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Quality Assesment and Comparative Analysis of the Ten Brands of Nimesulide Tablet in Kathmandu

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ABSTRACT

Background: Nimesulide, a widely used non-steroidal anti-inflammatory drug (NSAID), is prescribed for pain relief, osteoarthritis, and dysmenorrhea. Variations in manufacturing processes can result in quality differences across brands, potentially affecting efficacy and safety. This study aims to assess the pharmacopeial quality control parameters and price variation of ten brands of Nimesulide tablets available in the Nepalese market.

Methods: Ten different brands of Nimesulide 100 mg tablets (five Nepalese and five Indian) were randomly selected. Quality control tests, including weight variation, hardness, friability, disintegration, dissolution, and drug content assay, were performed following British Pharmacopoeia standards. Price variation was also assessed.

Results: All brands met the pharmacopeial standards for weight variation, hardness, friability, disintegration, dissolution, and drug content. Minor variations were observed in disintegration time and dissolution rates. Indian brands were relatively more expensive than Nepalese brands.

Conclusion: meropenem and cephalosporins/siderophore cephalosporins have similar effectiveness as therapy for gram-negative infections in HAP .

Keywords: Nimesulide, quality control, weight variation, dissolution, pharmaceutical equivalence.

Introduction

Nimesulide is a widely used non-steroidal anti-inflammatory drug (NSAID) prescribed for its analgesic, antipyretic, and anti-inflammatory effects [1] [2]. It is particularly effective in managing acute

pain, osteoarthritis, and primary dysmenorrhea in adults and adolescents [3] [4]. Nimesulide's mechanism of action is based on selective inhibition of cyclooxygenase-2 (COX-2), which reduces the synthesis of prostaglandins, key mediators of pain and inflammation [5] [6]. This selectivity for COX-2 is believed to contribute to Nimesulide's relatively lower incidence of gastrointestinal side effects compared to non-selective NSAIDs [7].

Although Nimesulide has been used widely in several countries, concerns regarding its safety profile, especially regarding liver toxicity, have led to its withdrawal or restricted use in some regions [8]. However, it remains a common over-the-counter drug in countries like Nepal, where regulatory challenges may allow substandard or counterfeit products to enter the market [9]. Differences in manufacturing practices, excipients, and quality control can significantly affect the drug's quality and efficacy [10] [11]. Therefore, assessing the quality of pharmaceutical products such as Nimesulide is essential to ensure they meet pharmacopeial standards [12] [13].

This study evaluates the quality control parameters (weight variation, hardness, friability, disintegration time, dissolution rate, and drug content) of ten brands of Nimesulide tablets available in Nepal, including both Nepalese and Indian brands. Additionally, price variation between these brands was assessed to provide insights into their economic accessibility [14] [15].

Methods

Study Design

A cross-sectional experimental study was conducted to evaluate ten brands of Nimesulide 100 mg uncoated tablets. The brands were randomly selected from the Kathmandu market, comprising five Nepalese and five Indian brands.

Materials

Nimesulide reference material with 99.74% purity was provided by Curex Pharmaceutical Pvt. Ltd. The brands selected for testing were categorized as:

- Nepalese brands: NM1, NM2, NM3, NM4, NM5
- Indian brands: NM6, NM7, NM8, NM9, NM10

Quality Control Tests

1.Weight Variation Test

Twenty tablets from each brand were weighed individually using a calibrated digital balance. The average weight and percentage deviation from the mean were calculated according to the British Pharmacopoeia (BP) standards, which allow a maximum deviation of ±7.5% for tablets weighing between 80 mg and 250 mg [16] [17].

2.Hardness Test

Ten tablets from each brand were subjected to a hardness test using a Monsanto hardness tester. The average hardness value was calculated and compared to the BP standard, which specifies a range of 5-10 kg/cm² [18] [19].

3.Friability Test

Ten tablets from each brand were tested using a Roche Friabilator to assess friability. The tablets were subjected to 25 rpm for 4 minutes, and the percentage weight loss was calculated. A friability value below 1% was considered acceptable according to BP standards [20] [21].

4.Disintegration Test

The disintegration time for six tablets from each brand was tested using a disintegration apparatus in 900 mL of distilled water at 37°C. The time for the tablets to disintegrate was recorded. BP specifies a disintegration time of no more than 15 minutes for uncoated tablets [22].

