tablet. The hardness of a tablet depends on the weight of the material used, space between the upper and lower punches at the time of compression and pressure applied during compression. The hardness also depends on the nature and quantity of recipients 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 handing during packing and transporting[9].

Friability test

Friability test can be performed to evaluate the ability of the tablets to withstand abrasion in packing, handling and transporting. The Friabulator consists of a plastic chamber divided into two parts and revolves at 25 rpm. A fixed number of tablets are weighed, placed in the tumbling chamber and rotated for four minutes of 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. The loss in weight indicates the friability. The acceptable limits of weight loss should not be more than 0.8% t. The friability (f) is given by: $f = 100 (1-w_o/w)$, where, w_o = initial weight of the sample before friability and w = weight of the samples after friability test[10].

Dissolution test

Stated volume of the dissolution medium, free from dissolved air was introduced into the vessel of the apparatus. The dissolution medium was warmed between 36.5^o and 37.5^o. The tablet was allowed to sink to the bottom of the vessel prior to the rotation of the paddle. Wire helix was used to keep the tablet horizontal to avoid floating at the bottom of the vessel. Air bubbles were removed from the surface of the tablet. A sample from the surface of the dissolution medium was withdrawn, analysed for absorbance as directed in the standard monograph using spectrophotometer. The whole operation was repeated for five times and the amount of dissolved active ingredient of the tablet in the solution as a percentage of the stated amount was calculated[11].

RESULTS AND DISCUSSION

In our present study, tablets of niacinamide, ferrous fumerate, and paracetamol in combination with ibuprofen, nimesulide and ciprofloxacin of two different pharmaceutical companies 'X' and 'Y' were used. The basic drugs in all the tablets were same with a slight variation in the composition of excipients. The post-formulation tests of hardness, friability and dissolution rate on the tablets have been made using the prescribed methods and standard instruments as discussed in the earlier. Using the experimental observations, various plots have been drawn.

Fig. 1 to 5 show, % friability Vs Hardness. In case of nimesulide and ferrous fumerate with the increase in percentage friability there was a linear increase in hardness of products of company Y whereas it was reverse/stable in case of X company products. However in the rest of the product there was no much appreciable change.

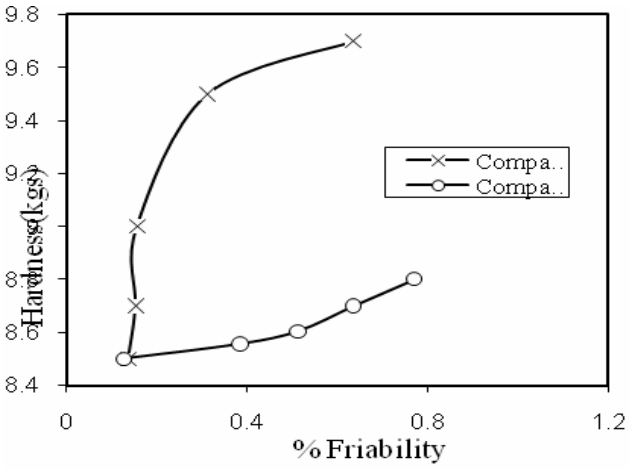

Fig. 1: % Friability vs hardness (Niacinamide)

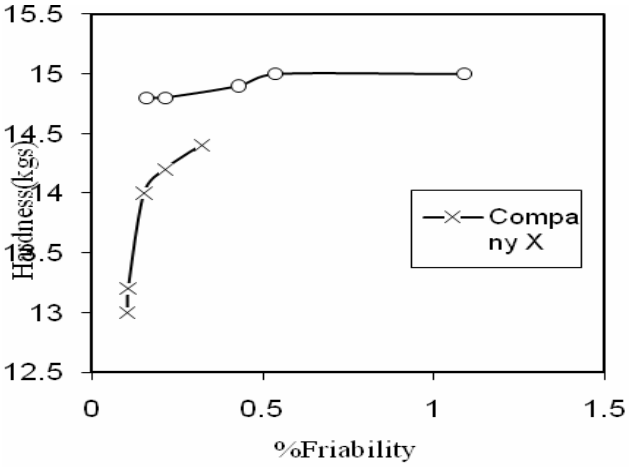

Fig. 2: %Friability vs hardness (Ferrous fumerate)

