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Comparative Evaluation of Marketed Metformin 500 mg Tablet Brands Using Standard Pharmacopoeial Tests: A Comprehensive Review

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Abstract: *Metformin hydrochloride stands as the globally endorsed first-line pharmacotherapy for type 2 diabetes mellitus (T2DM), yet the pharmaceutical quality of its numerous marketed formulations can differ substantially. This review critically examines and contextualises a comparative evaluation conducted on three commercially available Metformin 500 mg brands — Metsmall 500 (immediate-release), Glycomet 500 SR (sustained-release), and Gluconorm SR 500 (sustained-release) — against standard pharmacopoeial quality tests. The evaluation encompassed weight variation, hardness, friability, thickness uniformity, and a preliminary dissolution observation performed under controlled laboratory conditions. All three brands demonstrated complete compliance with accepted pharmacopoeial specifications: weight variation remained within the ±5% limit, hardness exceeded the minimum threshold of 4 kg/cm², friability stayed below the 1% ceiling, and tablet thickness was uniformly consistent across all brands. The preliminary dissolution observation confirmed that the sustained-release formulations exhibited markedly slower dispersion patterns relative to the immediate-release brand, which is mechanistically consistent with their controlled drug delivery design. This review situates these findings within the broader pharmaceutical quality control literature, discusses their clinical implications for glycaemic management, and underscores the public health importance of routine post-marketing surveillance for antidiabetic medicines. The results collectively affirm that the three evaluated brands maintain satisfactory pharmaceutical quality and may be regarded as therapeutically comparable from a quality-control standpoint, though rigorous bioequivalence studies remain essential before definitive clinical interchangeability can be established.*

Keywords: - Metformin hydrochloride, tablet evaluation, weight variation, hardness, friability, dissolution, pharmacopoeial standards, sustained release, quality control, type 2 diabetes mellitus.

I. INTRODUCTION

Diabetes mellitus is one of the most pervasive and rapidly expanding non-communicable diseases of the modern era, burdening hundreds of millions of people across the globe. Among its principal forms, type 2 diabetes mellitus (T2DM) constitutes the overwhelming majority of cases. Defined by progressive insulin resistance, impaired beta-cell secretory capacity, and persistent hyperglycaemia, T2DM poses a profound and growing public health challenge. Left inadequately controlled, the condition triggers a relentless cascade of complications — encompassing cardiovascular disease, nephropathy, retinopathy, and peripheral neuropathy — that erode quality of life and impose enormous economic costs on healthcare systems.

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Against this challenging backdrop, pharmacological management occupies a central position, and metformin hydrochloride has retained its status as the unchallenged cornerstone of T2DM therapy for more than six decades. Endorsed as the preferred first-line agent by the World Health Organization (WHO), the American Diabetes Association (ADA), the European Association for the Study of Diabetes (EASD), and nearly every major national diabetes guideline worldwide, metformin's combination of proven efficacy, robust safety record, affordability, and oral convenience remains unmatched by any single alternative.

Beyond its established antidiabetic role, metformin has attracted growing attention for its broader therapeutic potential. Investigational applications now span oncology, cardiovascular risk reduction, non-alcoholic fatty liver disease (NAFLD), polycystic ovarian syndrome (PCOS), gestational diabetes, and even the biology of ageing. This expanding therapeutic horizon has only amplified global demand for high-quality metformin formulations. In India alone, the drug is manufactured and marketed under dozens of brand names in both immediate-release (IR) and sustained-release (SR) formats, creating a complex and competitive pharmaceutical landscape that demands rigorous quality oversight.

The proliferation of brands inevitably raises an important clinical question: do commercially available formulations actually perform equivalently in terms of pharmaceutical quality? A tablet that fails basic pharmacopoeial quality tests — whether through excessive weight variation, insufficient hardness, elevated friability, or aberrant drug release — may deliver a suboptimal or inconsistent dose, directly undermining glycaemic control and patient safety. Comparative evaluation of marketed brands is therefore not merely an academic exercise; it is a matter of genuine public health significance. This review comprehensively examines the outcomes of a comparative quality evaluation performed on three marketed Metformin 500 mg brands and contextualises those findings within established pharmacopoeial standards and contemporary pharmaceutical literature.

