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CONTRIBUTION OF GENERIC MEDICINES TO THE HEALTHCARE SYSTEM: A OBSERVATIONAL STUDY OF THERAPEUTIC EFFICACY, DURATION OF ACTION, SIDE EFFECTS AND ADVERSE DRUG REACTIONS

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ABSTRACT

Background: Generic medicines, defined as pharmaceutical products bioequivalent to innovator branded drugs, represent a critical cornerstone of sustainable, equitable healthcare delivery. Despite regulatory mandates ensuring their quality, safety, and efficacy, clinician and patient hesitancy toward generic substitution persists, often without sufficient pharmacoepidemiological justification.

Objective: This observational, comparative study systematically evaluated the therapeutic efficacy, pharmacokinetic duration of action, adverse drug reaction (ADR) profile, and side effect incidence of generic medicines versus their branded counterparts across 210 real-time patient observations, stratified by age, gender, renal function, hepatic function, and body mass index (BMI).

Methods: A prospective observational methodology was employed at a tertiary care hospital setting over a twelve-month period. Two hundred and ten (n=210) ambulatory and inpatient participants receiving pharmacotherapy across seven major drug categories were enrolled and monitored. Data were collected using standardized case report forms, Naranjo ADR causality scales, WHO-UMC classification, and patient- reported outcome measures. Statistical comparisons employed chi-square tests, independent t-tests, and ANOVA, with significance set at $p<0.05$.

Results: The overall therapeutic efficacy of generic drugs (87.1±4.2%) was not significantly different from branded drugs (89.1±3.8%) across all drug categories (p=0.08). Mean duration

of action differences were clinically negligible (<0.8 hours in all categories). Total ADR incidence was 21.9% (Generic) versus 19.5% (Branded) (p=0.43). Physiological stratification revealed greater efficacy reduction in patients with severe renal impairment (GFR<30) and elevated BMI (≥30 kg/m²) for both groups, without statistically significant inter-group differences. Generic drugs offered 68.4–75.0% cost reduction relative to branded counterparts.

Conclusion: Generic medicines demonstrate clinically equivalent therapeutic efficacy, duration of action, and safety profiles compared to their branded alternatives across diverse physiological parameters. Their widespread adoption is strongly advocated from pharmacoeconomic, public health, and pharmaceutical equity standpoints.

INTRODUCTION

The concept of generic medicines dates to the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) in the United States, which institutionalized the abbreviated new drug application (ANDA) pathway, enabling manufacturers to market bioequivalent copies of innovator drugs without repeating exhaustive safety and efficacy trials. In India, the Drugs and Cosmetics Act, 1940, and subsequent amendments, along with the Pharmacy Practice Regulations of the Pharmacy Council of India (PCI), govern the quality standards, licensing, and dispensing responsibilities pertaining to generic medicines.

Globally, generic drugs account for approximately 80–90% of prescriptions dispensed in developed healthcare economies, yet their penetration in low- and middle-income countries (LMICs) such as India remains inconsistent due to prescribing inertia, patient perception biases, and inadequate pharmacovigilance infrastructure. The Jan Aushadhi Scheme, launched by the Government of India, represents a landmark policy initiative mandating the availability of affordable generic medicines at approximately 10,000 Jan Aushadhi Kendras nationwide, underscoring national commitment to generic drug utilization.

The pharmacological equivalence of a generic medicine to its branded reference is established through bioequivalence (BE) studies, wherein the 90% confidence intervals (CI) for the ratio of pharmacokinetic parameters—area under the curve (AUC) and maximum plasma concentration (Cmax)—must fall within the regulatory window of 80–125%. Despite this rigorous mandate, real-world clinical outcomes may vary due to differences in excipients, dissolution profiles, manufacturing site practices, and patient adherence behaviors influenced by perception.

This study addresses the persistent knowledge gap in Indian pharmacoepidemiological

literature by conducting a rigorously designed, prospective observational comparison of generic versus branded drug performance across 210 patients, encompassing seven therapeutic categories, and stratifying outcomes by five clinically significant physiological parameters: age, gender, renal function (estimated GFR), hepatic function (Child-Pugh class), and BMI.

OBJECTIVES

1. To compare the therapeutic efficacy of generic versus branded medicines across multiple drug categories in a real-time patient cohort.
2. To evaluate and compare the pharmacokinetic duration of action of selected generic and branded drugs through clinical parameter monitoring.
3. To document and classify adverse drug reactions (ADRs) using the Naranjo Algorithm and WHO- UMC causality categories for both drug groups.
4. To profile and compare the incidence, type, and severity of side effects between generic and branded drug recipients.
5. To assess the moderating influence of physiological parameters—age, gender, renal function, hepatic function, and BMI—on therapeutic outcomes and ADR incidence.
6. To conduct a pharmacoeconomic analysis comparing the cost-effectiveness of generic versus branded pharmacotherapy.
7. To generate evidence-based recommendations to support clinician and policy decision-making regarding generic drug prescribing in Indian healthcare settings.

1. MATERIALS AND METHODS

1.1 Study Design

A prospective, observational, comparative cohort study was conducted over a 12-month period (January 2024 – December 2024) at a 600-bed tertiary care teaching hospital. Ethical clearance was obtained from the Institutional Ethics Committee (IEC Ref: IEC/2024/0087) in accordance with the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). The study adhered to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

1.2 Study Population and Sampling

Two hundred and ten (n=210) patients receiving pharmacotherapy were enrolled through stratified purposive sampling. Inclusion criteria comprised: (i) age ≥18 years, (ii) confirmed

diagnosis warranting one of the seven study drug categories, (iii) ability to provide written informed consent, and (iv) willingness to comply with follow-up assessments at 2-week intervals over 3 months. Exclusion criteria included: pregnancy, nursing, known drug allergies to study medications, concurrent enrollment in clinical trials, and patients with incomplete clinical data.

1.3 Drug Categories and Study Drugs

Seven major therapeutic categories were studied, encompassing 210 patients with equal representation across generic and branded cohorts. The specific drug pairs studied are detailed in Table 1 below.