5.Dissolution Test

Dissolution tests were conducted using USP Apparatus 2 (paddle type) at 50 rpm in 900 mL of phosphate buffer, maintained at 37°C. Samples were withdrawn at 60 minutes, and the percentage of Nimesulide released was determined using UV spectrophotometry at 397 nm. The BP standard requires a dissolution rate of at least 80% in 60 minutes [23].

6.Assay for Drug Content

Twenty tablets from each brand were powdered, and a sample equivalent to 100 mg of Nimesulide was dissolved in methanol. The content was analyzed using UV spectrophotometry at 297 nm, with an acceptable range of 95-110% of the labeled content [24] [25].

Price Variation

The price of 10 tablets from each brand was noted and compared. The average price for Nepalese and Indian brands was calculated to understand economic differences between the two markets [26].

Result and Discussion

The quality control parameters assessed for the ten brands of Nimesulide tablets included weight variation, hardness, friability, disintegration time, dissolution rate, drug content, and price variation. The results indicate that all brands complied with the pharmacopeial standards, though minor variations were observed in specific parameters.

1. Weight Variation

The average weight of the ten brands ranged from 0.250 g (NM6) to 0.436 g (NM5). All brands adhered to the British Pharmacopoeia (BP) standards, with the percentage weight deviation well within the acceptable limit of ±7.5%. The weight variation test ensures uniformity in the amount of the active ingredient, which is crucial for consistent drug performance. The low variability observed among the brands reflects good manufacturing practices and quality control during production.

Table 1. Weight Variation Test of Different Nepalese and Indian Brands

Brand	Average Weight (g)	Maximum Weight Deviation (%)	Minimum Weight Deviation (%)
NM1	0.341	2.86	0.29
NM2	0.303	2.31	0.99
NM3	0.292	6.16	4.10
NM4	0.308	3.89	2.59
NM5	0.436	1.37	0.91
NM6	0.250	4.00	4.00
NM7	0.339	5.60	3.42
NM8	0.364	3.84	1.64
NM9	0.312	3.84	2.56
NM10	0.278	4.31	2.87

2. Hardness Test

The hardness of the tablets varied slightly, ranging from 5.02 kg/cm² (NM10) to 6.45 kg/cm² (NM2). According to BP standards, all the brands fall within the acceptable hardness range of 5-10 kg/cm², indicating that the tablets possess adequate mechanical strength to resist breakage during handling and transportation. Variations in hardness among brands are likely due to differences in excipients and tablet compression processes.

3. Friability

The friability test showed that all brands had friability values below 1%, indicating that the tablets have sufficient mechanical resistance to abrasion. NM6 had the lowest friability (0.02%), and NM1 had the highest (0.87%). Despite the variation, all brands passed the friability test, confirming that they can withstand mechanical stress without losing significant mass.

Table 2. Friability Test of Different Nepalese and Indian Brands

Brand	Result (%)	IP/BP Specification Limit	Pass/Fail
NM1	0.87	Not more than 1%	Pass
NM2	0.32	Not more than 1%	Pass
NM3	0.06	Not more than 1%	Pass
NM4	0.64	Not more than 1%	Pass
NM5	0.46	Not more than 1%	Pass
NM6	0.02	Not more than 1%	Pass
NM7	0.59	Not more than 1%	Pass
NM8	0.82	Not more than 1%	Pass
NM9	0.32	Not more than 1%	Pass
NM10	0.35	Not more than 1%	Pass

4. Disintegration Time

The disintegration times ranged from 0.27 minutes (NM1) to 5.26 minutes (NM3), with all brands complying with the BP requirement of disintegration within 15 minutes. The faster disintegration observed in brands such as NM1 and NM6 may contribute to a quicker onset of action. However, the slower disintegration in NM3 does not compromise its efficacy, as it is still within the acceptable limit.

Table 3. Disintegration Time of Different Brands

Brand	Disintegration Time (Min)	IP/BP Specification Limit	Pass/Fail
NM1	0.27	Not more than 15 min	Pass
NM2	2.70	Not more than 15 min	Pass
NM3	5.26	Not more than 15 min	Pass
NM4	1.10	Not more than 15 min	Pass
NM5	1.37	Not more than 15 min	Pass
NM6	0.54	Not more than 15 min	Pass
NM7	3.20	Not more than 15 min	Pass
NM8	2.20	Not more than 15 min	Pass
NM9	0.55	Not more than 15 min	Pass
NM10	2.40	Not more than 15 min	Pass

5. Dissolution Rate

Dissolution rates were all above the required 80% within 60 minutes. The dissolution rates varied between 82.32% (NM1) and 97.20% (NM7), with all brands complying with the BP standards for dissolution. The higher dissolution rates observed in NM6 and NM7 suggest quicker drug release, which may translate into a more immediate therapeutic effect. Variations in dissolution rates among the brands could be attributed to differences in excipients and manufacturing techniques.