II . DRUG PROFILE OF METFORMIN

Metformin hydrochloride (DrugBank ID: DB00331) is chemically designated as 1,1-dimethylbiguanide hydrochloride, carrying the molecular formula $C_4H_{11}N_5 \cdot HCl$ and a molecular weight of 165.62 g/mol. It presents as a white to off-white crystalline powder with high aqueous solubility, a property that greatly facilitates its formulation into solid oral dosage forms. The molecule's biguanide scaffold — two guanidine groups bridged by a nitrogen, bearing two methyl substituents on the terminal nitrogen — is directly responsible for its pharmacological activity.

Mechanistically, metformin's primary action centres on the inhibition of mitochondrial complex I within hepatocytes. This transiently reduces intracellular ATP levels and elevates the AMP:ATP ratio, activating AMP-activated protein kinase (AMPK) — a master regulator of cellular energy balance. AMPK activation suppresses hepatic gluconeogenesis, the primary driver of fasting hyperglycaemia in T2DM. Secondarily, metformin enhances peripheral insulin sensitivity in skeletal muscle and reduces intestinal glucose absorption. Crucially, it does not stimulate pancreatic insulin secretion, conferring a negligible intrinsic risk of hypoglycaemia — a major clinical advantage over secretagogues such as sulfonylureas.

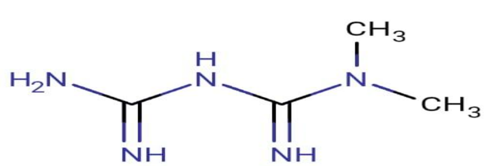

Figure 1: Chemical structure of Metformin (1,1-dimethylbiguanide hydrochloride)

Pharmacokinetically, metformin is absorbed primarily from the small intestine, achieving an absolute bioavailability of approximately 50–60% under fasting conditions. It is not significantly bound to plasma proteins and is excreted virtually unchanged in the urine through active renal tubular secretion. The plasma half-life ranges from 4 to 9 hours for immediate-release formulations; sustained-release variants extend the plasma concentration-time profile

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considerably, enabling once-daily dosing and substantially improving gastrointestinal tolerability. Renal function is a critical safety determinant: dose adjustment or discontinuation is recommended when the estimated glomerular filtration rate (eGFR) falls below 30 mL/min/1.73 m², owing to the rare but serious risk of lactic acidosis in the setting of severe renal impairment.

2.1 Historical Background

The therapeutic journey of metformin is a narrative of discovery, near-oblivion, and remarkable vindication. The pharmacological potential of biguanide compounds was first hinted at through centuries of European folk medicine use of Galega officinalis (Goat's Rue), a guanidine-rich plant observed to lower blood glucose. Structural derivatisation of its active constituents led to the synthesis of metformin in the 1920s, though its glucose-lowering potential received only brief attention before insulin's discovery overshadowed biguanide research for decades.

It was not until 1957 that French physician Jean Sterne conducted rigorous clinical trials in Paris and formally documented metformin's antihyperglycaemic efficacy. Sterne christened it Glucophage — meaning 'glucose-eater' — a name adopted commercially and still widely recognised today. Regulatory approval proceeded cautiously: Canada approved metformin in 1972, while the United States Food and Drug Administration (FDA) granted approval only in 1995. Since then, metformin has become the most widely prescribed antidiabetic agent globally and occupies a place on the WHO Model List of Essential Medicines. Contemporary research continues to uncover novel mechanisms, including its modulation of the mTOR pathway and gut microbiome, reinforcing its relevance far beyond glycaemic control alone.

III. IMPORTANCE OF TABLET QUALITY EVALUATION

The pharmaceutical quality of a tablet is far more than a regulatory formality — it represents the biochemical bridge between the manufacturing process and the patient's therapeutic outcome. For metformin, typically taken daily over decades, even minor and persistent variations in tablet quality can translate into clinically meaningful differences in drug exposure, glycaemic control, and patient safety. Tablet evaluation therefore occupies a critical role in both the pre-market approval process and ongoing post-marketing quality assurance.

