Comparative in vitro assessment of marketed Nimesulide tablet formulations

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Abstract:
This study evaluated the in vitro quality control parameters of two marketed nimesulide tablet formulations, Dr. Reddy's (Nise) and Cipla (Nicip), both of 100 mg strength. The tablets were assessed for size, shape, weight variation, hardness, friability, drug content, disintegration time, and dissolution profile according to the British Pharmacopoeia (B.P.) guidelines. Dr. Reddy's tablets were sunset yellow, and Cipla tablets were quinoline yellow, with both exhibiting slightly curved, round, and biconvex shapes. Hardness values ranged from 4.2 to 4.4 kg, and friability was well below 1%, indicating good mechanical strength. Both brands complied with weight variation, drug content, and disintegration tests, with Cipla tablets disintegrating slightly faster (1 min 55 sec) than Dr. Reddy's (2 min 15 sec). Dissolution studies showed satisfactory drug release for both brands, with Cipla demonstrating a marginally quicker release. Overall, the results indicate that both brands meet pharmacopeial standards and are likely to provide effective therapeutic outcomes. Minor differences in disintegration and dissolution profiles may be attributed to formulation variations between the manufacturers.

Keywords: Nimesulide, Tablet Evaluation, Dissolution, Disintegration, Quality Control

I. Introduction

Nimesulide is chemically N-(4-Nitro-2-phenoxyphenyl) [7]. Nimesulide is a nonsteroidal anti-inflammatory drug (NSAID) belonging to the sulfonamide group [2]. It shows selective action towards the COX-2 (cyclo-oxygenase-2) enzyme, which gives it anti-inflammatory, pain-relieving, and fever-reducing properties. When taken at the recommended dose, nimesulide generally causes fewer side effects and is better tolerated compared to other NSAIDs such as diclofenac, ketoprofen, naproxen, and piroxicam. After oral administration, nimesulide is quickly absorbed into the body, leading to a fast onset of action, with noticeable relief from pain and inflammation observed within 15 minutes [7].

Nimesulide is a sulfonanilide derivative with a melting point of approximately 143 °C. It is weakly acidic, with a pKa value of around 6.5, due to the presence of the sulfonamide group [1,2]. The drug is practically insoluble in water (about 10 µg/mL) but dissolves well in methanol and ethanol at room temperature. According to the Biopharmaceutics Classification System (BCS), nimesulide belongs to Class II, indicating low solubility but high permeability. Therefore, its rate of dissolution often serves as the limiting factor in its absorption process [3].

The primary goal of an oral tablet is to deliver a specific and accurate dose of a drug into the body through the gastrointestinal tract. Research on drug bioavailability from different dosage forms has shown that tablets containing the same drug and dose may not always produce identical therapeutic effects [4–6]. This variation can arise due to differences in formulation additives, the physical form of the drug, and the manufacturing process used by different manufacturers, all of which can influence the dissolution profile and therapeutic outcome.

Pharmaceutical availability, or in vitro availability, is an important aspect of overall drug bioavailability. Among the various tests performed on tablets, the dissolution test is considered one of the most reliable and sensitive methods for predicting how a drug will behave in the body [8,9].

Therefore, the present study aims to assess the in vitro quality control parameters of two marketed nimesulide tablet formulations, with particular focus on their dissolution rate profiles [7].

II. Materials and Methods

Nimesulide tablets (100 mg strength) from two different brands were procured from the local market in Sangamner, Maharashtra, India. These samples were coded as A (Dr. Reddy's, Nise) and B (Cipla, Nicip) for identification. All the tablets were manufactured within six months prior to the study, and each brand had a labeled shelf life of 36 months from the date of manufacture.

The collected tablet samples were evaluated for various quality control parameters, including uniformity of weight, hardness, friability, drug content, disintegration time, and dissolution profile, following the procedures outlined in the British Pharmacopoeia (B.P) [8]. The size and shape of the tablets were determined using a Vernier caliper [5].

A standard sample of nimesulide with a purity of 99.80% was obtained from the National Institute for Quality Control in Health. Nisulid® (manufactured by Aché Laboratory) was used as the reference formulation for comparison [2].

The hardness of the tablets was determined using a Pfizer tablet hardness tester, while the Roche friability tester (Labin LIFT-1) was used to assess friability. All experiments were performed in triplicate, and the average values obtained were recorded and presented in Table 1 [4,6].

Size and Shape

The dimensions of the nimesulide tablets, including diameter and thickness, were measured using a Vernier caliper. Each sample was tested three times, and the mean values were calculated and listed in Table 1 [5].

Weight Variation

Twenty tablets were randomly selected and individually weighed using an electronic balance (Shimadzu, BL-2200H). The average weight of the tablets was calculated, and the maximum percentage deviation from the mean was determined. The results are summarized in Table 1 [6].

