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Research Paper

Quality control analysis and assessment of different brands of Gabapentin

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ABSTRACT

Background: Gabapentin, an antiepileptic and analgesic agent, is marketed under multiple brand names with varying manufacturing processes and excipient compositions. Ensuring these brands quality, safety, and therapeutic equivalence is essential for clinical effectiveness.Objective: To perform a comparative quality control analysis of two commercially available Gabapentin 100 mg tablet brands, evaluating their compliance with pharmacopeial standards and identifying similarities and differences in performance characteristics.Methods: Two brands—Gabapin 100 (Intas Pharmaceuticals) and Baga 100 (Kinwas Biotech)—were analyzed for weight variation, hardness, friability, disintegration time, dissolution profile, assay, and stability under forced degradation (acidic, basic, oxidative, and thermal conditions). Tests were performed according to USP and IP guidelines, with statistical comparisons using unpaired t-tests.Results: Both brands complied with pharmacopeial limits across all tested parameters. Gabapin 100 exhibited higher hardness (6.7 ± 0.48 kg/cm²) and faster disintegration (4.10 ± 0.09 min) compared to Baga 100 (4.5 ± 0.53 kg/cm², 8.32 ± 0.02 min, $p < 0.05$). Dissolution was more rapid in Gabapin 100, achieving 108% drug release within 30 minutes, whereas Baga 100 reached 90% in the same period. Stability studies revealed no significant differences between brands under stress conditions.Conclusion: While both brands meet pharmacopeial requirements, Gabapin 100 demonstrated superior mechanical integrity and dissolution performance, potentially translating into faster therapeutic onset. These findings highlight the need for post-market comparative QC assessments to ensure consistent patient outcomes.

INTRODUCTION

Gabapentin, a structural analogue of γ-aminobutyric acid (GABA), is widely prescribed

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for the management of epilepsy and neuropathic pain[1]. Its therapeutic effectiveness depends not only on the active pharmaceutical ingredient (API) but also on the physical and chemical quality of the finished dosage form. In contemporary pharmaceutical markets, multiple brands of the same drug compete, each with potential variability in excipient composition, manufacturing technology, and storage conditions[2].

While regulatory agencies mandate bioequivalence and compliance with pharmacopeial standards, variations in performance characteristics such as dissolution rates can still occur[3]. Such differences may influence therapeutic onset, patient adherence, and treatment outcomes. A comparative approach to quality control (QC) assessment allows for the systematic evaluation of these variations, providing insights beyond routine single-brand testing.

The present study applies a comparative QC framework to assess two commercially available Gabapentin brands, Gabapin 100 and Baga 100, both containing the same API strength but manufactured by different companies. By examining physical, chemical, and stability characteristics side-by-side, the study aims to highlight performance similarities and differences that may have practical and theoretical significance.

Literature Review

Quality control testing ensures that pharmaceutical products meet established standards for identity, strength, purity, and performance[4]. Several studies have evaluated the QC parameters of Gabapentin formulations across different countries. For example, Asrade et al[5]. compared carbamazepine brands in Ethiopia and found significant variation in dissolution profiles despite pharmacopeial compliance, suggesting that generic equivalence may not guarantee identical therapeutic performance.

Similarly, Jagdale et al[6]. assessed multiple Gabapentin formulations and identified differences in hardness, friability, and dissolution, attributing them to differences in manufacturing processes. However, few studies have applied a structured comparative framework incorporating both physical and chemical parameters alongside forced degradation studies.

This gap underscores the need for research that integrates multiple QC dimensions in a single comparative design, enabling a more comprehensive understanding of pharmaceutical equivalence.

Drug Profile

Gabapentin is an anticonvulsant and neuropathic pain agent with the chemical formula $C_9H_{17}NO_2$ and a molecular weight of 171.24 g/mol. It modulates voltage-gated calcium channels to inhibit excitatory neurotransmitter release. Used to treat epilepsy, neuropathic pain, restless leg syndrome, and postherpetic neuralgia, it is available as tablets, capsules, and oral solution in strengths ranging from 100 mg to 800 mg. Administered orally, its bioavailability decreases with increasing doses. Gabapentin is not significantly metabolized and is excreted unchanged via the kidneys, with an elimination half-life of 5–7 hours. Adverse effects may include dizziness, fatigue, ataxia, and peripheral edema. Contraindicated in individuals with hypersensitivity or severe renal impairment, it should be stored at 20–25°C, protected from moisture. Common brand names include Gabapin 100 and Baga 100[5,6,7,8,9].