Pharmacopoeial compendia — including the Indian Pharmacopoeia (IP), United States Pharmacopeia (USP), and British Pharmacopoeia (BP) — establish legally binding quality standards for pharmaceutical products. These standards define acceptable ranges for physical, chemical, and biopharmaceutical parameters that a tablet must satisfy before being deemed fit for patient use. Among the principal parameters evaluated are weight variation, hardness, friability, thickness, disintegration, and dissolution.

Weight variation testing ensures that each tablet in a batch delivers approximately the same quantity of active drug. Hardness and friability together assess mechanical robustness — one from the perspective of compressive strength, the other from resistance to abrasive wear during handling and transport. Thickness uniformity contributes to consistent packaging and patient dose identification. Dissolution testing, widely regarded as the most clinically relevant in vitro parameter, simulates the drug release process in a controlled medium and provides predictive information about in vivo absorption. For sustained-release metformin, dissolution profiles are especially critical, as they define the temporal drug release pattern that governs the formulation's clinical behaviour and patient tolerability.

IV. REVIEW OF LITERATURE

A substantial and growing body of published literature addresses the comparative evaluation of marketed tablet formulations, with considerable focus on metformin given its unparalleled clinical prevalence. Collectively, these studies reinforce the view that pharmacopoeial evaluation is a reliable, reproducible, and practically accessible approach to assessing tablet quality across commercial brands.

Arora et al. (2021) conducted a comparative evaluation of metformin tablets obtained through government procurement channels alongside those available on the open commercial market in Delhi. Their study found that both categories generally complied with pharmacopoeial quality parameters, though minor quantitative differences were observed between government-supplied and commercial formulations. This finding carries particular relevance in the Indian healthcare context, where procurement pathways differ significantly and the quality equivalence of medicines supplied through public health channels is a recurring policy concern.

Hassan (2025) evaluated the weight variation characteristics of multiple brands of metformin 850 mg tablets, reporting satisfactory weight uniformity across all tested formulations. The author emphasised that weight variation is a fundamental indicator of manufacturing precision and dose reliability, and that compliance with pharmacopoeial limits represents a necessary — though not sufficient — condition for overall product quality. Saleem et al. (2014) underscored the practical importance of friability testing as a predictor of tablet durability during real-world handling conditions, demonstrating that tablets with friability values below the 1% threshold sustained substantially less physical damage during simulated transport compared to those exceeding the limit.

Hashem, Nasr, and Sammour (2020) investigated the formulation and stability of metformin hydrochloride controlled-release tablets, highlighting that dissolution profile and release kinetics are defining quality attributes for sustained-release dosage forms. Their work reinforced that dissolution testing must be integral to SR formulation quality evaluation. Complementing this, Pichandy et al. (2008) demonstrated through their design and evaluation of extended-release metformin tablets that polymer selection and compression parameters profoundly influence drug release kinetics, providing a formulation science rationale for the characteristically different dissolution profiles observed between IR and SR metformin brands.

Sultana (2024) further contextualised the relationship between coating technologies and mechanical strength, showing that coating processes can markedly alter measured hardness values. Reddy and Navaneetha (2012) and Billa et al. identified thickness uniformity as an underappreciated yet practically important quality attribute, noting that inconsistent thickness can signal irregularities in the compression process and potentially affect dose consistency across a batch. Together, this body of literature forms the quality science foundation upon which the present comparative evaluation is interpreted and contextualised.

V. AIM AND OBJECTIVES

5.1 Aim

To perform a comprehensive comparative evaluation of three commercially marketed brands of Metformin 500 mg tablets using standard pharmacopoeial quality tests, and to critically interpret the findings in the context of established pharmaceutical quality benchmarks and contemporary literature.

5.2 Objectives

The specific objectives of this study were: (i) to compare the physical and mechanical quality attributes of three marketed Metformin tablet brands; (ii) to conduct weight variation testing and assess compliance with pharmacopoeial limits; (iii) to evaluate tablet hardness as a measure of mechanical compressive strength; (iv) to determine percentage friability and assess resistance to physical attrition; (v) to measure tablet thickness uniformity across selected brands; and (vi) to conduct a preliminary dissolution observation to study the comparative dispersion behaviour of immediate-release versus sustained-release formulations in an aqueous medium.

