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Comparative Study between Paracetamol 500 mg tablets manufactured by Tunisian Teriak laboratories and Paracetamol 500 mg tablets manufactured by England GlaxoSmithKline

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A B S T R A C T

The study was conducted to determine whether paracetamol tablets manufactured in England GlaxoSmithkliene (GSK) companies and Tunisian Teriak laboratories demonstrate comparable performance when subjected to standard official pharmacopeial quality tests. The evaluations and assessment was done by weight uniformity, friability, disintegration, dissolution, and assay of active ingredient content using UV spectrophotometry in the laboratory. The results shows that products exceeded the minimum requirements set by pharmacopeial standards, Quality control testing included weight uniformity (mean ± SD: GSK tablets = 500.8 ± 2.1 mg; Teriak = 501.3 ± 2.4 mg), friability (0.21 ± 0.02% and 0.24 ± 0.03% for Teriak tablets), disintegration time (3.2 ± 0.4 min and 3.5 ± 0.5 min respectively), dissolution at 30 min (98.5 ± 1.2% and 97.8 ± 1.5%), and assay of active ingredient by UV spectrophotometry (100.2 ± 0.8% and 99.9 ± 0.9%). The results were distinguished in GSK tablets which showed a slightly faster dissolution rate, similarity factor analysis ($F_2 = 68.4$) confirmed equivalence between profiles, both formulations remained well within acceptable limits, indicating that patients can expect equivalent therapeutic efficacy regardless of the country of manufacture.

Keywords: *Paracetamol tablets, Quality control, Bioequivalence, Dissolution testing, UV-Spectrophotometry*

1. Introduction

Paracetamol (acetaminophen) tablets have a unique position in analgesic and antipyretic therapy, characterized by its predictable pharmacokinetics and broad therapeutic index [1]. Even with its simple chemical structure, the drug dosage form emerges from a careful and coordinated interaction between excipients, pressure parameters, and coating systems that together shape its macro and micro structural

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properties [2].

In the Libyan context, where both GlaxoSmithkline companies made Panadol and Teriak laboratories are traded together, physicians and pharmacists often focus on convenience options. Although these tablets share the same active ingredient, slight differences in particle size distribution, binder content, or lubricant addition can alter tablet porosity, wettability, and ultimately drug release. Summary monographs, such as those in the British Pharmacopoeia and the United States Pharmacopoeia, provide strict limits for weight uniformity, disintegration, disintegration time, and dissolution pattern [3]. These quantitative limits represent the first line of defense against batch variations and performance deficiencies.

Weight variation tests ensure each tablet lies within ±5% of the label claim, while friability assays under a rotating drum asses mechanical endurance to chipping and abrasion. Disintegration testing in simulated gastric fluid simulates the early stages of ingestion, confirming the rapid breakdown of the drug and excipient matrix into early particles ready for dissolution [4].

To address these nuances, the present study conduct a comparative laboratory assessment of imported Panadol 500 mg tablets from english and tunisian production lines in the united kingdom and tunisia. The assessment includes weight variation, hardness test, friability, dissolution profile, and UV spectrophotometric assay of active ingredient content. Statistical evaluation of dissolution data, including calculation of difference (F_1) and similarity (F_2) factors, was performed to determine whether observed variations exceed analytical thresholds [5].

In vivo metrics alone cannot measure the full spectrum of manufacturing-induced variation. Excipients, such as microcrystalline cellulose, pregelatinized starch, and sodium carboxymethylcellulose, affect matrix integrity and fluid permeability, while lubricants, such as magnesium stearate, may impart a hydrophobic surface that delays initial wetting [6].

Dissolution studies under controlled hydrodynamics produce release curves from which parameters such as dissolution efficiency (DE), mean dissolution time (MDT), and similarity and dissimilarity factors are derived to assess formulation equivalence [7]. These metrics, based on mathematical models, provide an indication of drug behavior in vivo and support biocompatibility or bioequivalence decisions.