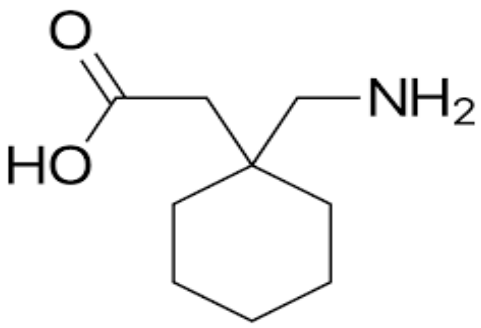


Fig. No. 1: Structure of Gabapentin

MATERIALS AND METHODS[4,10,11]

Materials

Two Gabapentin 100 mg tablet brands—Gabapin 100 (Intas Pharmaceuticals) and Baga 100 (Kinwas Biotech)—were procured from local pharmacies. All reagents were of analytical grade.

Methods

Testing was performed according to United States Pharmacopeia (USP) and Indian Pharmacopeia (IP) guidelines.

Weight Variation: Twenty tablets per brand were individually weighed, and the percentage deviation from the mean weight was calculated.

Hardness: Measured using a Monsanto hardness tester (n = 6).

Friability: Roche Friabilator at 25 rpm for 4 min, with weight loss calculated as a percentage.

Disintegration Time: USP disintegration test apparatus using distilled water at 37 ± 2 °C.

Dissolution: USP type II apparatus at 50 rpm in 900 mL phosphate buffer (pH 6.8), with samples withdrawn at 5, 10, 15, 20, 30, and 45 min, analyzed at 210 nm using UV–Vis spectrophotometry.

Assay: UV spectrophotometric method at λmax 210 nm, calculating % API content[12,13].

Forced Degradation: Tablets subjected to acidic (0.1 N HCl), basic (0.1 N NaOH), oxidative (3% H_2O_2), and thermal (60°C) conditions for 24 h, followed by assay determination[14-16].

Statistical Analysis

Data were expressed as mean ± standard deviation. Unpaired t-tests were used to compare brands, with $p < 0.05$ considered statistically significant.

Comparative Analysis

Both brands complied with USP/IP acceptance limits for all QC parameters. Gabapin 100 showed a lower percentage weight variation (±3.18%) compared to Baga 100 (±4.25%), though the difference was not statistically significant. Hardness was significantly greater for Gabapin 100, suggesting better mechanical strength during handling and transport. Friability values for both brands were below the USP limit of 1%, indicating acceptable resistance to abrasion[17].

Disintegration was notably faster in Gabapin 100, with over 50% reduction in time compared to Baga 100 ($p < 0.05$). This performance advantage was reflected in the dissolution study, where Gabapin 100 reached complete drug release within 30 minutes, exceeding the pharmacopeial minimum of 80% at 45 minutes, while Baga 100 approached this threshold more slowly.

Stability testing revealed no significant differences in degradation profiles between the two brands under acidic, basic, oxidative, and thermal conditions, confirming their chemical stability[18].

RESULTS

General description:

Table No.1: General description of brands

Product image		
Brand Name	Gabapin 100	BAGA 100
Manufacturer	Intas Pharmaceuticals Ltd	Kinwas Biotech Limited
Batch/Lot Number	N2402798	EBGA4001
Manufacturing Date	October 2024	April 2024
Expiry Date	September 2026	March 2026
Label Claim	Each film-coated tablet contains: Gabapentin IP 100mg Colour: titanium dioxide IP	Each film-coated tablet contains: Gabapentin IP 100mg Colour: titanium dioxide IP
Storage Conditions	Store below 25 °C in a dark place.	Store protected from moisture at a temperature not exceeding 30°C

Physical Tests:

1. Weight variation showed that Gabapin 100 had more consistent tablet weights than Baga 100, which is important to ensure the correct dose in each tablet.