VI. MATERIALS AND METHODOLOGY

6.1 Selected Brands

Three commercially available brands of Metformin 500 mg tablets were selected: Metsmall 500 (immediate-release), Glycomet 500 SR (sustained-release), and Gluconorm SR 500 (sustained-release). All brands were procured from licensed retail pharmacies and stored under conditions specified on their respective labels prior to evaluation. The selection intentionally encompassed both immediate-release and sustained-release formulation types, reflecting the clinical diversity of metformin products available to patients and prescribers.

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6.2 Instruments Used

The following instruments were employed: a calibrated digital weighing balance for gravimetric measurements; a Monsanto hardness tester for compressive strength determination; a digital programmable friability apparatus (Roche-type) for abrasion resistance testing; a Vernier caliper for thickness measurement; 250 mL glass beakers for dissolution observation; and a stopwatch for timing observations.

Figure 2: Digital programmable friability apparatus (Roche-type) used for abrasion resistance testing

6.3 Weight Variation Test

Twenty tablets from each brand were individually weighed using the digital balance and the average tablet weight was calculated. The permissible deviation limit for tablets weighing more than 250 mg, as stipulated by the Indian and United States Pharmacopoeias, is ±5% of the average weight. Upper and lower acceptable weight limits were computed for each brand, and individual tablet weights were verified against these limits.

6.4 Hardness Test

Five tablets from each brand were subjected to hardness testing using the Monsanto hardness tester. Each tablet was placed between the instrument anvils and progressively increasing compressive force was applied until fracture. The force at fracture (in kg/cm²) was recorded for each tablet and the mean hardness computed. An acceptable hardness range for standard uncoated tablets is 4–8 kg/cm², though SR polymer-matrix tablets may exhibit higher values due to formulation requirements.

6.5 Friability Test

Ten tablets from each brand were collectively weighed (initial weight, W_1) and placed in the rotating drum of the friability apparatus. The apparatus was operated at 25 rpm for 4 minutes (100 revolutions total), per pharmacopoeial guidelines. After the test, tablets were dedusted and reweighed (final weight, W_2). Percentage friability was calculated as: % Friability = $[(W_1 - W_2) / W_1] \times 100$. Values below 1% are considered acceptable.

6.6 Thickness Test

The thickness of five tablets from each brand was measured individually using a Vernier caliper accurate to 0.01 mm. The mean thickness was calculated and recorded. Uniform thickness across a batch indicates consistent compression force and die-fill control during manufacturing, and deviations may signal process variability.

6.7 Preliminary Dissolution Observation

A preliminary dissolution observation was performed by placing one tablet from each brand into a separate 250 mL beaker containing distilled water at room temperature. Tablets were observed for visible dispersion behaviour and the

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approximate time to complete macroscopic dispersion was recorded. This was a qualitative observation rather than a formal dissolution study, as a UV-Vis spectrophotometer for quantitative drug release measurement was unavailable; nonetheless, the observation provides meaningful comparative information on dispersion kinetics between IR and SR formulation types.

VII. RESULTS

7.1 Weight Variation Test

All three brands demonstrated weight variation comfortably within the ±5% pharmacopoeial limit. Metsmall 500 had an average tablet weight of 0.6825 g (acceptable range: 0.649–0.716 g); Glycomet 500 SR averaged 0.715 g (acceptable range: 0.679–0.751 g); and Gluconorm SR 500 recorded an average of 0.698 g (acceptable range: 0.663–0.733 g). All 60 sampled tablets (20 per brand) fell within their computed limits, confirming satisfactory weight uniformity and dose consistency.

Brand	Avg Wt (g)	Upper (g)	Lower (g)	Result
Metsmall 500	0.6825	0.716	0.649	PASS
Glycomet 500 SR	0.715	0.751	0.679	PASS
Gluconorm SR 500	0.698	0.733	0.663	PASS

Table 1: Weight Variation Results for Three Metformin Brands

7.2 Hardness Test

All three brands exhibited satisfactory mechanical compressive strength. Metsmall 500 recorded a mean hardness of 14.9 kg/cm², Glycomet 500 SR achieved 15.4 kg/cm², and Gluconorm SR 500 measured 15.1 kg/cm². These values substantially exceed the minimum acceptable threshold, with the marginally higher values for SR brands reflecting the greater compressive force applied during polymer matrix tablet manufacture to regulate drug diffusion.