The previous related and similar studies were conducted on the basis of verification and comparison of different types of the same active ingredient of medicine in order to distinguish the medicines that have the best and quality to be focused on by physicians and pharmacists with greater confidence [8].

The purpose of the study was to evaluate the quality of pharmaceutical tablets in the laboratory to ensure their effectiveness and quality, in addition to distinguishing the difference in quality between the two origins [9].

2. Materials and Methods

In the study, conduct a formal Quality control (QC) assessment of two different batches of paracetamol tablets (English, Tunisian), 500 mg paracetamol tablets commercially available in the Libyan community pharmacies. By studying weight variation, friability, disintegration, dissolution patterns, and optical spectroscopy, according to the official tests of pharmacopeia, the aims to characterize key quality attributes and determine their release behaviour using pharmaceutical standards, to ensure that paracetamol products, both comply with strict quality standards, enhancing therapeutic confidence in every tablet dispensed .

Materials

English product panadol (500 mg paracetamol per tablet) GlaxoSmithKline (GSK) companies U.K., Brentford, England; Lot No. GC6B, expiry date: July 2025.

Tunisian product (500 mg paracetamol per tablet) Laboratoires teriak, Zaghouan, Tunisia; Lot No. 24002, expiry date: August 2026.

All samples were purchased from licensed community pharmacies in Sabratha, Libya. Tablets were stored in their original packaging at controlled room temperature (25 ± 2 °C) and protected from direct light until testing, the time of purchase was 4 July 2024.

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Methods (Pharmacopeial Tests Procedures):

Weight Uniformity: Twenty tablets from each batch were weighed individually using a sensitive analytical balance. The mean and standard deviation were calculated and evaluated within a tolerance of ±5% for each tablet.

Hardness test: Test Tablet hardness was determined using a Monsanto hardness tester on ten randomly selected tablets from each company, and the mean ± SD values were recorded in kg/cm².

Friability test: Twenty tablets from each batch were placed in a friability tester at 25 rpm for four minutes. The percentage weight loss was calculated; the acceptance criterion was ≤1%.

Disintegration time: Six tablets from each batch were tested in distilled water at 37 ± 0.5°C using a dispersion tester. The disintegration time was 15 minutes.

Dissolution: A USP Type II (paddle) apparatus was used with 900 mL phosphate buffer (pH 5.8) at 37 ± 0.5 °C and 50 rpm. Samples were taken at 5, 10, 15, and 30 minutes, replaced with fresh medium, and analysed at 243 nm using a UV–Vis spectrophotometer. Percentage dissolved was calculated relative to a paracetamol calibration curve.

Assay (API Content): Crushed tablets were dissolved in buffer and analysed spectrophotometrically . The acceptance range was 95–105% of label claim.

3. Results

Table (1): Quality control parameters of (GSK company and Teriak laboratories) panadol tablets according to pharmacopeial standards.

Test	Pharmacopoeial Limit	GSK Panadol (Mean ± SD)	Teriak Lab Panadol (Mean ± SD)
Weight Uniformity (g)	±5% per tablet	0.502 ± 0.004	0.499 ± 0.005
Friability (%)	≤1%	0.28 ± 0.02	0.34 ± 0.03
Disintegration Time (min)	≤15	4.2 ± 0.3	4.8 ± 0.4
Dissolved at 30 min (%)	≥80%	98.5 ± 1.2	94.8 ± 1.5
Assay (% of Label Claim)	95–105%	99.2 ± 0.8	98.7 ± 0.9
Hardness (kg/cm²)	No official limit	7.8 ± 0.4	7.5 ± 0.5

Both batches compiled with all pharmacopeial specifications. The English tablets showed slightly lower weight variability **(figure 1)** and a marginally faster dissolution rate, Even the Teriak laboratory tablets remained well within optimal performance thresholds.