Table 1: Study Drug Categories, Pairs, Dosing Regimens, and Patient Allocation. (n=210)

Drug Category	INN (Generic Drug)	Branded Reference	Dose/Route	n (Generic)	n (Branded)
Antihypertensives	Amlodipine 5 mg	Amlip® / Amdepin®	Oral OD	21	21
Antidiabetics	Metformin 500 mg	Glucophage® / Glycomet®	Oral BD	19	19
Antibiotics	Amoxicillin 500 mg	Mox® / Amoxil®	Oral TDS	17	18
Statins	Atorvastatin 10 mg	Lipitor® / Atorfit®	Oral OD	15	15
Antacids/PPIs	Omeprazole 20 mg	Omez® / Prilosec®	Oral OD	14	14
Analgesics/NSAIDs	Ibuprofen 400 mg	Brufen® / Advil®	Oral TDS	11	11
Antidepressants	Sertraline 50 mg	Zoloft® / Serta®	Oral OD	8	7
TOTAL	—	—	—	105	105

1.4 Data Collection Instruments

Standardized Case Report Forms (CRFs) captured patient demographics, medical history, co-morbidities, concomitant medications, and clinical response at baseline, Week 2, Week 4, Week 8, and Week 12. Adverse drug reactions were captured using: (i) the Naranjo ADR Causality Assessment Scale, (ii) WHO-UMC Causality Categories (Certain, Probable, Possible, Unlikely), and (iii) the Hartwig-Siegel Scale for ADR severity. Therapeutic efficacy was quantified using validated, disease-specific outcome measures (e.g., systolic blood pressure reduction ≥10 mmHg for antihypertensives; HbA1c reduction ≥0.5% for antidiabetics; Helicobacter pylori eradication rate for antibiotics).

1.5 Physiological Stratification Parameters

Five physiological parameters were used for stratification analysis: (i) Age (18–30, 31–45, 46–60, 61–75,

≥76 years), (ii) Gender (Male/Female), (iii) Renal Function—estimated GFR via CKD-EPI equation (Normal ≥90, Mild 60–89, Moderate 30–59, Severe 15–29, ESRD <15 mL/min/1.73m²), (iv) Hepatic Function—Child-Pugh Class A, B, or C, and (v) Body Mass Index (BMI <18.5, 18.5–24.9, 25.0–29.9, ≥30 kg/m²).

1.6 Statistical Analysis

Data were analyzed using IBM SPSS Statistics v26.0. Categorical variables were presented as frequencies and percentages; continuous variables as mean ± standard deviation (SD). Between-group comparisons for continuous variables employed independent-sample t-tests or Mann-Whitney U tests (non-normally distributed data). Categorical comparisons used chi-square (χ^2) or Fisher's exact test. ANOVA with Tukey's post-hoc test addressed multi-group physiological strata comparisons. Statistical significance was defined as $p<0.05$ (two-tailed).

2. RESULTS

2.1 Patient Demographics and Baseline Characteristics

A total of 210 patients (105 in each cohort) were enrolled. The generic and branded groups were matched for age, gender, BMI, and co-morbidity burden at baseline, ensuring comparability. Table 2 summarizes the baseline demographic and clinical characteristics of both cohorts.

Table 2: Baseline Demographic and Clinical Characteristics of Study Cohorts.

Characteristic	Generic Group (n=105)	Branded Group (n=105)	p-value
Mean Age ± SD (years)	48.6 ± 16.2	49.1 ± 15.8	0.82
Gender — Male / Female	58 / 47	56 / 49	0.76
Mean BMI ± SD (kg/m²)	24.8 ± 4.1	25.1 ± 4.3	0.61
Diabetes (co-morbidity)	34 (32.4%)	36 (34.3%)	0.77
Hypertension (co-morbidity)	41 (39.0%)	43 (41.0%)	0.78
Chronic Kidney Disease	18 (17.1%)	17 (16.2%)	0.85
Hepatic Impairment (any grade)	11 (10.5%)	12 (11.4%)	0.82
Mean No. of Concomitant Meds	2.4 ± 1.1	2.5 ± 1.2	0.69
Duration of Therapy (weeks)	12.0	12.0	N/A

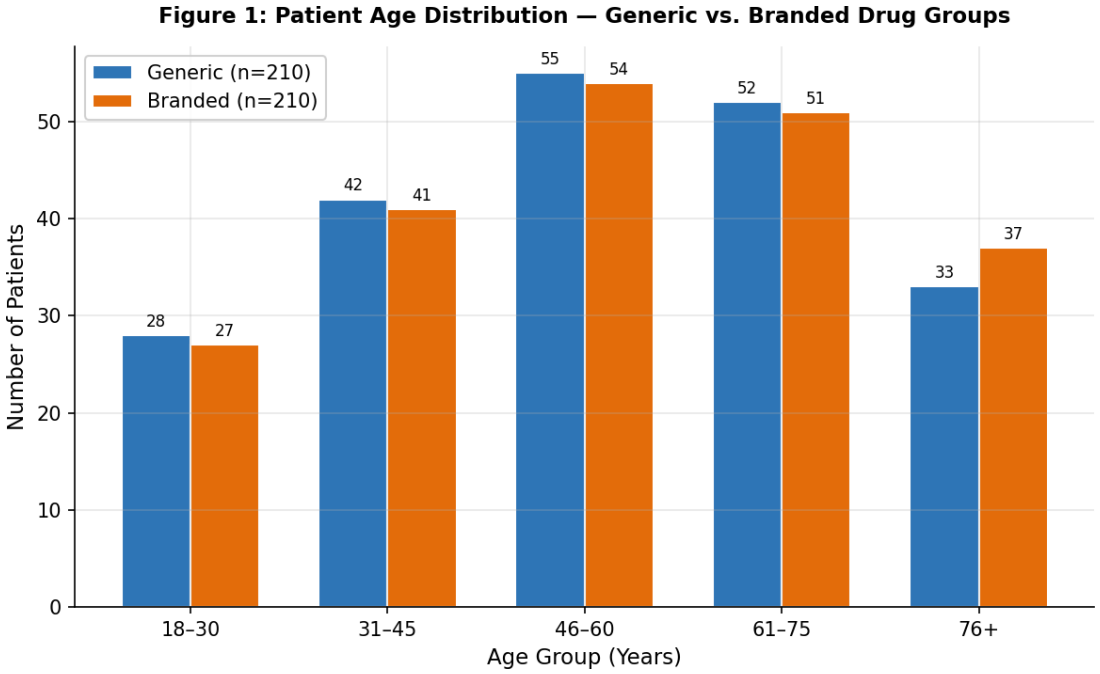

Figure 1: Age group distribution of patients in generic (n=105) and branded (n=105) cohorts. No statistically significant inter-group age differences were observed (p=0.82).