Brand	Avg Hardness (kg/cm²)	Result
Metsmall 500	14.9	PASS
Glycomet 500 SR	15.4	PASS
Gluconorm SR 500	15.1	PASS

Table 2: Hardness Test Results

7.3 Friability Test

Percentage friability for all brands fell well within the pharmacopoeial threshold of less than 1%. Metsmall 500 showed the lowest value at 0.14%, while Glycomet 500 SR and Gluconorm SR 500 recorded 0.41% and 0.42% respectively. Although the SR formulations exhibited marginally higher friability than the IR brand, all values remained comfortably below the permissible limit, confirming acceptable resistance to chipping and abrasion during routine handling and transport.

Brand	W_1 (g)	W_2 (g)	% Friability	Result
Metsmall 500	6.84	6.83	0.14%	PASS
Glycomet 500 SR	7.15	7.12	0.41%	PASS

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Gluconorm SR 500	6.98	6.95	0.42%	PASS

Table 3: Friability Test Results

7.4 Thickness Test

The mean tablet thickness was uniformly 9 mm across all three brands. This consistency is a positive indicator of well-controlled manufacturing processes and reflects that compression force and die-fill were adequately maintained across these commercial formulations. Uniform thickness also facilitates automated blister packaging and aids reliable patient dose identification.

7.5 Preliminary Dissolution Observation

The dissolution observation revealed clear differences in dispersion behaviour between the IR and SR formulations. Metsmall 500 displayed comparatively rapid visible dispersion, with complete macroscopic dissolution occurring within approximately 18–20 minutes. In contrast, Glycomet 500 SR required 30–35 minutes, while Gluconorm SR 500 demonstrated the most sustained dispersion pattern at 32–38 minutes. These differences are entirely consistent with the intended release characteristics of the respective formulation designs and align with expected pharmacokinetic distinctions between IR and SR metformin products.

Brand	Observation	Approx. Time
Metsmall 500	Faster dispersion	18–20 min
Glycomet 500 SR	Slow, controlled dispersion	30–35 min
Gluconorm SR 500	Sustained dispersion pattern	32–38 min

Table 4: Preliminary Dissolution Observation Results

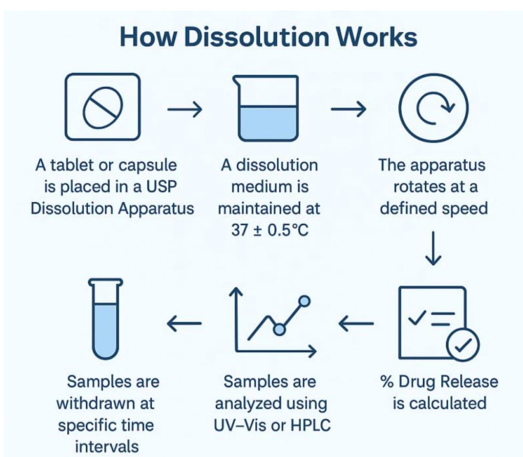

Figure 3: Schematic representation of a standard dissolution testing apparatus (USP Dissolution Apparatus Type II)

VIII. DISCUSSION

The findings of this comparative evaluation affirm that all three marketed brands of Metformin 500 mg — Metsmall 500, Glycomet 500 SR, and Gluconorm SR 500 — satisfy the key physical and mechanical quality requirements established by pharmacopoeial standards. This is a reassuring outcome from a public health perspective, given that these brands are widely prescribed and dispensed across India for the long-term management of T2DM.

The weight variation data are particularly encouraging. For a drug taken daily, often alongside other antidiabetic agents and sometimes for life, consistent tablet weight translates directly into consistent drug delivery. The fact that all 60 sampled tablets fell within the ±5% pharmacopoeial limit suggests that the manufacturing processes for these brands maintain adequate blend uniformity and die-fill control. From a clinical standpoint, weight uniformity reduces the risk of dose variability that might otherwise cause oscillating glycaemic control or heightened adverse event risk.