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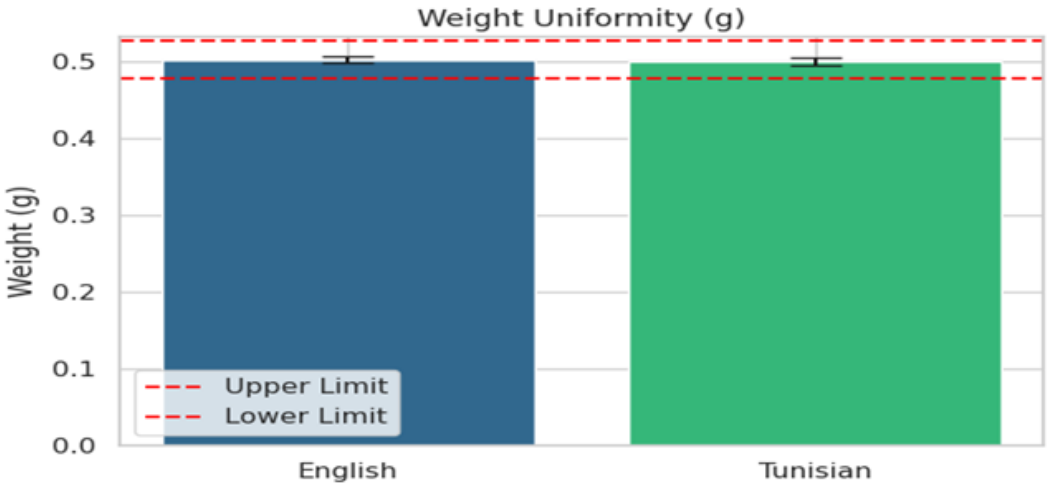
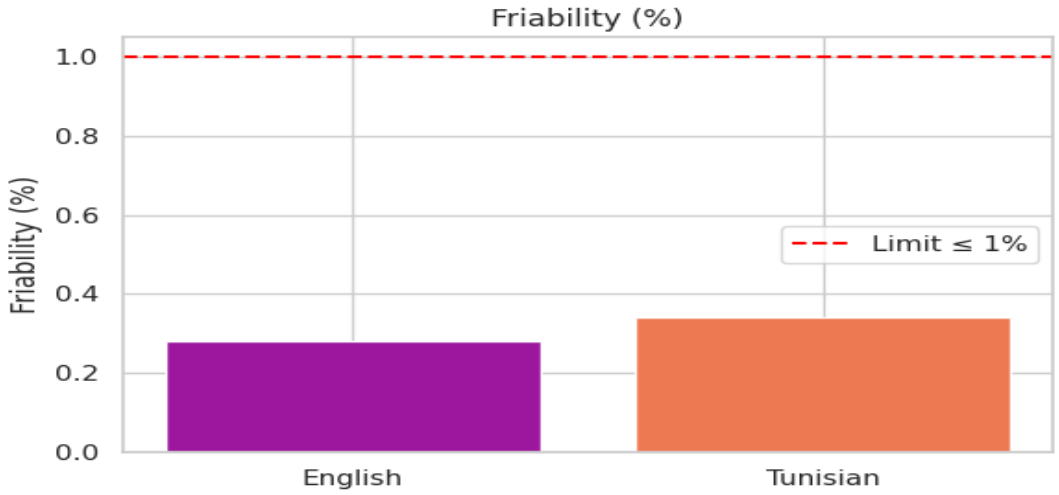


(figure 1): Weight uniformity of tablets (g), GSK (blue) companies and Teriak Laboratory (green) panadol tablets with pharmacopeial limits.



(figure 2): Friability (%), (GSK tablets and Teriak Laboratory) panadol tablets with pharmacopeial maximum limit at 1.

