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The Evaluation of National Formulations as Tablet Dosage Form by Using Physical and Mechanical tests

Graduation research Submitted to Al- Zahrawi University College / Department of Pharmacy

By

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Abstract

Background: Tablet dosage forms are widely used due to their ease of administration, accurate dosing, stability, and patient compliance. Ensuring the quality of these formulations is critical to their efficacy and safety. National tablet formulations, which are manufactured domestically in adherence to local regulatory standards, require comprehensive evaluation to assess their physical and mechanical properties and confirm their compliance with pharmacopoeial standards.

Objective: This study aims to evaluate the quality of national tablet formulations through a systematic analysis of their physical and mechanical properties, including weight variation, hardness, friability, and disintegration time. These assessments help determine the consistency, reliability, and suitability of these formulations for therapeutic use.

Methods: The study involved a comparative evaluation of national and imported pharmaceutical tablets, including Panadol, Levetiracetam, Azithromycin, Naproxen, and Allopurinol. Standardized testing methods were employed to assess weight variation, hardness, friability, and disintegration time in accordance with United States Pharmacopeia (USP) guidelines. Weight variation was measured by individually weighing twenty tablets per formulation, while hardness was evaluated using an electronic hardness tester. Friability was assessed by subjecting ten tablets to mechanical stress in a Friabilator, and disintegration time was determined using a disintegration apparatus with 0.1N HCl as the dissolution medium.

Results: All national tablet formulations complied with USP weight variation limits, demonstrating consistent manufacturing quality. Hardness values ranged between 6.1 and 6.9 kg, exceeding the minimum requirement of 4 kg, indicating sufficient mechanical strength for handling and transport. Friability results ranged from 0.3% to 0.61%, well below the USP threshold of 1%, confirming minimal susceptibility to mechanical degradation. Disintegration times for all tested tablets were within the acceptable limit of 30 minutes, ensuring appropriate dissolution profiles for effective drug release.

In conclusion, the findings of this study confirm that national tablet formulations meet the required pharmacopoeial standards for weight variation, hardness, friability, and disintegration time. The results indicate consistent manufacturing quality, adequate mechanical strength, and appropriate dissolution profiles, ensuring their suitability for

therapeutic use. These findings support the reliability of domestically produced tablets and highlight their compliance with international quality benchmarks.

Introduction:

Tablet dosage forms are one of the most widely used pharmaceutical formulations due to their ease of administration, accurate dosing, stability, and patient compliance [(1)]. Evaluating the quality of tablet formulations is essential to ensure their efficacy, safety, and overall performance [(2)]. National formulations refer to pharmaceutical products developed and manufactured within a specific country, adhering to local regulatory standards and guidelines.

The evaluation of tablet formulations involves assessing their physical and mechanical properties, which directly affect the tablet's performance during manufacturing, storage, and administration. These tests ensure that tablets meet the required specifications for hardness, friability, disintegration, weight uniformity, and other critical quality attributes [(3)].

Physical tests focus on parameters such as tablet size, shape, weight variation, and appearance, while mechanical tests evaluate the tablet’s strength and integrity under stress [(4)]. For instance, hardness testing determines the tablet's resistance to mechanical pressure, and friability testing assesses its ability to withstand abrasion during handling and transport [(5)].

This study aims to evaluate national tablet formulations through a comprehensive analysis of their physical and mechanical properties. By conducting these tests, it is possible to identify formulation consistency, compliance with pharmacopoeial standards, and the overall quality of the tablets. Such evaluations are crucial for ensuring patient safety, therapeutic efficacy, and maintaining public confidence in locally produced pharmaceuticals.

Materials and Method

Materials

The table (1),show agents, as well as their manufacturing companies which had been used in the study.

Table 1: tables used in the study

Agents	National companies	Trade name	Importing companies	Trade name
Paracetamol 500 mg	Pioneer	Piodol	Glaxosimth kline (united kindom)	Panadol
Leveteracitam 500 mg	Sama Al-Fayhaa	Kepracetam	Glaxosimth kline (united kindom)	Keppra
Azithromycin 500mg	Sammara drug industrial	Azithrosam	Britiwell (united kindom)	Azithromycin
Naproxen 500mg	Pioneer	Napron	Al-Hikma (Jordan)	Nopain
Allopurinol 300 mg	Sammara drug industrial	Hyporic	Aspen	Zyloric

Method

Weight variation:

The weight of each of the ten tablets was individually measured by use electrical balance , and subsequently, the average weight of triplicate record was calculated. To meet the requirements, the weights of no more than two tablets should fall outside the percentage limit specified by USP, as shown in Table (2). Additionally, no tablet should deviate in weight by more than double that percentage [(6)].

Table 2: USP Standards for Weight Variation [8].

Weight of tablet (mg)	Allowed deviation from the mean
≤ 130	10%
130-324	7.5%
>324	5%

Hardness test:

The hardness test assesses the tablet's crushing strength, ensuring its ability to endure various handling, transportation, and storage conditions. Three tablets were selected randomly from each drugs that had selected include the national and imported drugs . The measurements were recorded by an electronic hardness tester as in figure (1). It was calibrated to zero, and the load was gradually raised until the tablet reached a point of fracture or breakage [4].