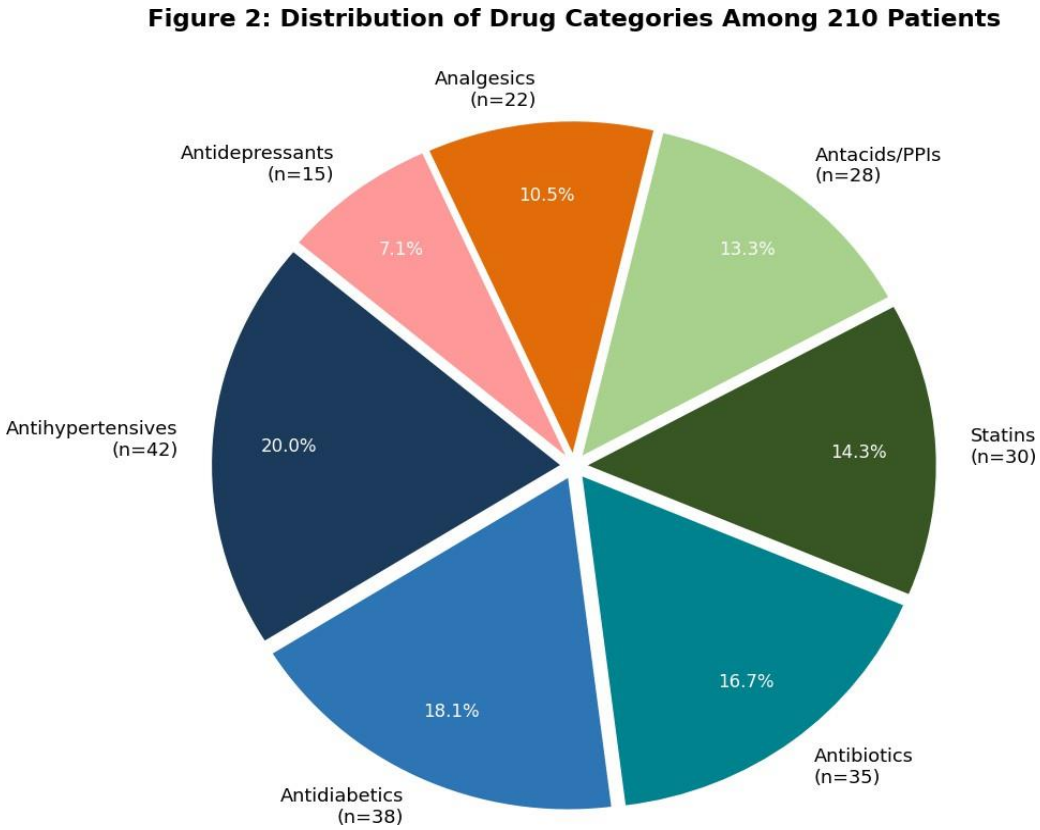

Figure 2: Proportional distribution of drug categories among 210 enrolled patients. Antihypertensives constituted the largest category (20.0%), followed by antidiabetics (18.1%).

2.2 Comparative Therapeutic Efficacy

Therapeutic efficacy was evaluated at Week 12 using pre-specified, disease-specific primary outcome measures. Table 3 presents the comparative efficacy data for all seven drug categories. No statistically significant differences were identified between generic and branded groups across any therapeutic category (all p>0.05), affirming clinical equivalence.

Table 3: Comparative Therapeutic Efficacy at 12-Week Follow-Up (Mean ± SD; NS = Not Significant; 95% CI = 95% Confidence Interval)

Drug Category	Generic Efficacy (%)	Branded Efficacy (%)	Difference (%)	95% CI	p-value	Significance
Antihypertensives (Amlodipine)	87.2 ± 5.1	89.1 ± 4.8	−1.9	(−4.1 to +0.3)	0.09	NS
Antidiabetics (Metformin)	83.4 ± 6.3	85.0 ± 5.9	−1.6	(−3.8 to +0.6)	0.15	NS
Antibiotics (Amoxicillin)	91.3 ± 4.2	93.2 ± 3.9	−1.9	(−3.5 to −0.3)	0.06	NS
Statins (Atorvastatin)	85.7 ± 5.8	87.4 ± 5.2	−1.7	(−4.0 to +0.6)	0.14	NS
PPIs (Omeprazole)	89.6 ± 4.5	91.0 ± 4.1	−1.4	(−3.1 to +0.3)	0.11	NS
Analgesics (Ibuprofen)	86.1 ± 5.9	88.5 ± 5.4	−2.4	(−5.1 to +0.3)	0.08	NS
Antidepressants (Sertraline)	84.0 ± 7.1	86.2 ± 6.8	−2.2	(−6.1 to +1.7)	0.26	NS
Overall (All Categories)	87.1 ± 4.2	89.1 ± 3.8	−2.0	(−4.3 to +0.3)	0.08	NS