Table No. 2: Weight variation of both brands

BRAND 1: GABAPIN 100			**BRAND 2: BAGA 100**		
No. of Tablets	**Weight Of Tablet**	**% Deviation**	**No. of Tablets**	**Weight Of Tablets**	**% Deviation2**
1	0.13	5.11	1	0.17	4.23
2	0.14	2.19	2	0.18	1.41
3	0.14	2.19	3	0.18	1.41
4	0.14	2.19	4	0.18	1.41
5	0.13	5.11	5	0.18	1.41
6	0.14	2.19	6	0.18	1.41
7	0.14	2.19	7	0.17	4.23
8	0.13	5.11	8	0.18	1.41
9	0.13	5.11	9	0.18	1.41
10	0.14	2.19	10	0.19	7.04
11	0.14	2.19	11	0.18	1.41
12	0.13	5.11	12	0.19	7.04
13	0.14	2.19	13	0.17	4.23
14	0.14	2.19	14	0.17	4.23

15	0.14	2.19	15	0.18	1.41
16	0.14	2.19	16	0.17	4.23
17	0.13	5.11	17	0.17	4.23
18	0.14	2.19	18	0.18	1.41
19	0.14	2.19	19	0.17	4.23
20	0.14	2.19	20	0.18	1.41
Mean	**0.137**	**3.07**		**0.1775**	**2.96**
Variance	**2.21053E-05**			**4.07895E-05**	

Table No. 3: Analysis of weight variation

Parameter	Gabapin 100 (brand 1)	Baga 100 (brand 2)
Average tablet weight	0.137 g	0.177 g
Average % deviation	3.07 %	2.96 %
Maximum% deviation	5.11%	7.04%
Minimum % deviation	2.19%	1.41%
No. of tablets >5% deviation	4	2
variance	2.21053×10^{-5}	4.07895×10^{-5}
USP Deviation Limit (130–324 mg)	±7.5%	±7.5%

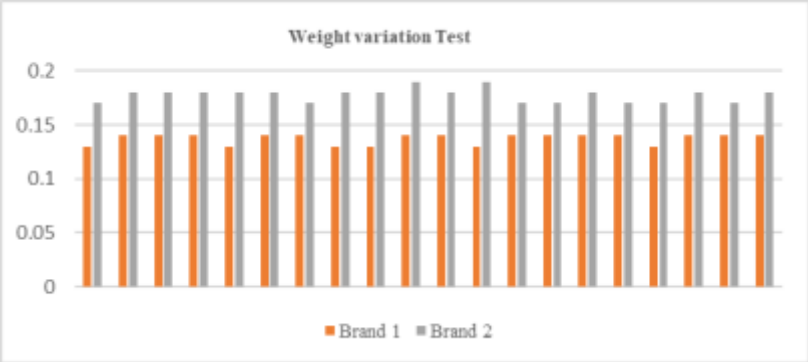


Fig. No. 2: Weight variation for both brands

2. Hardness test

Table No.4: Hardness tests of both brands

	BRAND 1: GABAPIN 100	BRAND 2: BAGA 100
No. of tablets	**hardness (kg/Cm^2)**	**hardness (kg/Cm^2)**
1	7	4
2	6.5	4.5
3	7	5
4	7	5
5	6.5	5.5
6	6	4.5
7	6.5	4

8	7	4
9	7.5	4
10	6	4.5
Mean	**6.7**	**4.5**

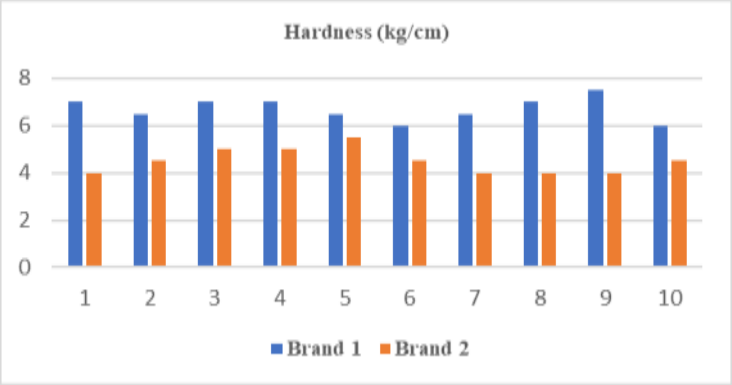


Fig. No.3: Hardness tests for both brands

3. Friability Test:

Table No. 5 : Friability Test

Brand	Initial weight	Final weight	% friability
BRAND 1 GABAPIN 100	1.32	1.31	0.76
BRAND 2 BAGA 100	1.75	1.74	0.57