Figure 1: hardness tester

Friability test:

The friability test assesses the impact of friction and shocks on tablets, which can result in chipping, capping, or breakage. Ten tablets were precisely weighed (W initial) and placed into the Friabilator as in figure (2), where they were rotated for 4 minutes at 25 rpm. Subsequently, the tablets were removed,

cleaned to remove dust, and then accurately reweighed (W final). The accepted weight loss should not exceed 1% [7]

$$\textbf{Friability}\% = \frac{\textbf{W intial} - \textbf{W final}}{\textbf{W intial}} * 100 \text{ .....eq 1.} \quad [7]$$

The friability test is being implemented on the national and imported drugs in same process steps.

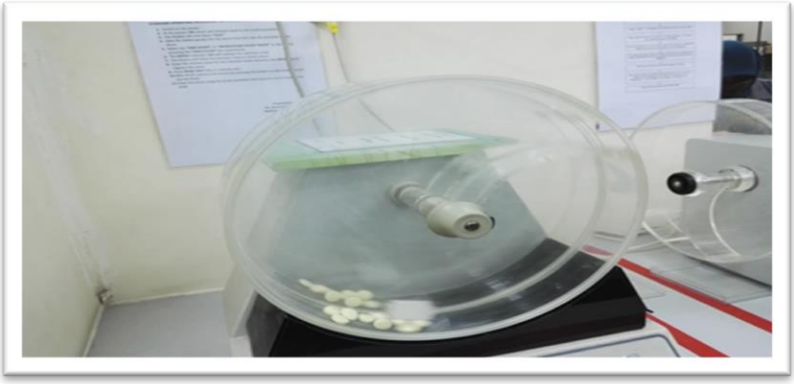

Figure (2): Friabilator

Disintegration time test:

The disintegration time was determined for tablets. Using a disintegration apparatus consisting of a basket rack assembly containing six open-ended tubes as showen in figure (3). A single tablet was placed in each tube, and the basket, with a stainless-steel screen (mesh no. 10) on its bottom surface, was immersed in 900 ml of 0.1N HCl at 37 ±0.5 ºC. The time taken for complete disintegration of the tablet in each tube was measured using a stopwatch [8] .The disintegration time test is being implemented on the national and imported drugs in same conditions.

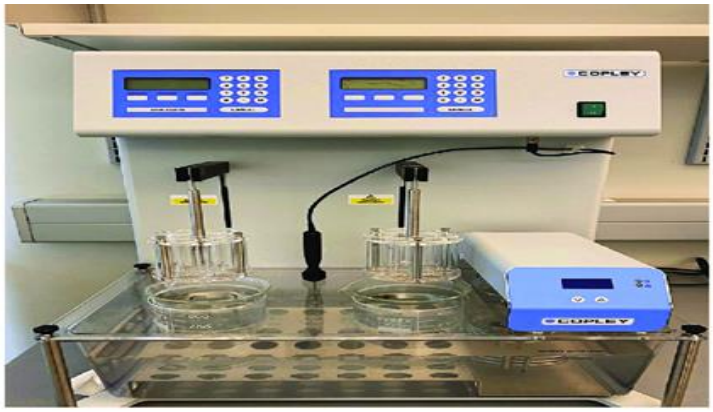

Figure 3: disintegration apparatus

Statistical analysis

The mean and standard deviation (SD) of the triplicate samples were calculated and presented as the outcomes of the experiments. The statistical analysis was performed using one-way analysis of variance (ANOVA) and the test level of significance was set at ($P < 0.05$). The statistical software used for the analysis was SPSS version 26.

Results and Discussion :

Weight variation:

According to USP standards, all the prepared tablets had weights within the acceptable range [7] as shown in table (3). When comparing the weight variation of national and imported product , there is no significant difference ($p > 0.05$)between the two, as reflected in the results across the five groups involved in the experiment.