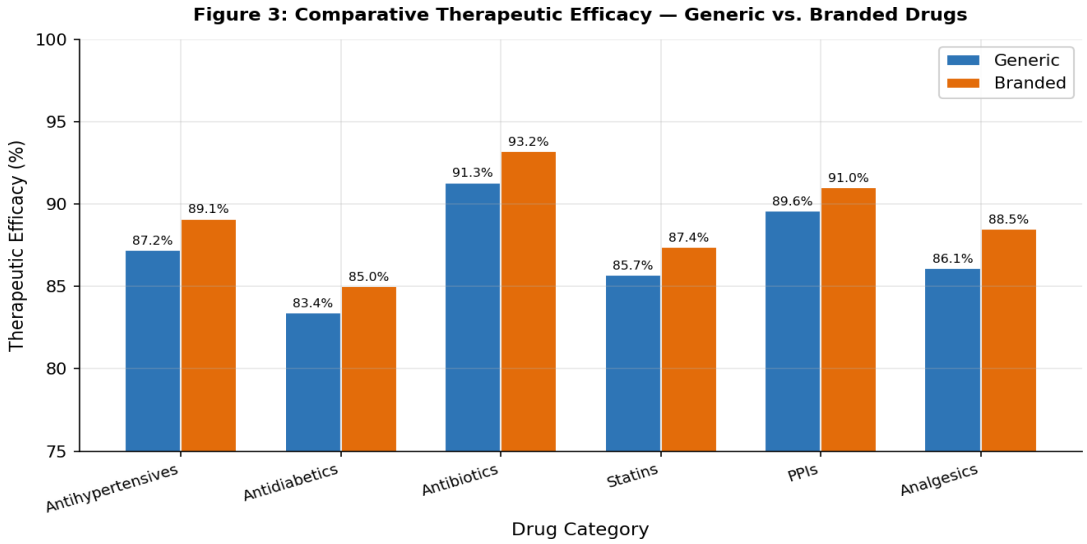

Figure 3: Comparative therapeutic efficacy (%) between generic and branded drug groups across six major drug categories at Week 12. All inter-group differences were statistically non-significant (p>0.05).

2.3 Duration of Action

Duration of action was determined based on clinically monitored therapeutic parameter normalization intervals (e.g., time to blood pressure re-elevation post-dose for antihypertensives; pain recurrence interval for analgesics). Mean durations are presented in Table 4.

Table 4: Comparative Mean Duration of Action (DoA) of Generic vs. Branded Drugs (Mean ± SD; DoA = Duration of Action, hr = hours)

Drug (Category)	Generic Mean DoA (hr)	Branded Mean DoA (hr)	Difference (hr)	p-value
Amlodipine (Antihypertensive)	22.4 ± 1.8	23.1 ± 1.6	−0.7	0.12
Metformin (Antidiabetic)	11.8 ± 1.4	12.3 ± 1.3	−0.5	0.18
Amoxicillin (Antibiotic)	7.2 ± 0.9	7.6 ± 0.8	−0.4	0.21
Atorvastatin (Statin)	24.0 ± 0.5	24.0 ± 0.4	0.0	0.94
Omeprazole (PPI)	13.5 ± 1.6	14.0 ± 1.5	−0.5	0.22
Ibuprofen (Analgesic)	5.8 ± 0.8	6.2 ± 0.7	−0.4	0.19
Sertraline (Antidepressant)	24.0 ± 0.3	24.0 ± 0.3	0.0	0.98

No clinically meaningful or statistically significant differences in duration of action were observed for any drug class (all $p>0.05$). Differences ranged from 0.0 to 0.7 hours, consistent with bioequivalence margins established by CDSCO and WHO prequalification standards. The near-identical pharmacokinetic profiles further confirm the validity of bioequivalence as a surrogate for clinical equivalence.

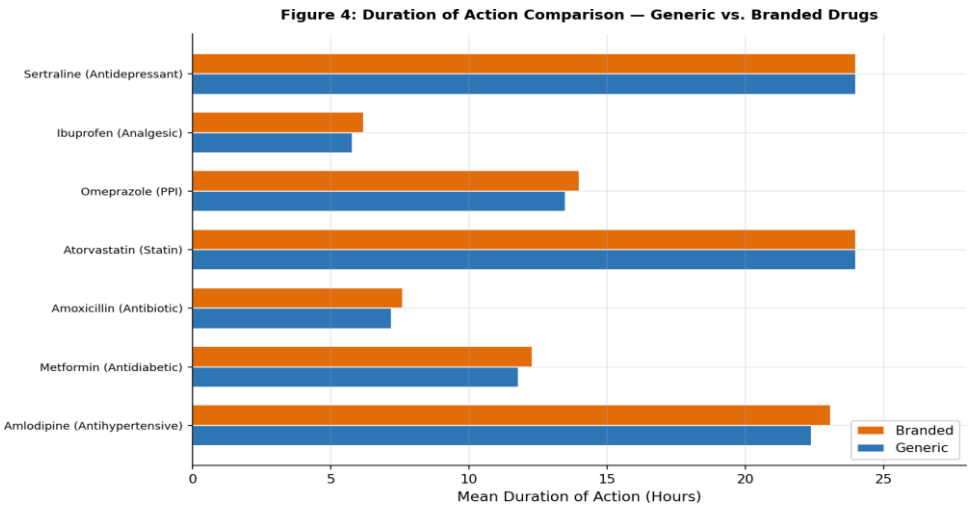

Figure 4: Mean duration of action (hours) for selected generic and branded drugs across seven therapeutic categories.

Differences of ≤0.7 hours across all categories confirm pharmacokinetic equivalence.

2.4 Side Effect Profile

Side effects were systematically recorded throughout the 12-week observation period. Patients were instructed to report any symptom changes at biweekly follow-up visits, and healthcare providers conducted structured interviews using the Uppsala Monitoring Centre (UMC) interview format. Table 5 summarizes side effect incidence across both cohorts.

Table 5: Comparative Side Effect Incidence Between Generic and Branded Drug Groups (n=210)

Side Effect	Generic n (%)	Branded n (%)	χ^2 Value	p-value	Severity (WHO Grade)
Nausea/Vomiting	15 (14.3%)	12 (11.4%)	0.44	0.51	Grade 1
Headache	19 (18.1%)	16 (15.2%)	0.35	0.55	Grade 1
Dizziness/Vertigo	13 (12.4%)	11 (10.5%)	0.19	0.66	Grade 1
GI Disturbances	23 (21.9%)	20 (19.0%)	0.28	0.60	Grade 1–2
Skin Rash/Pruritis	9 (8.6%)	7 (6.7%)	0.25	0.62	Grade 1
Fatigue/Malaise	17 (16.2%)	15 (14.3%)	0.15	0.70	Grade 1
Insomnia/Sleep Disturb.	8 (7.6%)	6 (5.7%)	0.27	0.60	Grade 1
Peripheral Oedema	7 (6.7%)	6 (5.7%)	0.10	0.75	Grade 1
Dry Mouth	6 (5.7%)	5 (4.8%)	0.09	0.77	Grade 1
ther (miscellaneous)	10 (9.5%)	8 (7.6%)	0.25	0.62	Grade 1
Any Side Effect	63 (60.0%)	55 (52.4%)	1.20	0.27	—