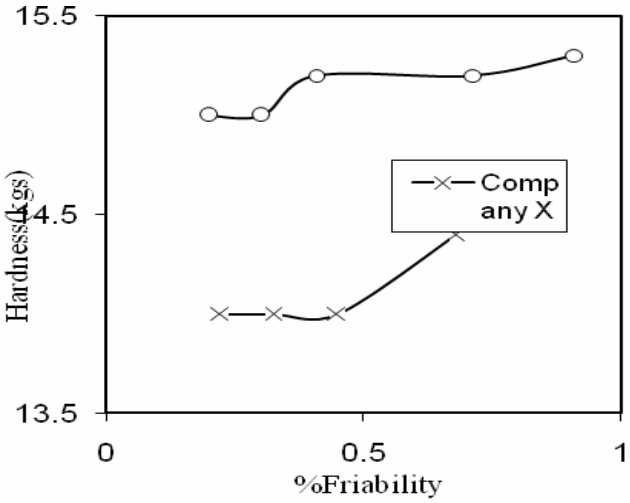

Fig. 3: % Friability vs hardness (Paracetamol and Ibuprofene)

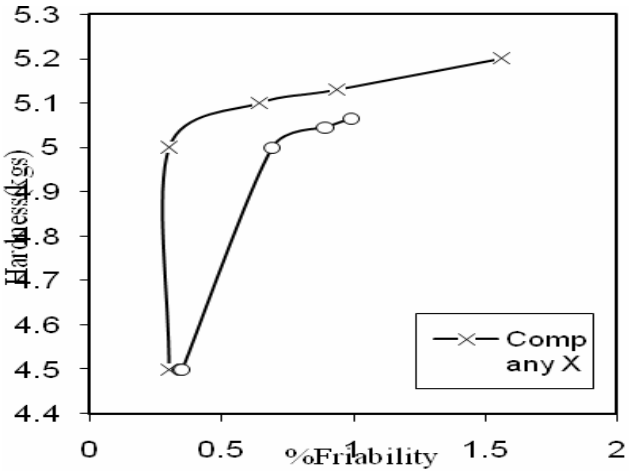

Fig. 4: % Friability vs hardness (Nimesulide)

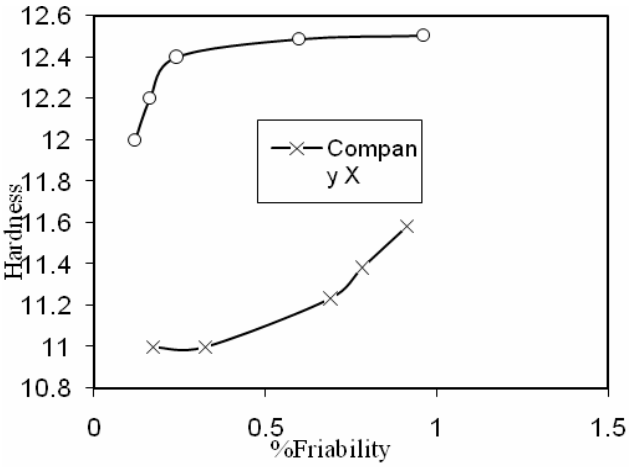

Fig. 5: % Friability vs hardness (Ciproflaxacine)

From Fig. 6 to 11, the absorbance has been increased with increase in time for niacinamide, ferrous fumerate, paracetamol, nimesulide and ciprofloxacin except in case of ibuprofen for both the companies.

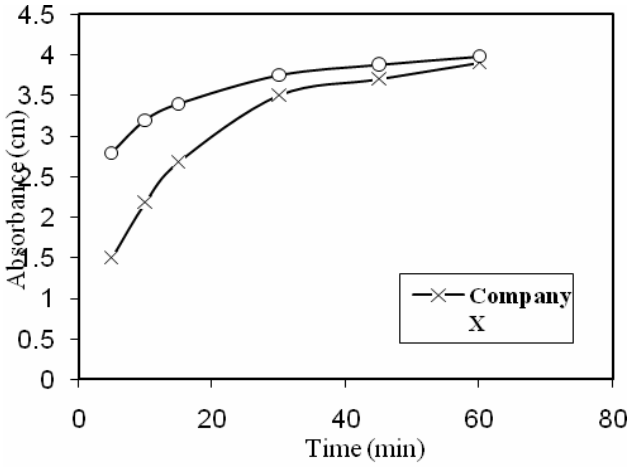

Fig. 6: Time vs dissolution rate (Niacinamide)

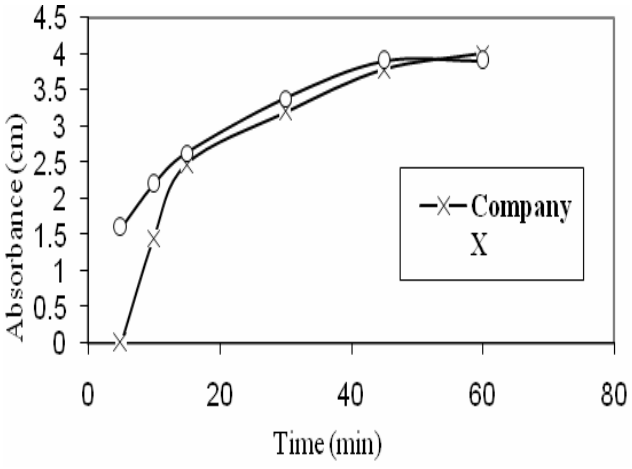

Fig. 7: Time vs dissolution rate (Ferrous fumerate)