Hardness Test

The hardness of nimesulide tablets was measured using a Pfizer hardness tester, which functions on a principle similar to that of pliers. The instrument measures the force needed to break a tablet, expressed in kilograms. Generally, oral tablets exhibit a hardness range of 4–10 kg/cm². The average hardness values for the tested tablets were determined and presented in Table 1 [4,6].

Friability Test

The friability of nimesulide tablets was evaluated using a Roche Friability Tester. Tablets were placed in a rotating plastic drum at 25 rpm for 100 revolutions to expose them to abrasion and mechanical shock. The percentage friability for each tablet brand was calculated and presented in Table 1 [6].

Drug Content

Drug content was determined according to the B.P. procedure. The solution was filtered using a 0.45 µm nylon disc filter and analyzed for nimesulide concentration by measuring the UV absorbance at 397 nm using a UV-Visible spectrophotometer (Shimadzu-1800) [7,12].

Disintegration Test

Disintegration testing was performed as per B.P. guidelines using a Disintegration Test Apparatus (Electrolab, ED-2L). Six tablets were tested in distilled water at 37°C. The average disintegration time was recorded and presented in Table 1 [8].

Dissolution Test

In vitro dissolution studies were performed in 900 mL of pH 7.4 phosphate buffer using a USP XXI Type 2 dissolution apparatus (Electrolab, TDT 08L) at 50 rpm and 37 ± 1°C. At specified intervals, 5 mL samples were withdrawn, filtered (0.45 µm nylon), replaced with fresh medium, and analyzed at 397 nm. Results are summarized in Table 1 [8,9,12]

Figure1

Figure 2

Figure 3

figure 4

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

Brand name (manufacturer)	Acceptable limit(B.P)	Nise(A) (Dr.Reddys)	Nicip(B) (Cipla)
Size (diameter) (mm)	-----	9.6	9.7
Size(Thickness) (mm)	-----	4.3	4.1
Uniformity of weight (Maximum deviation in % of average weight of tablets)	5 %	1.72 %	1.85 %
Friability	N.M.T1%	0.137%	0.093%

Hardness	-----	4.2 kgs	4.4 kgs
Disintegration Time(min)	Less than 15 min	1 min 55 sec	2 min 15 sec
Dissolution test	N.M.T.80%	78%	79%
Assay	N.L.T 95.0% - N.M.T100.5%	98.60%	100.12%

III. Result and Discussion

The general appearance of the tablets differed slightly between the brands. Dr. Reddy's tablets were sunset yellow, while Cipla tablets were quinoline yellow. Both were slightly curved, round, and biconvex.

Hardness values were within an acceptable range (Dr. Reddy's 4.2 kg; Cipla 4.3 kg), ensuring adequate strength for handling and transportation. Friability was excellent, with Dr. Reddy's at 0.137% and Cipla at 0.093%, indicating high resistance to abrasion.

Drug content for both brands met B.P. specifications, ensuring uniformity. Weight variation tests confirmed consistent tablet mass. Disintegration times were rapid: Cipla 1 min 55 sec, Dr. Reddy's 2 min 15 sec. Dissolution studies showed satisfactory drug release, with Cipla releasing slightly faster, consistent with its quicker disintegration.

Overall, both brands exhibited good mechanical strength, uniformity, rapid disintegration, and efficient in vitro drug release, with minor variations likely due to differences in formulation or manufacturing processes [7–12].

IV. Conclusion:

The present study evaluated the in vitro quality control parameters of two marketed nimesulide tablet formulations, Dr. Reddy's (Nise) and Cipla (Nicip), with the aim of assessing their physicochemical and mechanical properties. Both brands exhibited uniform size, shape, and weight, indicating consistent manufacturing practices. Hardness and friability tests confirmed that the tablets possessed adequate mechanical strength, making them suitable for handling, packaging, and transportation without risk of breakage. The drug content analysis showed that both formulations complied with British Pharmacopoeia standards, ensuring accurate dosage and therapeutic reliability. Disintegration testing revealed that both brands would rapidly disintegrate in the gastrointestinal tract, with Cipla tablets disintegrating slightly faster than Dr. Reddy's, which could influence the initial rate of drug absorption. Dissolution studies further demonstrated that both brands provided efficient in vitro drug release, with Cipla tablets showing a marginally higher dissolution rate, likely due to formulation differences. Overall, the findings indicate that both nimesulide tablet brands are of high quality, safe, and effective for oral administration. Minor variations in disintegration and dissolution profiles are expected between manufacturers but do not compromise therapeutic efficacy. These results underscore the importance of routine quality control testing to ensure consistency and reliability of marketed formulations.

V. References

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