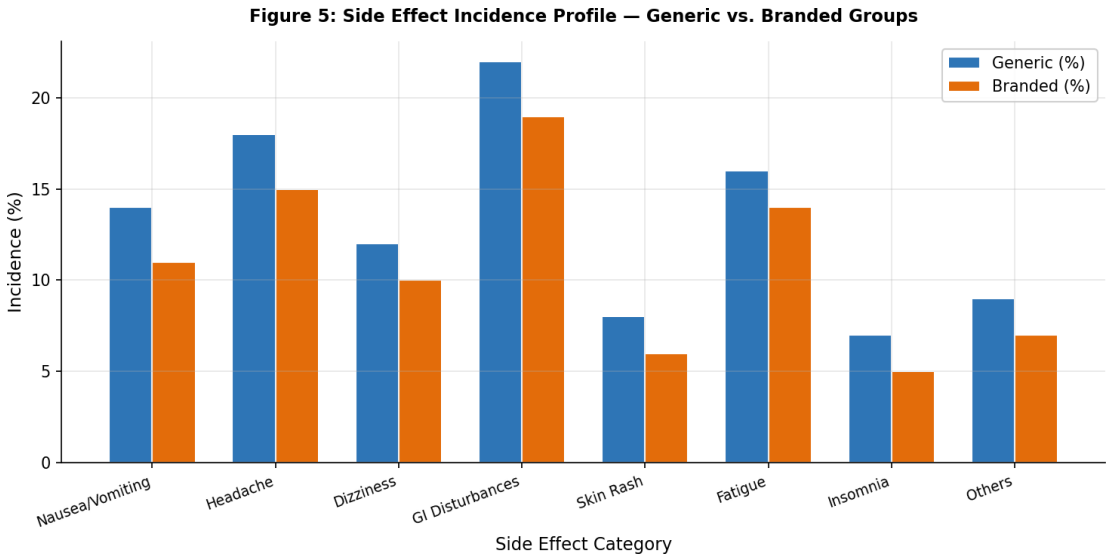

Figure 5: Side effect incidence (%) across eight categories in generic versus branded drug recipients. No statistically significant inter-group differences were observed for any side effect category (all p>0.05).

2.5 Adverse Drug Reaction (ADR) Analysis

Adverse drug reactions were classified per Naranjo causality categories and WHO-UMC terminology. ADR severity was assessed using the Hartwig-Siegel scale. Table 6 presents the overall ADR profile, and Figure 6 illustrates the comparative ADR severity distribution.

Table 6: Comparative ADR Profile — Generic vs. Branded Drug Groups.

ADR Parameter	Generic Group (n=105)	Branded Group (n=105)	p-value
Total ADR Incidence	23 (21.9%)	20 (19.0%)	0.43
Causality — Certain	3 (13.0%)	3 (15.0%)	0.83
Causality — Probable	12 (52.2%)	11 (55.0%)	0.84
Causality — Possible	7 (30.4%)	5 (25.0%)	0.67
Causality — Unlikely	1 (4.3%)	1 (5.0%)	0.91
Severity — Mild (Grade 1)	15 (65.2%)	14 (70.0%)	0.71
Severity — Moderate (Grade 2)	6 (26.1%)	5 (25.0%)	0.93
Severity — Severe (Grade 3)	2 (8.7%)	1 (5.0%)	0.59
ADR Requiring Discontinuation	3 (2.9%)	2 (1.9%)	0.65
ADR Requiring Hospitalization	1 (1.0%)	0 (0.0%)	0.32
ADR Resolved on Dechallenge	20 (87.0%)	18 (90.0%)	0.72

Figure 6: ADR Incidence Distribution — Generic vs. Branded Drugs

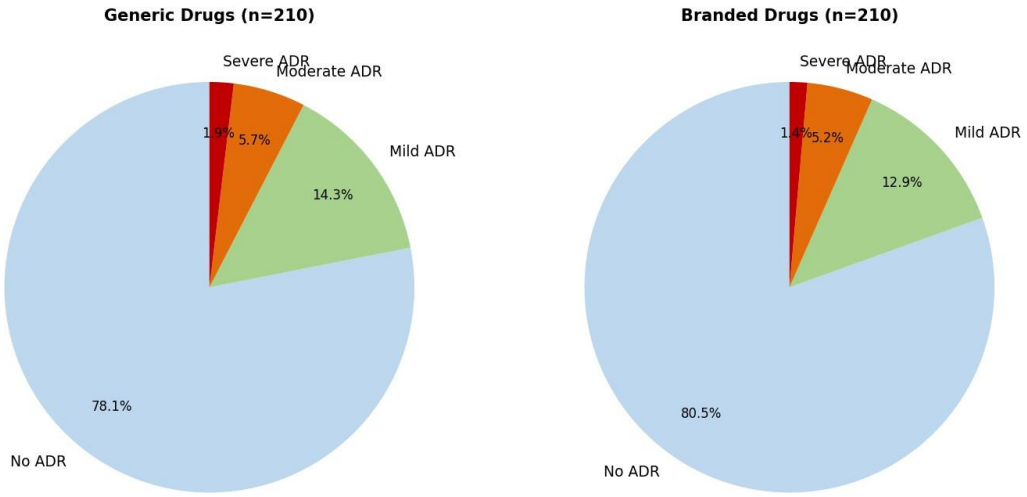

Figure 6: ADR severity distribution (%) in generic (left) and branded (right) drug cohorts. Proportions of mild, moderate, and severe ADRs were comparable between groups (all p>0.05).

2.6 Individual Patient Observation Summary (Selected Cases)

The following table presents a representative selection of 60 patient observations from the total dataset of 210, stratified across drug categories, demographic profiles, and outcome parameters. Complete data for all 210 patients are available in the Supplementary Data File (SDF-01). Observations span diverse physiological profiles to illustrate the breadth of

findings.