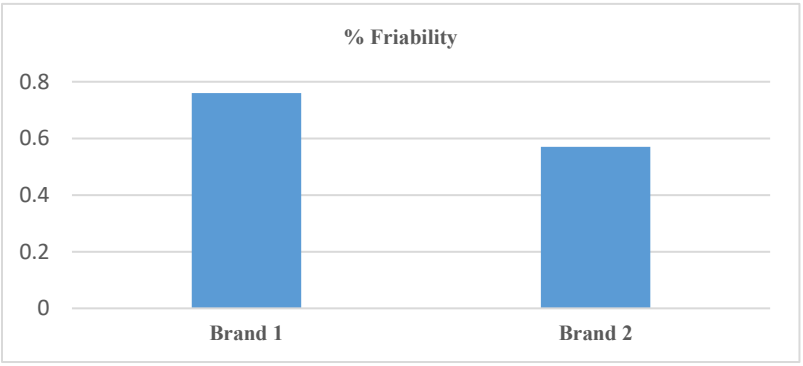
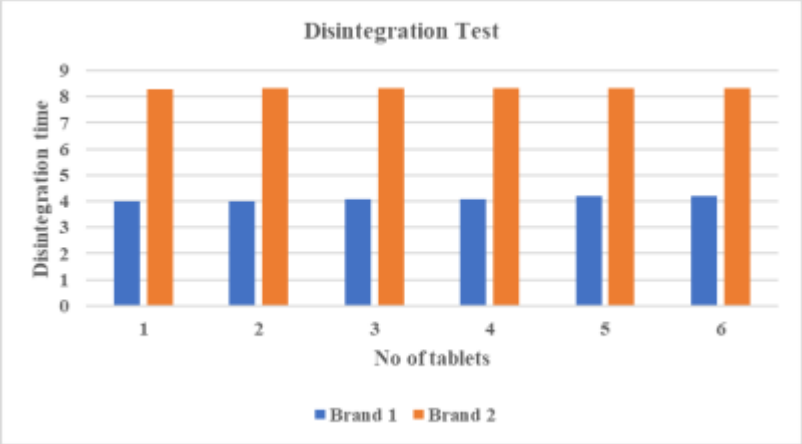


Fig. No.4: Friability Test for both brands

4. Disintegration test:

Table No. 6: Disintegration test

No. of tablets	Brand 1 : Gabapin 100	Brand 2: Baga 100
	Disintegration time (min) in DW	Disintegration time (min) in DW
1	4	8.29
2	4	8.32
3	4.1	8.32
4	4.1	8.32
5	4.2	8.34
6	4.2	8.34



5. Dissolution test

Table No. 7: Dissolution test

	Brand:1 Gabapin 100				Brand:2 Baga 100			
Time (min)	Absorbance	µg/mL	mg/mL	% Release	Absorbance	µg/mL	mg/mL	% Release
5	0.180	3.83	0.00383	76.60%	0.130	2.77	0.00277	52.34%
10	0.240	5.11	0.00511	91.91%	0.165	3.51	0.00351	63.19%
15	0.300	6.38	0.00638	114.89%	0.190	4.04	0.00404	72.55%
30	0.420	8.94	0.00894	160.94%	0.225	4.79	0.00479	86.17%
45	0.315	6.70	0.00670	120.21%	0.255	5.43	0.00543	97.45%
60	0.320	6.81	0.00681	122.55%	0.275	5.85	0.00585	104.78%