Table 3: Weight variation test for All Tablets

Keppra	Kepracetam	Hyporic	Zyloric	Azithromycin	Azithroscam	Piodol	Panadol	Napron	Nopain
0.552 ±0.002	0.606 ±0.001	0.0454 ±0.002	0.0464 ±0.002	0.887± 0.003	0.782±0.002	0.574±0.011	0.619±0.01	1.167±0.011	1.167±0.01
0.544 ±0.002	0.593 ±0.001	0.0453 ±0.002	0.0457 ±0.001	0.908± 0.003	0.758±0.002	0.577±0.011	0.613±0.01	1.158±0.011	1.158±0.01
0.554 ±0.001	0.619 ±0.002	0.0463 ±0.002	0.0454 ±0.002	0.903±	0.755±0.001	0.581±0.011	0.616±0.01	1.151±0.011	1.151±0.01
0.552 ±0.001	0.603 ±0.001	0.0446 ±0.003	0.0465 ±0.002	0.899± 0.003	0.760±0.002	0.576±0.011	0.618±0.01	1.163±0.011	1.163±0.01
0.550 ±0.001	0.601 ±0.002	0.0437 ±0.001	0.0456 ±0.003	0.909± 0.002	0.764±0.001	0.579±0.011	0.623±0.01	1.165±0.011	1.165±0.01
0.548 ±0.002	0.611 ±0.001	0.0446 ±0.002	0.0446 ±0.001	0.892± 0.002	0.772±0.002	0.572±0.011	0.616±0.01	1.166±0.011	1.166±0.01
0.553 ±0.001	0.507 ±0.001	0.0453 ±0.002	0.0464 ±0.002	0.894± 0.002	0.768±0.002	0.577±0.011	0.608±0.01	1.159±0.011	1.159±0.01
0.545 ±0.002	0.601 ±0.002	0.0453 ± 0.002	0.0465 ±0.004	0.909± 0.003	0.755±0.002	0.586±0.011	0.614±0.01	1.168±0.011	1.168±0.01
0.553 ±0.001	0.607 ±0.001	0.0465 ± 0.002	0.0445 ±0.003	0.918± 0.003	0.761±0.001	0.576±0.011	0.621±0.01	1.166±0.011	1.166±0.01
0.553 ±0.001	0.601 ±0.001	0.0447 ± 0.002	0.0456 ±0.002	0.913± 0.003	0.763±	0.880±0.011	0.622±0.01	1.160±0.011	1.160±0.01

Hardness test:

All the tablets had hardness measurements within the range of (5.1- 6.7 kg) , which meets the acceptable requirement of being equal to or greater than 4. This indicates that all the tablets can withstand chipping, abrasion, or breakage during handling, transportation, and storage conditions [(8)] The variation in tablet hardness is may be due to differences in binder concentration. A higher binder concentration results in increased tablet hardness. Additionally, the hardness is also affected by the compression pressure applied during tablet formation [(9)]. The results of the tablet hardness test are presented in table (4)

Friability test:

All the tablets had friability measurements within the range of (0.3% to 0.67%), However, all batches exhibited a friability lower than 1% and met the compendial requirements. that is represented by table (4). The highest significant effects for the friability of tablets were observed for the binder type and lubricant type [10], so the difference in present of these excipients in addition compression force, die diameter, and punch shape may causes the difference in friability value between the national drug as compared with imported drug [11].

Disintegration time test:

All the tablets was within the acceptable range (less than 30 minutes), as specified by the USP for uncoated tablets (8) as shown in table (4). From the five coupled of drug in this study, there is significant difference ($p > 0.05$)between the coupled of drug . The difference may be differentiated through the compression force used in the manufacturing process or two different compression force levels. The disintegration time increased along with the compression force. Also an increased surface area was responsible for the faster disintegration, as more liquid could penetrate the solid matrix of the tablet. Moreover, increasing diameters are related to lower pressures which result in higher porosity that enables quick liquid penetration and further disintegration [11] .

Table 4: Hardness, Friability, and Disintegration Time Tests.

Drug	**Hardness (Kg) Mean ±SD (n=3)**	**Friability % Mean (n=10)**	**Disintegration time (sec) Mean ±SD (n=3)**
Kepracetam	6.2±0.60	0.61%	166±4.5
Keppra	6.7±0.50	0.59%	170±6.0
Hyporic	5.1±0.20	0.41%	139±4.1
Zyloric	5.6±0.22	0.33%	149±7.5
Azithromycin	5.4±0.40	0.58%	144±3.6

Azithrosam	5.9±0.42	0.55%	150±5.5
Piodol	6.6±0.41	0.61%	156±6.6
Panadol	6.3±0.16	0.67%	162±7.0
Napron	6.2±0.23	0.41%	163±5.4
Nopain	6.4±0.21	0.45%	169±5.0

conclusion:

this study demonstrates that national tablet formulations meet the required pharmacopoeial standards for weight variation, hardness, friability, and disintegration time. All tested formulations exhibited acceptable physical and mechanical properties, indicating their quality, consistency, and suitability for therapeutic use. While minor variations were observed between national and imported tablets, these differences can be attributed to formulation factors such as binder concentration, compression force, and excipient composition. Overall, the results support the reliability of domestically produced pharmaceutical tablets and highlight their compliance with international quality benchmarks, reinforcing confidence in their efficacy and safety.

Recommendation: Based on the findings of this study, the following recommendations are proposed to further enhance the quality of national tablet formulations:

1.Future studies should focus on optimizing binder concentration and compression force to ensure consistent hardness and friability within acceptable limits and Evaluating different excipients and their impact on tablet strength and disintegration time can help improve formulation consistency.

2.Additional research should include a wider range of national and imported formulations to strengthen comparative analyses and ensure robust conclusions and exploring different therapeutic categories and dosage forms will provide a broader understanding of formulation performance.

Acknowledgments

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Ethics Statements

No ethical statement is required (no *in vivo* study was conducted).

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