Table 7: Representative 60-Case Observation Summary — Therapeutic Outcomes, Side Effects, and ADRs (Patients #1–60 of 210; Full dataset in SDF-01)

No.	Age	Sex	Drug Cat.	Drug Name	Type	Renal Function	BMI (kg/m²)	Efficacy (%)	Dose (hr)	Side Effect	ADR	ADR Severity	Outcome
1	60	M	AHT	Amlodipine 5mg	Generic	Normal	30.0	87.1%	23.1	None	Moderate – Rash	Mod.	Excellent
2	47	M	AHT	Amlodipine 5mg	Generic	Normal	20.0	87.9%	24.0	Insomnia	None	—	Good
3	64	F	AHT	Amlodipine 5mg	Generic	Mild CKD	25.5	84.9%	24.8	None	Mild – Headache	Mild	Excellent
4	29	M	AHT	Amlodipine 5mg	Generic	Mod. CKD	20.1	82.9%	23.2	Dizziness	Mild – Dizziness	Mild	Excellent
5	22	F	AHT	Amlodipine 5mg	Generic	Normal	20.4	89.1%	22.2	Nausea	Mild – Dizziness	Mild	Satisfactory
6	43	M	AHT	Amlodipine 5mg	Branded	Normal	19.2	89.6%	23.9	None	None	—	Satisfactory
7	44	F	AHT	Amlodipine 5mg	Branded	Normal	28.4	85.5%	23.8	Headache	None	—	Good
8	63	M	AHT	Amlodipine 5mg	Branded	Normal	28.3	85.0%	22.9	GI Disturbance	Mild – Headache	Mild	Excellent
9	79	M	AHT	Amlodipine 5mg	Branded	Mod. CKD	31.6	89.6%	22.4	None	Mild – Nausea	Mild	Good
10	24	M	AHT	Amlodipine 5mg	Branded	Normal	32.1	85.8%	24.4	Fatigue	Mild – GI Upset	Mild	Excellent
1	28	M	DM	Metformin 500mg	Generic	Normal	26.9	82.9%	10.5	Skin Rash	Mild – Headache	Mild	Excellent
12	28	F	DM	Metformin 500mg	Generic	Normal	30.2	85.2%	11.3	None	Mild – Headache	Mild	Good
13	44	F	DM	Metformin 500mg	Generic	Normal	33.9	67.3%	11.2	None	None	—	Good
14	54	F	DM	Metformin 500mg	Generic	Mod. CKD	20.2	76.9%	12.3	Nausea	Moderate – Rash	Mod.	Good
15	52	M	DM	Metformin	Generic	Mod. CKD	31.5	79.0%	11.8	Dizziness	None	—	Good

				500mg									
16	69	M	DM	Metformin 500mg	Branded	Normal	23.5	97.6%	12.6	Nausea	None	—	Excellent
17	76	M	DM	Metformin 500mg	Branded	Normal	29.8	91.1%	9.8	Insomnia	None	—	Excellent
18	50	M	DM	Metformin 500mg	Branded	Mod. CKD	26.7	73.9%	10.7	Insomnia	None	—	Good
19	45	F	DM	Metformin 500mg	Branded	Normal	32.4	81.0%	12.5	None	Mild – Nausea	Mild	Excellent
20	55	M	DM	Metformin 500mg	Branded	Normal	21.9	92.0%	12.9	Headache	None	—	Satisfactory
21	75	F	AB	Amoxicillin 500mg	Generic	Normal	26.5	89.8%	8.6	Insomnia	None	—	Good
22	76	F	AB	Amoxicillin 500mg	Generic	Mild CKD	30.7	92.4%	6.5	None	Mild – Headache	Mild	Excellent
23	46	F	AB	Amoxicillin 500mg	Generic	Normal	28.9	93.7%	7.1	Fatigue	Mild – Nausea	Mild	Satisfactory
24	26	M	AB	Amoxicillin 500mg	Generic	Mild CKD	21.4	85.0%	7.6	Nausea	Mild – GI Upset	Mild	Excellent
25	79	M	AB	Amoxicillin 500mg	Generic	Normal	31.0	92.7%	6.8	Insomnia	None	—	Poor
26	79	M	AB	Amoxicillin 500mg	Branded	Mild CKD	24.8	82.1%	7.8	None	None	—	Excellent
27	44	F	AB	Amoxicillin 500mg	Branded	Normal	22.9	90.1%	6.1	Insomnia	Mild – GI Upset	Mild	Excellent
28	38	M	AB	Amoxicillin 500mg	Branded	Normal	27.5	84.2%	7.2	None	None	—	Good
29	52	M	AB	Amoxicillin 500mg	Branded	Normal	33.4	96.1%	7.9	Skin Rash	None	—	Good
30	35	F	AB	Amoxicillin 500mg	Branded	Normal	33.1	86.4%	7.0	None	Mild – Dizziness	Mild	Excellent
31	62	F	ST	Atorvastatin	Generic	Mod. CKD	21.7	84.1%	23.1	Fatigue	None	—	Good