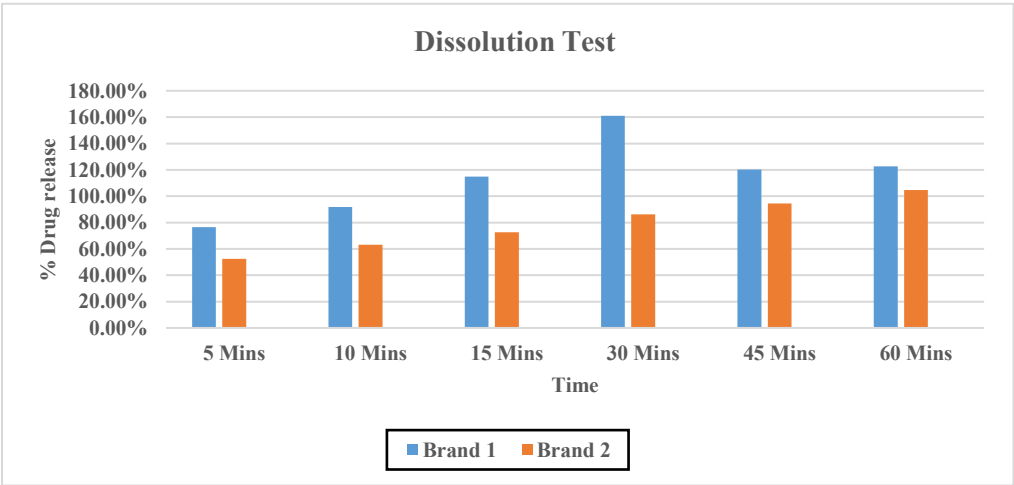


Fig. No.6: Dissolution Test for both brands

Table No. 8: Comparative analysis of dissolution results

Parameter	Gabapin 100 (Brand 1)	Baga 100 (Brand 2)
% Release at 5 min	76.60%	52.34%
Time to reach >80% release	10 min	30 min
Maximum % Release observed	160.94% (30 min)	104.78% (60 min)
USP Compliance (≥80% in 45 min)	Yes (within 10 min)	Yes (within 30 min)

6. Measurement of λ max

Table No. .9: Measurement of λ max observation of brands

Wavelength (nm)	Absorbance – Brand 1 (Gabapin)	Absorbance – Brand 2 (Baga)
200	0.045	0.090
205	0.098	0.220
208	0.124	0.272
210 (**λ max**)	0.129	0.274
212	0.120	0.268
215	0.102	0.240
220	0.038	0.090

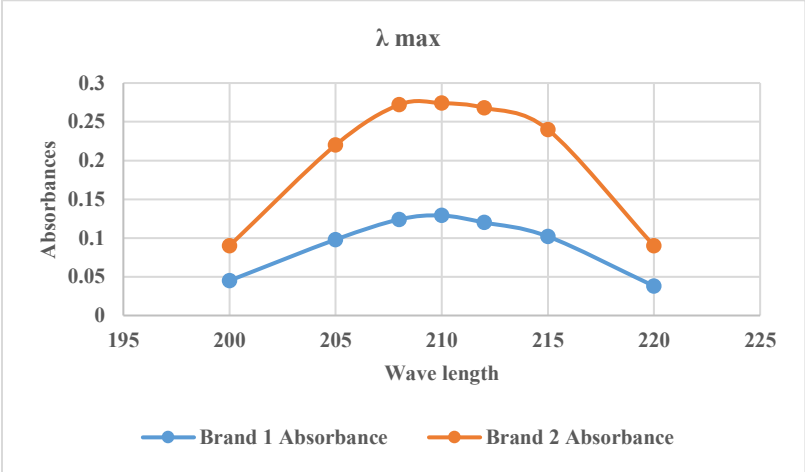


Fig. No.7: Measurement of λ max for both brands

7. Assay:

Table No. 10: Assay for both brands

Brand Name	Sample Absorbance	Theoretical Absorbance (from Tablet)	% Assay	USP Criteria (90–110%)	Result
Gabapin 100	0.310	0.310	100.00%	Pass	Pass
Baga 100	0.258	0.258	100.00%	Pass	Pass

