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COMPARATIVE *IN VITRO* EVALUATION OF COMMERCIAL NIMESULIDE TABLETS

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ABSTRACT

Five Indian Brands (coded as A,B,C,D,E) of 100 mg Nimesulide tablets were evaluated for various *In vitro* parameters, i.e. size and shape, uniformity of weight, hardness, friability, content, disintegration time and dissolution profile. All the products met the requirements of British Pharmacopoeia for tablet formulation. The hardness of all the brands was found to be in the range of 4.2-4.4 kg, while friability was less than 1 %. The disintegration time of all brands was found to be in the range of 2min 22 sec to 5min 29 sec. All brands comply the B.P weight variation test while brands A, B, C and D comply the B.P dissolution test except brand E. Formulation additives in the tablet, physical form of the drug used in the tablet and manufacturing process vary from manufacturer to manufacturer which is responsible for the variation in the observed dissolution profiles.

INTRODUCTION: Nimesulide is chemically N-(4-Nitro-2-phenoxyphenyl) methane sulfonamide which is COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) analgesic and antipyretic [1, 11]. A wide variety of Nimesulide formulations are available on Indian market. There are various commercial brands of Nimesulide tablets available in market. Nimesulide is rapidly absorbed following oral administration and gives rapid onset of action, with meaningful reductions in pain and inflammation observed within 15 minutes from drug intake [2].

The main purpose of an oral tablet is to deliver to the human body a certain and defined amount of drug through the gastro-intestinal system. Studies on the bioavailability of drugs from a given dosage forms revealed that, in many situations, tablet with same drug and drug content did not give the same therapeutic effect. Formulation additives in the tablet, physical form of the drug used in the tablet and tablet manufacturing process very from manufacture to manufacture, which is responsible for in variation observed dissolution profiles and therapeutic effects [3].

Pharmaceutical availability or in vitro availability is one of the aspects of drug bioavailability. Of the tests that can be performed on tablets, the dissolution test is considered to be sensitive, reliable and rational for predicting in-vivo drug availability behavior [3].

Thus, the present study has been undertaken to evaluate various in vitro quality control parameters of five available marketed Nimesulide tablets with special attention to dissolution rate studies.

MATERIALS AND METHODS: Nimesulide tablets of 100mg strength, of five different brands were purchased from local market from Nasik, Maharashtra, India. The products were coded as A, B, C, D, and E. All products were manufactured within six months at the time of study. The labeled shelf life of all brands of tablets was 36 month from date of manufacturing. All brands of tablets were evaluated for uniformity of weight, hardness, friability, content, disintegration time and dissolution profile as per B.P procedures. Size and Shape of tablets was found out using Vernier Callipers.

Hardness of tablets was found out using Pfizer tablet hardness tester. Friability of tablets was found out using Roche friability tester [4,10].

All the trials were carried out three times and the averages reported as in **table 1**.

Size and shape: Size of Nimesulide tablet i.e its diameter and thickness were measured by using vernier calliper. The determinations were carried in triplicate and averages reported [5] **(Table 1).**

Weight Variation: 20 units selected at random were weighed individually on electronic balance (Shimadzu, BL-2200H), the average weight was calculated and maximum percentage deviation were calculated [6] **(Table 1).**

Hardness test: Hardness of Nimesulide tablets was determined by using Pfizer hardness tester. [4] This tester operates on same principle as that of a pair of pliers. The force required to break the tablet is measured in kilograms and oral tablets normally have a hardness of 4 to 10kg/cm^2 [6]. The average hardness of tablets was calculated and reported. **(Table 1)**

Friability test: Friability of Nimesulide tablets was determined by using Roche Friability tester (Labin LI-FT-1). Number of tablets to the combined effects of abrasions and shock by utilizing a plastic chamber that revolves at 25 rpm, for 100 revolutions. And the percent friability of each brand of tablets was calculated and reported [7] **(Table 1).**

Drug content: Drug content was calculated as per procedure described in B.P. The solution was filtered through a 0.45µ nylon disc filter and was analyzed for drug content by measuring UV absorbance at 397 nm on UV-visible spectrophotometer (Shimadzu-1800) [8].