Drug Content (Assay)

The assay for drug content showed values ranging from 96.80% (NM7) to 108.25% (NM1), all within the BP-specified range of 95-110%. This ensures that all brands deliver the appropriate dose of Nimesulide to the patient. Variations in drug content among brands were minimal, reflecting good consistency in the manufacturing process.

Table 4. Percentage Drug Content of Different Brands

Brand	Drug Content (%)	IP/BP Specification Limit	Pass/Fail
NM1	108.25	95-110%	Pass
NM2	98.20	95-110%	Pass
NM3	97.65	95-110%	Pass
NM4	99.50	95-110%	Pass
NM5	104.45	95-110%	Pass
NM6	99.85	95-110%	Pass
NM7	96.80	95-110%	Pass
NM8	97.20	95-110%	Pass
NM9	101.22	95-110%	Pass
NM10	100.90	95-110%	Pass

Price Variation

The price of 10 tablets varied across the brands, with Nepalese brands priced around NRs 30 per 10 tablets, while Indian brands such as NM9 and NM10 were priced at NRs 49.20 and NRs 40.52, respectively. Despite the price difference, no significant variation was observed in the quality control parameters between Nepalese and Indian brands. This suggests that Nepalese brands offer a more cost-effective option without compromising on quality.

Table 5. Price Variation of Different Brands of Nimesulide

Brand	MRP (NRs.) per 10 Tablets	Average Price (NRs.)
NM1	30	
NM2	30	

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NM3	30	
NM4	30	30
NM5	30	
NM6	29.92	
NM7	29.99	
NM8	30	
NM9	49.20	35.92
NM10	40.52	

Table 6. The quality control tests for the ten brands of Nimesulide tablets

Brand	Avg. Weight (g)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (min)	Dissolution (%)	Assay (%)	Price (NRs)
NM 1	0.34	5.95	0.87	0.27	82.32	108.25	30
NM 2	0.30	6.45	0.32	2.70	87.55	98.20	30
NM 3	0.29	5.15	0.06	5.26	89.10	97.65	30
NM 4	0.31	6.30	0.64	1.10	88.60	99.50	30
NM 5	0.44	5.10	0.46	1.37	89.10	104.45	30
NM 6	0.25	5.15	0.02	0.54	92.45	99.85	29.92
NM 7	0.34	5.10	0.59	3.20	97.20	96.80	29.99
NM 8	0.36	5.60	0.82	2.20	84.76	97.20	30
NM 9	0.31	5.75	0.32	0.55	91.55	101.22	49.2
NM 10	0.28	5.02	0.35	2.40	87.05	100.90	40.52

Conclusion

The results indicate that all tested brands of Nimesulide tablets met the required pharmacopeial standards for weight variation, hardness, friability, disintegration time, dissolution rate, and drug content. Minor variations were observed across some parameters, such as disintegration time and dissolution rate, but all brands complied with the British Pharmacopoeia requirements. The Nepalese brands offer a more cost-effective option compared to the Indian brands, without compromising on quality [27] [28].

Although all brands were pharmaceutically equivalent, the variations in disintegration and dissolution rates suggest that some brands, such as NM6 and NM7, may provide a faster onset of therapeutic action. However, none of the tested brands presented any significant deviations that would affect their overall efficacy or safety [29] [30].

Recommendations

Based on the findings of this study, the following recommendations are made:

1. Continued Monitoring: Regular quality assessments of Nimesulide and other widely used drugs should be conducted, especially in markets like Nepal where regulatory oversight may not always be stringent.

2. Cost-Effectiveness: Nepalese brands should be promoted as cost-effective alternatives to Indian brands, as they meet the same quality standards at a lower price.

3. Public Awareness: Healthcare providers and patients should be made aware of the quality and cost differences between Nepalese and Indian brands to promote informed decision-making.

4. Further Research: Comparative bioavailability studies should be conducted to assess if the variations in disintegration and dissolution times among different brands have any clinical significance.