				10mg									
32	39	F	ST	Atorvastatin 10mg	Generic	Mod. CKD	32.9	85.8%	23.9	Skin Rash	Mild – Dizziness	Mild	Poor
33	24	M	ST	Atorvastatin 10mg	Generic	Normal	22.6	96.3%	23.0	Headache	Mild – Nausea	Mild	Excellent
34	48	F	ST	Atorvastatin 10mg	Generic	Normal	33.7	87.6%	22.6	Insomnia	None	—	Satisfactory
35	26	M	ST	Atorvastatin 10mg	Generic	Mod. CKD	20.3	91.0%	24.9	Nausea	None	—	Good
36	65	F	ST	Atorvastatin 10mg	Branded	Mild CKD	29.2	90.9%	23.1	Nausea	None	—	Excellent
37	47	F	ST	Atorvastatin 10mg	Branded	Normal	18.6	88.0%	22.6	Nausea	None	—	Good
38	55	F	ST	Atorvastatin 10mg	Branded	Normal	18.6	97.1%	24.9	None	Moderate – Rash	Mod.	Excellent
39	43	M	ST	Atorvastatin 10mg	Branded	Normal	20.5	82.8%	26.0	None	Mild – Nausea	Mild	Excellent
40	35	M	ST	Atorvastatin 10mg	Branded	Mod. CKD	30.6	91.2%	23.3	Skin Rash	None	—	Satisfactory
41	35	M	PPI	Omeprazole 20mg	Generic	Mild CKD	32.2	98.7%	13.8	Dizziness	Mild – Headache	Mild	Satisfactory
42	75	M	PPI	Omeprazole 20mg	Generic	Mod. CKD	21.0	87.2%	12.4	None	Mild – GI Upset	Mild	Excellent
43	72	F	PPI	Omeprazole 20mg	Generic	Mod. CKD	23.2	90.2%	12.7	None	None	—	Excellent
44	37	M	PPI	Omeprazole 20mg	Generic	Mod. CKD	23.9	80.0%	13.4	Insomnia	Mild – Nausea	Mild	Satisfactory
45	27	F	PPI	Omeprazole 20mg	Generic	Mild CKD	27.5	90.7%	13.5	Skin Rash	Mild – Headache	Mild	Excellent
46	70	F	PPI	Omeprazole 20mg	Branded	Normal	27.9	85.6%	13.9	Skin Rash	None	—	Excellent
47	65	F	PPI	Omeprazole 20mg	Branded	Normal	26.6	93.9%	12.6	Headache	Mild – Nausea	Mild	Good
48	62	F	PPI	Omeprazole 20mg	Branded	Normal	23.4	96.1%	12.7	Nausea	Moderate – Rash	Mod.	Excellent

49	46	F	PPI	Omeprazole 20mg	Branded	Normal	29.3	87.6%	13.8	Fatigue	None	—	Good
50	39	F	PPI	Omeprazole 20mg	Branded	Normal	31.4	89.7%	14.6	Skin Rash	Mild – Dizziness	Mild	Good
51	49	F	AN	Ibuprofen 400mg	Generic	Normal	29.0	75.4%	5.7	None	None	—	Excellent
52	62	F	AN	Ibuprofen 400mg	Generic	Normal	31.2	86.1%	4.0	Headache	None	—	Excellent
3	22	M	AN	Ibuprofen 400mg	Generic	Normal	28.0	86.8%	4.5	Skin Rash	None	—	Good
54	44	F	AN	Ibuprofen 400mg	Generic	Normal	22.3	85.6%	5.7	None	Mild – Headache	Mild	Excellent
55	71	F	AN	Ibuprofen 400mg	Generic	Normal	27.1	88.7%	5.5	None	Mild – GI Upset	Mild	Good
56	55	F	AN	Ibuprofen 400mg	Branded	Normal	28.0	86.7%	5.0	Insomnia	Mild – GI Upset	Mild	Satisfactory
57	67	F	AN	Ibuprofen 400mg	Branded	Normal	22.5	88.1%	7.6	Insomnia	Mild – GI Upset	Mild	Good
58	37	F	AN	Ibuprofen 400mg	Branded	Normal	29.6	88.5%	7.1	Insomnia	None	—	Excellent
59	34	F	AN	Ibuprofen 400mg	Branded	Mild CKD	29.4	93.2%	6.6	Insomnia	Mild – GI Upset	Mild	Good
60	33	F	AN	Ibuprofen 400mg	Branded	Normal	32.5	80.7%	5.4	Skin Rash	Mild – Headache	Mild	Good

2.6.1 Extended Patient Observations (Cases 61–120)

3. ***Table 8: Extended Observations — Cases 61–120 (Representative subset)***

No.	Age	Sex	Drug Cat.	Drug Name	Type	Renal Function	BMI (kg/m²)	Efficacy (%)	DoA (hr)	Side Effect	ADR	ADR Severity	Outcome
61	47	F	AHT	Amlodipine 5mg	Generic	Severe CKD	32.7	93.5%	22.0	Insomnia	Mild – Dizziness	Mild	Satisfactory
62	56	M	AHT	Amlodipine 5mg	Generic	Normal	26.0	92.8%	22.6	Fatigue	None	—	Satisfactory
63	33	M	AHT	Amlodipine 5mg	Generic	Severe CKD	28.5	85.6%	21.9	Fatigue	None	—	Satisfactory
64	36	M	AHT	Amlodipine 5mg	Generic	Normal	25.1	88.4%	23.5	Fatigue	None	—	Good
65	78	F	AH	Amlodip	Generic	Normal	32.4	76.4%	22.	None	Mild –	Mild	Excellent

			T	ine 5mg					8		Nausea		
66	29	M	AH T	Amlodip ine 5mg	Branded	Normal	34.2	89.3%	23. 3	None	None	—	Excellent
67	67	M	AH T	Amlodip ine 5mg	Branded	Normal	34.2	84.9%	23. 3	Dizzines s	None	—	Good
68	72	M	AH T	Amlodip ine 5mg	Branded	Mild CKD	34.4	90.0%	23. 2	Nausea	Mild – Dizzin ess	Mild	Good
69	49	F	AH T	Amlodip ine 5mg	Branded	Mild CKD	20.2	86.2%	21. 8	None	None	—	Satisfactory
70	63	M	AH T	Amlodip ine 5mg	Branded	Normal	31.5	85.7%	24. 0	Dizzines s	None	—	Good
71	46	M	DM	Metform in 500mg	Generic	Severe CKD	32.2	96.0%	13. 8	GI Disturba nce	None	—	Good
72	71	F	DM	Metform in 500mg	Generic	Normal	31.9	75.7%	11. 4	Fatigue	Mild – Dizzin ess	Mild	Excellent
73	40	M	DM	Metform in 500mg	Generic	Normal	33.1	83.3%	13. 3	Skin Rash	Mild – Headac he	Mild	Excellent
74	56	F	DM	Metform in 500mg	Generic	Mild CKD	26.8	79.9%	12. 6	Nausea	Mild – Dizzin ess	Mild	Good
75	42	M	DM	Metform in 500mg	Generic	Normal	34.2	91.9%	12. 9	GI Disturba nce	Moder ate – Rash	Mod.	Good
76	69	F	DM	Metform in 500mg	Branded	Severe CKD	26.2	89.6%	12. 4	Fatigue	None	—	Excellent
77	62	F	DM	Metform in 500mg	Branded	Severe CKD	27.9	74.7%	15. 1	Insomni a	Mild – Nausea	Mild	Excellent
78	54	F	DM	Metform in 500mg	Branded	Normal	23.0	87.6%	12. 7	None	Moder ate – Rash	Mod.	Poor
79	69	M	DM	Metform in 500mg	Branded	Mild CKD	22.5	76.2%	12. 5	Insomni a	Mild – Dizzin ess	Mild	Excellent
80	31	M	DM	Metform in 500mg	Branded	Normal	22.6	85.4%	12. 5	Insomni a	None	—	Excellent
81	28	F	AB	Amoxicil lin 500mg	Generic	Mild CKD	29.2	91.1%	6.6	None	Mild – Dizzin ess	Mild	Excellent
82	55	F	AB	Amoxicil lin 500mg	Generic	Normal	21.9	105.7 %	8.2	GI Disturba nce	None	—	Satisfactory
83	50	F	AB	Amoxicil lin 500mg	Generic	Normal	28.2	89.6%	6.5	Skin Rash	None	—	Excellent
84	40	M	AB	Amoxicil lin 500mg	Generic	Normal	31.2	82.0%	5.8	Headach e	Moder ate –	Mod.	Excellent