Disintegration test: The Disintegration test was carried out according to B.P procedure on six tablets using Disintegration test apparatus (Electrolab, ED-2L) with disc in distilled water medium at 37^{o}C, and the average disintegration time was calculated [8] **(Table 1).**

Dissolution test: *In vitro* dissolution studies of tablet formulations were performed in 900 mL of dissolution medium, pH 7.4 phosphate buffer IP using a USP XXI type 2 dissolution rate test apparatus (Electrolab, TDT 08L) and a speed of 50 rpm and a temperature of 37±1°C were used in each test. A 5mL aliquot was withdrawn at different time intervals and filtered using a 0.45µm nylon disc filter; each sample was replaced with 5 mL of fresh dissolution medium. The filtered samples were suitably diluted, if necessary, and assayed by measuring the absorbance at 397 nm for Nimesulide [8, 9, 12] **(Table 1 and Fig 1).**

TABLE 1: *IN VITRO* PARAMETERS OF VARIOUS BRANDS OF NIMESULIDE TABLETS

Brand Name (Manufacturer)	Acceptable limits (B.P.)	Nise (A) (Dr. Reddy's)	Nicip (B) (Cipla)	Nicret (C) (Suprim)	Emsulide (D) (Emcure)	Nomo (E) (Lederle)
Size (diameter) (mm)	-----	9.08	9.08	9.07	10.03	9.08
Size(Thickness) (mm)	-----	4.09	4.08	4.09	4.09	4.07
Uniformity of weight (Maximum deviation in % of average weight of tablets)	5 %	1.72 %	1.85 %	2.35 %	2.12 %	2.84 %
Friability	N.M.T1%	0.64%	0.51%	0.57%	0.41%	0.31%
Hardness	-----	4.2 kgs	4.4 kgs	4.4 kgs	4.2 kgs	4.2 kgs
Disintegration Time(min)	Less than 15 min	2 min, 31 sec	2 min, 22 sec	4 min, 14 sec.	3 min, 38 sec.	5 min, 29 sec.
Dissolution test	N.M.T.80%	78%	79%	77.85%	78%	82.33%
Assay	N.L.T 95.0% - N.M.T100.5%	98.60%	100.12%	97.60%	99.87%	96.85%

n=3

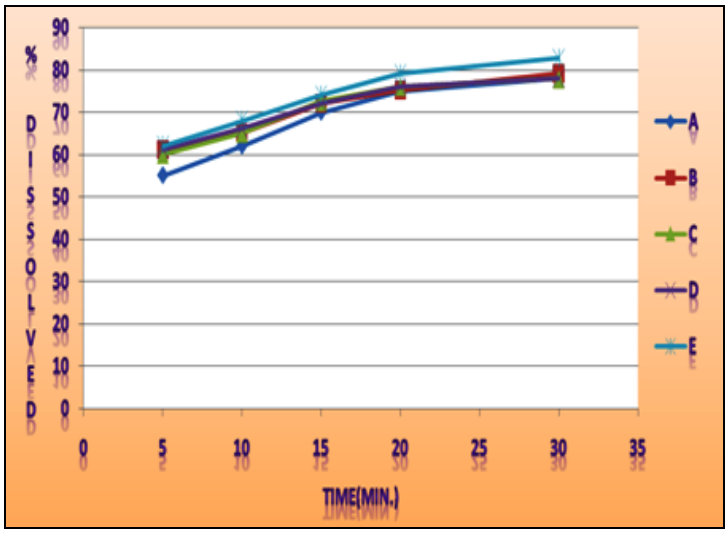

Fig. 1: % OF NIMESULIDE DISSOLVED FROM DIFFERENT BRANDS VERSUS TIME

RESULTS AND DISCUSSION: All brands showed general appearance as follows: colour-sunset yellow for brands B and C while quinoline yellow for brands A, D and E.

All brands have slightly curved round, biconvex shape.

All the brands exhibited good hardness strength, which is required for safe handling and transportation. The hardness was found to be in the range of 4.2-4.4 kg (Table 1).

All brands had friability of less than 1%, brand E had minimum friability of 0.31% while brand A had maximum friability of 0.64%.

All brands had acceptable limits of friability & hardness, showing good mechanical strengths (Table 1).

The content of Nimesulide in each tablet brands complies as described in B.P.

All the brands of tablet passed the weight variation test as prescribed by B.P. All brands of tablets passed the B.P disintegration time indicating that they will rapidly disintegrate in gastrointestinal tract fluid on oral administration. However, there was large variation in disintegration time from brand to brand. Formulation B showed minimum disintegration time of only 2 min 22 sec while formulation E showed maximum disintegration time of 5 min & 29 sec (Table 1).

Brands A, B, C and D comply the B.P dissolution test except brand E (Table 1 and Fig. 1).

CONCLUSION: Almost all brands passed all the official tests prescribed by B.P. Formulation additives in the tablet, physical form of the drug in the tablet and manufacturing process vary from manufacture to manufacture which is responsible for variation in observed dissolution profiles.

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