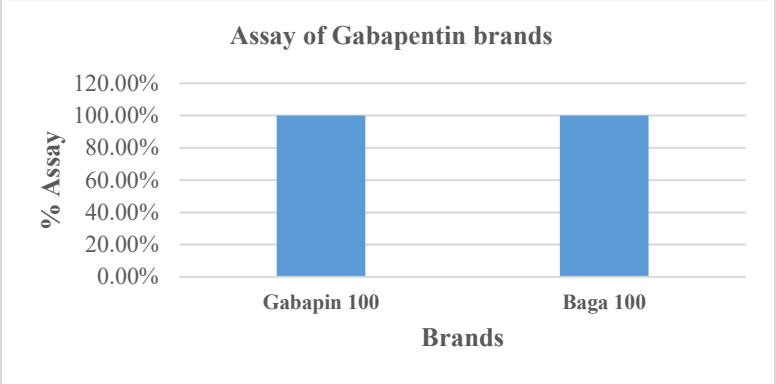


Fig. No.8: Assay for both brands

8. Forced Degradation Studies:

(a) Acid hydrolysis

Table No. 11: Acid hydrolysis

Time (min)	Brand 1 Absorbance	% Drug Remaining (B1)	Brand 2 Absorbance	% Drug Remaining (B2)
0	0.251	100.00%	0.187	100.00%
30	0.238	94.82%	0.179	95.72%
60	0.223	88.84%	0.169	90.37%
120	0.211	84.06%	0.158	84.49%

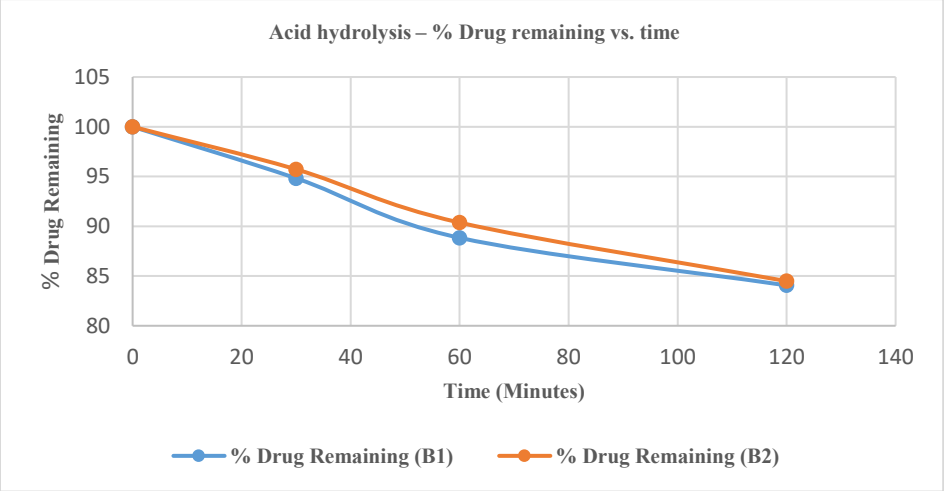


Fig. No.9: Acid hydrolysis for both brands

(b) Basic Hydrolysis

Table No. 12: Basic hydrolysis

Time (min)	Brand 1 Absorbance	% Drug Remaining (B1)	Brand 2 Absorbance	% Drug Remaining (B2)
0	0.129	100.00%	0.274	100.00%
30	0.124	96.12%	0.267	97.45%
60	0.117	90.70%	0.258	94.16%
120	0.106	82.17%	0.242	88.32%

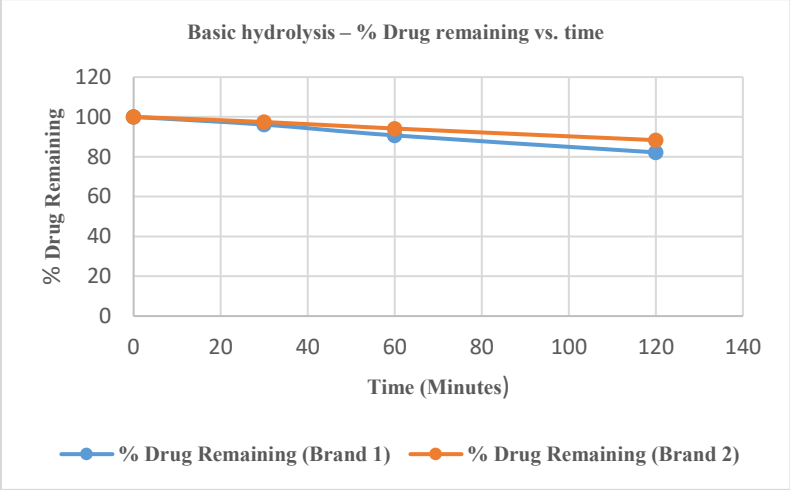


Fig. No.10: Basic hydrolysis for both brands

(c) Oxidative degradation:

Table No. 13: Oxidative degradation

Time (min)	Brand 1 Absorbance	% Drug Remaining (B1)	Brand 2 Absorbance	% Drug Remaining (B2)
0	0.340	100.00%	0.360	100.00%
15	0.339	99.71%	0.335	93.06%
30	0.341	100.29%	0.359	99.72%
60	0.338	99.41%	0.355	98.61%

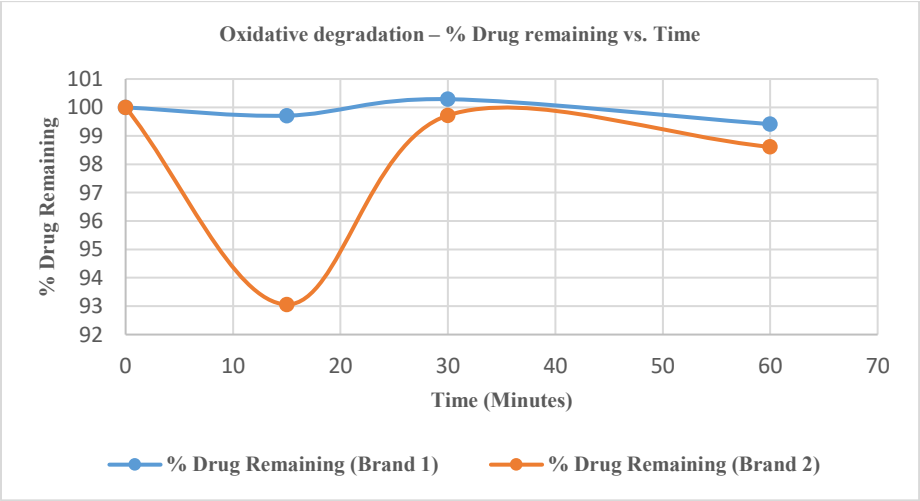


Fig. No.11: Oxidative degradation for both brands

(d) Thermal degradation:

Table No.14: Thermal degradation

Time	Brand 1 Absorbance	% Drug Remaining (B1)	Brand 2 Absorbance	% Drug Remaining (B2)
1 hour	0.227	100.00%	0.164	100.00%

24 hours	0.216	95.16%	0.159	96.95%
48 hours	0.204	89.87%	0.153	93.29%
72 hours	0.191	84.14%	0.148	90.24%