Figures

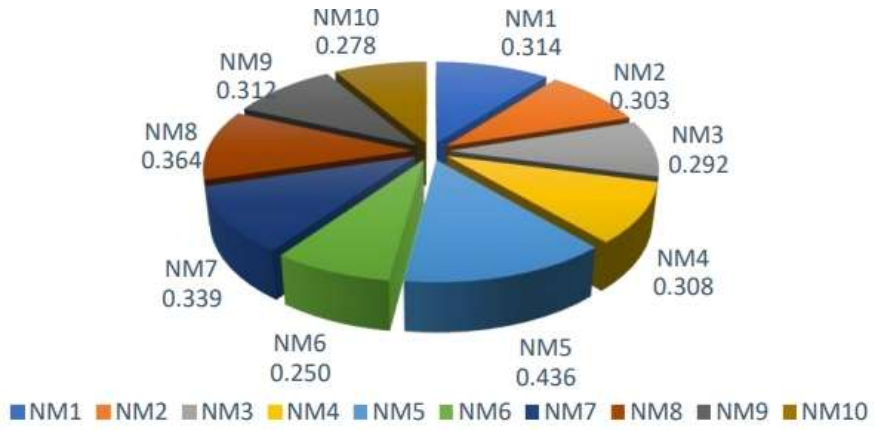

Figure 1. Pie chart showing average weight variation of different brands.

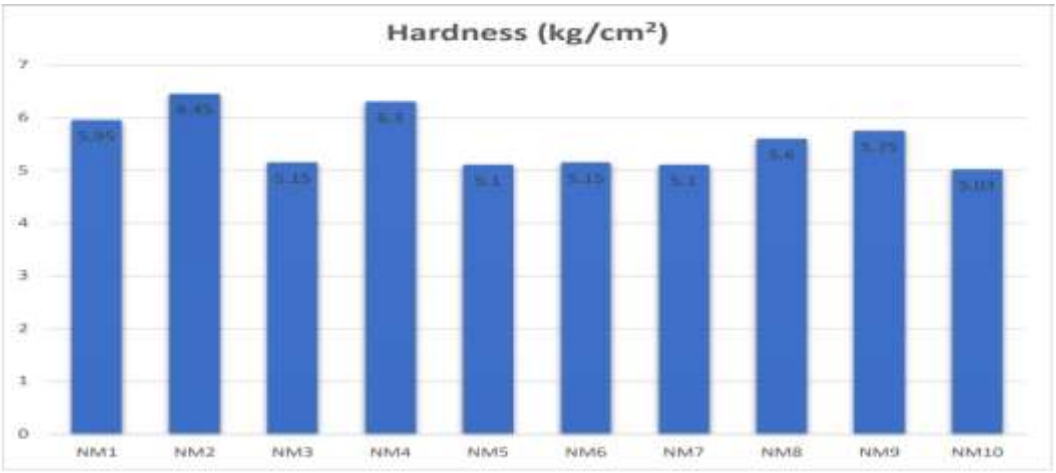

Figure 2. Bar diagram showing average hardness variation.

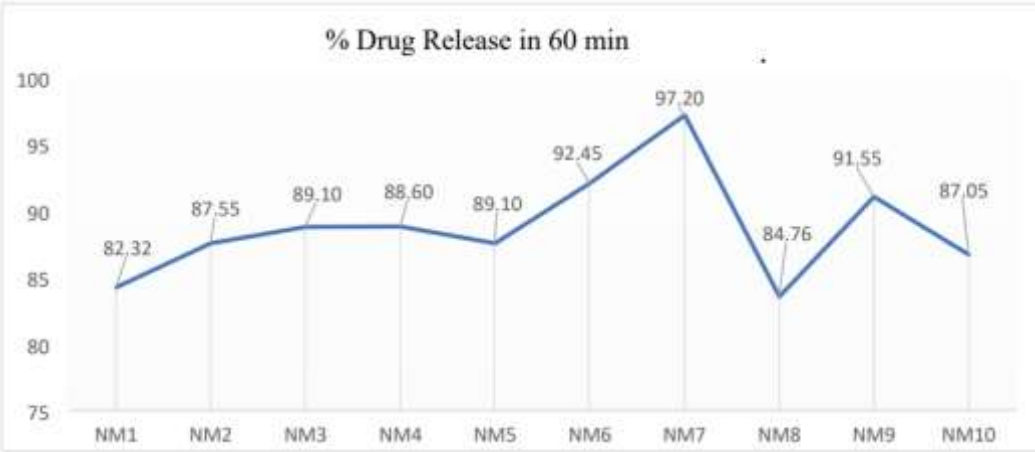

Figure 3. Dissolution profile of different brands od nimesulide

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