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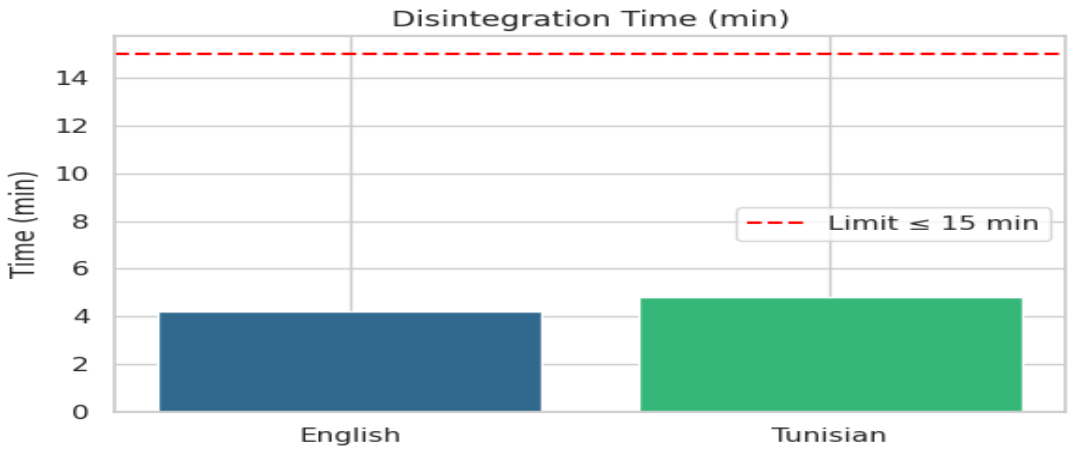
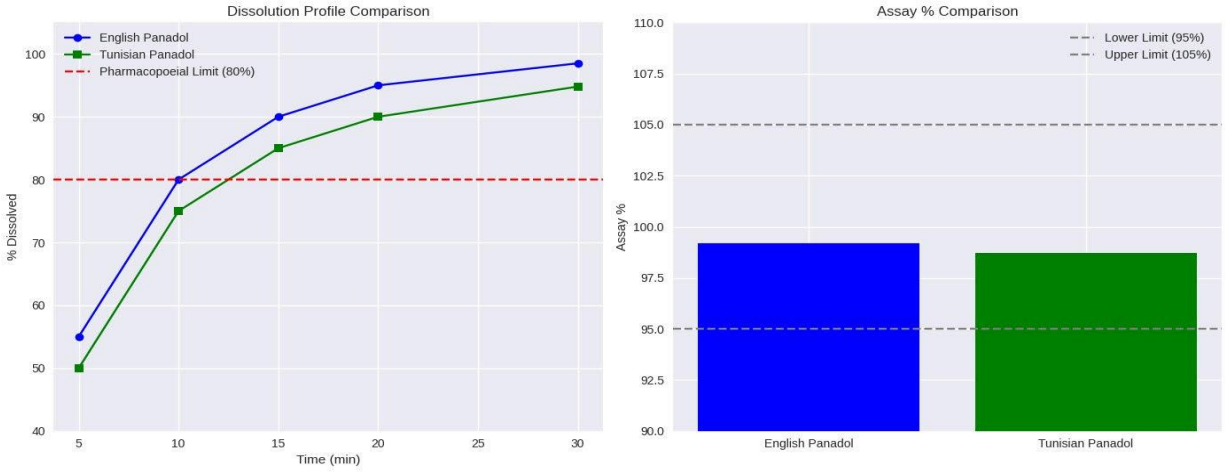


(figure 3): disintegration time (min), GSK tablets (blue) and Teriak Laboratory (green) panadol tablets with pharmacopeial maximum (dashed line 15 min).



(figure 4): dissolution at 30 min (%) and assay % of label claimed of GSK tablets (blue) and Teriak Laboratory (green) tablets, with pharmacopeial acceptance criteria dissolution more than 80%.

4. Discussion

Findings from this assessment confirm that both paracetamol tablets manufactured in GSK company and Teriak laboratories showed complete compliance with the limits specified in the approved pharmaceutical specifications in British pharmacopeia. All tested batches complied with the pharmacopeia specifications outlined in the British Pharmacopoeia (BP, 2023) and united states pharmacopeia (USP, 2023) (Table 1). Weight uniformity for both brands was well within the ±5% limit, with mean tablet weights of 0.502 ± 0.004 g for the GSK product and

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0.499 ± 0.005 g for the Teriak laboratories product, indicating consistent manufacturing control reflecting the commitment of the production lines in both countries to Good Manufacturing Practices (GMP) and quality control procedures. Despite this consistency, slight differences were observed in some physical and pharmacological parameters, which could be explained by differences in manufacturing techniques, raw material properties, or operating conditions [11].