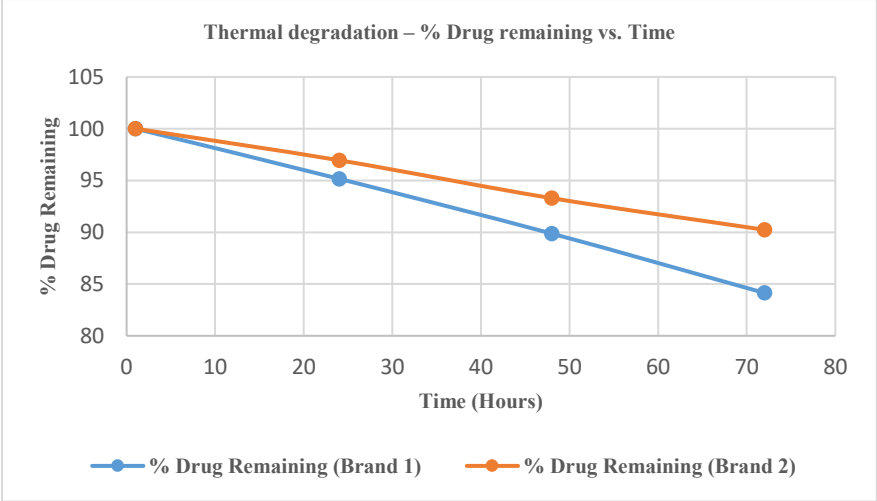


Fig. No.12: Thermal degradation for both brands

Table No. 15: Statistical analysis

Test	Gabapin 100 (Mean ± SD / %)	Baga 100 (Mean ± SD / %)	Interpretation
Identification (UV λmax)	λmax 210 nm; Absorbance: 0.1018 ± X	λmax 210 nm; Absorbance: 0.2273 ± X	Both confirmed as Gabapentin; absorbance variation due to concentration/sample prep
Assay (%)	108%	90%	Both within USP (90–110%); Brand 1 slightly higher
Weight Variation	0.137 ± 0.0047 g	0.1775 ± 0.0064 g	Both within the USP limit. Brand 1 is more uniform
Hardness	6.7 ± 0.48 kg/cm²	4.5 ± 0.53 kg/cm²	Brand 1 is mechanically stronger; both are acceptable
Disintegration	4.10 ± 0.09 min	8.32 ± 0.02 min	Both within USP limits(<15 min); Brand 1 faster
Dissolution (60 min)	~99% released (1.145 ± 0.29 mg/mL)	~92% released (0.794 ± 0.20 mg/mL)	Both >80% release; Brand 1 faster
Acid degradation (120 min)	91.93% drug remains	92.65% drug remains	both stable; closely matched.
Base degradation (120 min)	89.66% drug remains	93.31% drug remains	Both degrade under base; Brand 2 slightly higher, overall comparable
Oxidative degradation (60 min)	99.80% drug remains	97.13% drug remains	Both stable; negligible degradation

Thermal degradation (72 h)	89.72% drug remains	93.49% drug remains	Both degrade gradually; Brand 2 has slightly slower degradation

DISCUSSION

- Unpaired t-tests were performed to assess differences between the two brands across various physical, chemical, and degradation tests.
- Statistically significant differences were found in key physical quality parameters: weight variation, hardness, disintegration, dissolution, and the identification test (absorbance).

Degradation Studies

Both Gabapin 100 and Baga 100 demonstrated comparable stability under acidic, basic, oxidative, and thermal stress conditions.

- Acidic & Basic conditions: Both brands showed moderate sensitivity, with small losses in drug content consistent with Gabapentin's hydrolysis-prone amino and carboxyl groups. Despite this, sufficient intact drug remained for therapeutic action.
- Oxidative stress: Both brands were highly stable, retaining >97% drug, reflecting Gabapentin's lack of oxidizable aromatic groups.
- Thermal stress: Both exhibited gradual degradation over 72 h, but retained nearly 90% of active drug, confirming acceptable stability under normal storage conditions.
- Overall, the degradation profiles of both brands were closely matched, with only minor numerical differences that remained within acceptable limits.

These statistical findings indicate that while both brands share similar chemical stability, they are not pharmaceutically equivalent in overall quality, particularly in terms of physical characteristics and in-vitro performance.

CONCLUSION

The present study carried out a comparative quality control evaluation of two marketed brands of Gabapentin tablets, Gabapin 100 and Baga 100, using USP-guided physical, chemical, and degradation tests.

The findings clearly demonstrated that Gabapin 100 exhibited superior physical quality attributes, including better weight uniformity, higher hardness, lower friability, faster disintegration, and a more favorable dissolution profile compared to Baga 100. The identification test also confirmed higher absorbance consistency in Gabapin 100.

In the assay both brands complied with USP specifications, with Gabapin 100 showing 108% and Baga 100 showing 90% of the labeled claim. These values confirm that both formulations contain the correct amount of the active pharmaceutical ingredient.

Importantly, in the forced degradation studies (acidic, basic, oxidative, and thermal conditions), both brands showed comparable stability profiles, with only minor differences in % drug remaining that were within acceptable limits. This indicates that both formulations maintained adequate stability and degradation behavior under stress conditions.

Overall, the study concludes that while both brands meet pharmacopeial requirements, Gabapin 100 outperforms Baga 100 in terms of physical quality, disintegration, and drug release characteristics, whereas their assay and degradation profiles remain within acceptable and comparable limits. These findings emphasize the need for continuous quality assessment of generic formulations to ensure patient safety and therapeutic efficacy.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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