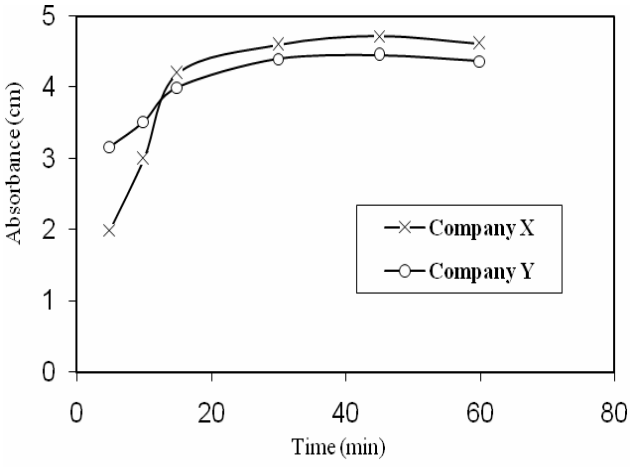

Fig. 8: Time vs dissplution rate (Paracetamol)

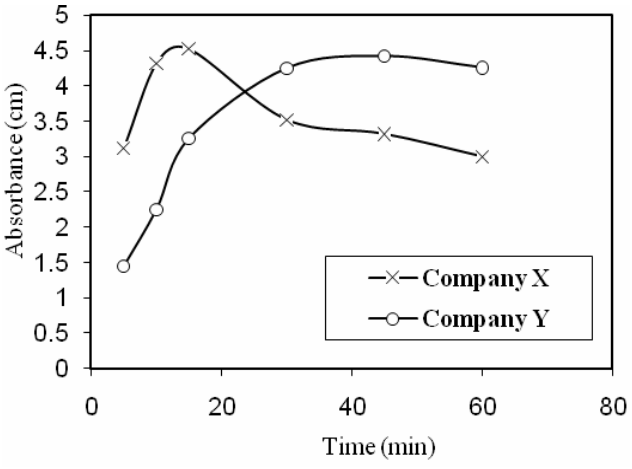

Fig. 9: Time vs dissolution rate (Ibuprofene)

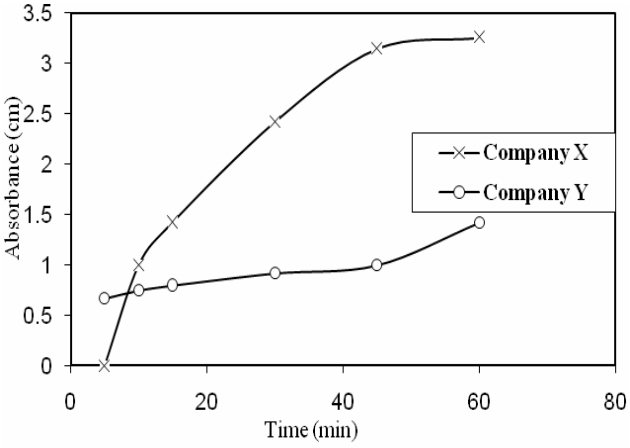

Fig. 10: Time vs dissolution rate (Nimesulide)

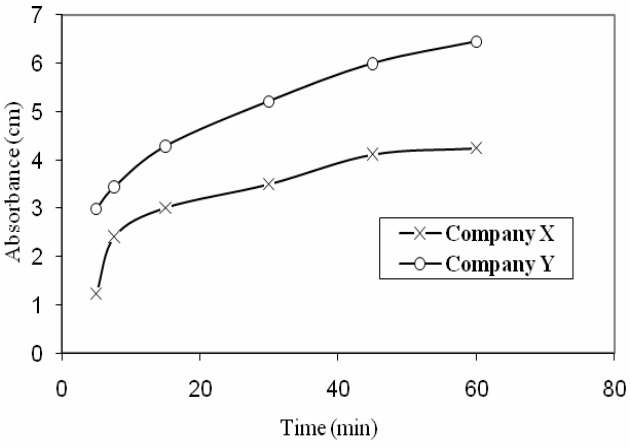

Fig. 11: Time vs dissolution rate (Ciproflaxacin)

CONCLUSION

In case of parameters of hardness and friability tests, there were considerable variations in the product formulations of both the companies. As far as the standard test dissolution rate is concerned, the product of formulations of both the companies have shown the same pattern and are as per I.P. Standards. Since there is a combination of other drugs in some of the formulations there may be an effect of these drugs in performing the qualitative tests. From the test results and plots, it was observed and can be concluded that the product formulations of company 'Y' have been better qualified than company 'X' except a few alterations in case of niacinamide and ferrous fumerate.

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