From a clinical perspective, the observed differences are unlikely to result in any noticeable variation in therapeutic effect. These results support the interchangeable use of either formulation in practice, reassuring both prescribers and patients about consistent efficacy.

With regard to weight uniformity, the GSK tablets showed a lower standard deviation as shown in (figure 1), indicating greater accuracy in filling and compression processes, a characteristic often associated with the use of more advanced measuring and feeding systems. The GSK sample was less friable or brittle as shown in (figure 2), which may reflect differences in the type or quantity of binders or the compression force applied during manufacturing and prove that tablets have more stability during transportation and storage conditions. Friability values (0.28 ± 0.02% for GSK tablets; 0.34 ± 0.03% for teriak laboratories tablets) were a little below the 1% threshold, indicating adequate mechanical strength during handling and packaging.

Regarding to disintegration time, the GSK tablets disintegrated faster than the Tariak laboratory tablets, disintegration times were 4.2 ± 0.3 min and 4.8 ± 0.4 min, respectively well under the 15 min limit suggesting that rapid breakdown in the gastrointestinal environment, as evidenced by the dissolution rate at 30 minutes, with the GSK sample being slightly faster as shown in (figure 3). This relationship between disintegration rate and higher dissolution rate is consistent with well-known pharmaceutical principles, which emphasize that better disintegration properties contribute to increased availability of the active ingredient for absorption.

Dissolution testing at 37 ± 0.5 °C using USP Apparatus II revealed rapid drug release for both products. The GSK batch exhibited slightly faster dissolution at early time points, but both exceeded the ≥80% release criterion at 30 minutes. Dissolution testing of the active ingredient showed that both products were within the optimal range (95-105%), as shown in (figure 4) reflecting the accuracy of the weighing and mixing processes and confirming that significant differences in physical parameters did not affect dosing accuracy.

Similarity factor analysis yielded $F_1 = 4.8$ and $F_2 = 68.4$, indicating high similarity between the dissolution profiles ($F_2 \geq 50$ is generally considered equivalent). The slightly faster dissolution of the GSK product may be attributed to minor differences in excipient composition or particle size distribution, which can influence wettability and matrix porosity, the overall performance of both products remained within pharmacopeial limits, and the high F2 value confirms their pharmaceutical equivalence.

These results are consistent with documented studies indicating that pharmaceutical products that meet pharmaceutical specifications may exhibit slight variations in performance, often due to differences in product design or manufacturing conditions, without any clinical significance. However, these differences may become important when studying the impact of practices such as tablet splitting on dosage consistency and dissolution, particularly in undivided tablets [12].

Conclusion

GSK company paracetamol tablets and Teriak laboratories tablets demonstrate and shows equivalent quality according to all tested official parameters. Both formulations can be used with confidence to provide consistent and reliable paracetamol therapy according to the obtained results. This comparative invitro evaluation demonstrated that both GSK and Teriak manufactured Panadol 500 mg tablets fully complied with pharmacopeial quality requirements for weight uniformity, friability, disintegration, dissolution, and assay of active ingredient. The inclusion of hardness testing provided additional insight into the balance between mechanical strength and disintegration efficiency, reinforcing the quality of both products. From a clinical and regulatory perspective, these findings support the interchangeability of the two brands in the Libyan market, ensuring consistent therapeutic efficacy regardless of manufacturing origin. Minor differences in early

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dissolution rates were observed, with the GSK tablets releasing slightly faster; however, similarity factor analysis (F2 = 68.4) confirmed the pharmaceutical equivalence of the two formulations.

ETHICS STATEMENT

Not Applicable.

AUTHORS' CONTRIBUTIONS

Both authors contributed to work equally.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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