The hardness values recorded across all three brands — ranging from 14.9 to 15.4 kg/cm² — substantially exceeded the minimum acceptable threshold. These higher-than-minimum values are not a cause for concern; rather, they are entirely consistent with the formulation requirements of polymer-based SR tablets, which typically demand greater compressive force to form coherent drug-release-controlling matrices. Excessively hard tablets can, in some contexts, compromise disintegration and dissolution; however, the dissolution observation in this study revealed no evidence of dissolution impairment for the SR brands — their delayed dispersion was by purposeful design, not by defect.

Friability results were uniformly excellent. The IR brand, Metsmall 500, showed the lowest friability (0.14%), which is expected given that IR tablets are generally simpler in composition and may employ more robust binding agents. The SR brands showed marginally higher friability (0.41–0.42%), likely reflecting differences in polymer matrix composition and the inherently different mechanical behaviour of controlled-release matrices. Critically, all values remain well below the 1% ceiling, confirming that all three brands can withstand the mechanical stresses of packaging, transport, and dispensing without meaningful physical deterioration.

The preliminary dissolution observation, though qualitative in nature, provided valuable insight into comparative release behaviour. The approximately 12–18-minute difference in dispersion time between Metsmall 500 and the SR brands reflects the pharmacokinetic distinction these formulations are engineered to achieve. Sustained-release metformin is designed to release the drug gradually over 12–24 hours, reducing peak plasma concentrations, minimising gastrointestinal adverse effects such as nausea and diarrhoea, and enabling once-daily dosing — all factors that demonstrably improve long-term patient adherence and therapeutic outcomes. The slower dispersion observed for the SR brands in this study is therefore mechanistically appropriate and clinically desirable.

The primary limitation of this evaluation was the unavailability of a UV-Vis spectrophotometer for conducting a formal, quantitative dissolution study. Such a study would have provided precise drug release profiles across defined time intervals — data considerably more informative than visual dispersion observations for assessing the therapeutic equivalence and bioequivalence of these brands. Future investigations should incorporate complete dissolution profiling using validated analytical methods, content uniformity testing, and, where resource constraints permit, in vivo pharmacokinetic assessments in healthy volunteers to construct a more complete picture of brand-to-brand equivalence.

IX. CONCLUSION

The comparative evaluation of three marketed brands of Metformin 500 mg tablets — Metsmall 500, Glycomet 500 SR, and Gluconorm SR 500 — using standard pharmacopoeial tests has yielded consistently positive results across all assessed parameters. Weight variation, hardness, friability, and thickness evaluations for all three brands fell within pharmacopoeially accepted limits, confirming satisfactory pharmaceutical quality and manufacturing consistency. The preliminary dissolution observation reinforced the expected and intended distinction between IR and SR formulation types, with SR brands displaying markedly slower, controlled dispersion profiles consistent with their polymer-matrix drug delivery mechanisms.

These findings carry genuine clinical significance in the context of T2DM management, where reliable and consistent drug delivery is fundamental to achieving and sustaining target glycaemic control. The quality equivalence demonstrated across all three brands suggests that they may be regarded as pharmaceutically acceptable alternatives from a quality-control perspective. However, it must be emphasised clearly that pharmaceutical quality equivalence does not constitute bioequivalence or therapeutic equivalence. Establishing definitive therapeutic interchangeability requires rigorous bioequivalence studies with pharmacokinetic endpoints conducted in accordance with regulatory guidelines.

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Future research should build upon this quality evaluation foundation by incorporating complete dissolution testing using validated analytical methods, drug content uniformity assays, accelerated stability studies, and, where feasible, in vivo bioequivalence studies. Furthermore, the importance of routine post-marketing surveillance of antidiabetic formulations cannot be overstated. Regular quality monitoring throughout a product's commercial lifetime — by independent bodies as well as manufacturers — is essential to ensure that quality standards maintained at the time of market approval are preserved through the full duration of the product's shelf life. This review underscores that pharmacopoeial evaluation is a practical, accessible, and scientifically sound tool for monitoring the quality of essential medicines and protecting public health.

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