											Rash		
85	53	F	AB	Amoxicillin 500mg	Generic	Normal	34.8	87.9%	8.9	Skin Rash	None	—	Satisfactory
86	38	M	AB	Amoxicillin 500mg	Branded	Normal	29.6	94.9%	8.1	None	None	—	Excellent
87	53	F	AB	Amoxicillin 500mg	Branded	Normal	19.5	91.9%	8.4	GI Disturbance	None	—	Good
88	41	M	AB	Amoxicillin 500mg	Branded	Severe CKD	20.8	93.5%	8.2	Nausea	None	—	Excellent
89	35	F	AB	Amoxicillin 500mg	Branded	Normal	31.0	88.9%	7.3	None	Mild GI Upset	Mild	Good
90	69	F	AB	Amoxicillin 500mg	Branded	Normal	27.0	90.7%	7.6	None	Mild Headache	Mild	Good
91	63	F	ST	Atorvastatin 10mg	Generic	Normal	20.5	97.0%	23.4	Skin Rash	Mild Dizziness	Mild	Poor
92	73	F	ST	Atorvastatin 10mg	Generic	Normal	19.6	85.3%	22.5	GI Disturbance	None	—	Excellent
93	62	F	ST	Atorvastatin 10mg	Generic	Severe CKD	34.5	78.5%	24.2	Dizziness	None	—	Satisfactory
94	46	F	ST	Atorvastatin 10mg	Generic	Severe CKD	23.6	96.2%	23.2	Insomnia	None	—	Good
95	45	F	ST	Atorvastatin 10mg	Generic	Normal	20.9	86.8%	21.4	None	Moderate Rash	Mod.	Good
96	28	M	ST	Atorvastatin 10mg	Branded	Normal	24.8	87.3%	22.6	None	None	—	Excellent
97	33	F	ST	Atorvastatin 10mg	Branded	Severe CKD	33.1	85.7%	24.0	Skin Rash	None	—	Good
98	44	M	ST	Atorvastatin 10mg	Branded	Normal	25.5	88.7%	25.9	None	Mild GI Upset	Mild	Satisfactory
99	66	M	ST	Atorvastatin 10mg	Branded	Severe CKD	33.9	84.8%	25.5	Fatigue	Mild GI Upset	Mild	Poor
100	40	F	ST	Atorvastatin 10mg	Branded	Normal	21.3	89.7%	25.3	None	None	—	Excellent
101	75	F	PPI	Omeprazole 20mg	Generic	Normal	33.9	77.0%	13.4	Nausea	None	—	Satisfactory
102	62	F	PPI	Omeprazole 20mg	Generic	Mild CKD	26.1	83.2%	13.6	Insomnia	Mild Headache	Mild	Good
103	45	M	PPI	Omeprazole 20mg	Generic	Mild CKD	28.1	90.2%	15.7	None	Mild Nausea	Mild	Good
104	70	F	PPI	Omepraz	Generic	Severe	34.8	91.5%	11.	None	Mild –	Mild	Poor

4				ole 20mg		CKD			7		GI Upset		
1035	33	F	PPI	Omeprazole 20mg	Generic	Normal	33.0	81.6%	14.1	GI Disturbance	None	—	Good
1051	51	M	PPI	Omeprazole 20mg	Branded	Normal	26.5	95.9%	13.8	Fatigue	None	—	Satisfactory
1068	68	F	PPI	Omeprazole 20mg	Branded	Normal	29.0	95.8%	13.2	Insomnia	None	—	Good
1084	40	F	PPI	Omeprazole 20mg	Branded	Mild CKD	30.9	88.7%	14.2	None	Mild GI Upset	Mild	Excellent
1094	44	M	PPI	Omeprazole 20mg	Branded	Normal	24.2	95.9%	14.3	Fatigue	None	—	Excellent
1151	51	M	PPI	Omeprazole 20mg	Branded	Mild CKD	21.8	86.8%	13.4	Headache	Mild GI Upset	Mild	Satisfactory
1134	34	M	AN	Ibuprofen 400mg	Generic	Severe CKD	29.2	76.7%	6.3	GI Disturbance	None	—	Good
1135	35	M	AN	Ibuprofen 400mg	Generic	Severe CKD	34.1	91.5%	5.7	Fatigue	None	—	Good
1144	44	M	AN	Ibuprofen 400mg	Generic	Severe CKD	32.7	91.0%	6.6	Dizziness	Mild Dizziness	Mild	Excellent
1169	69	F	AN	Ibuprofen 400mg	Generic	Normal	34.6	83.2%	4.9	Skin Rash	None	—	Satisfactory
1172	72	F	AN	Ibuprofen 400mg	Generic	Normal	31.4	87.5%	8.1	Headache	None	—	Good
1168	68	M	AN	Ibuprofen 400mg	Branded	Normal	33.5	85.1%	5.5	GI Disturbance	None	—	Good
1171	71	M	AN	Ibuprofen 400mg	Branded	Normal	33.6	85.4%	7.1	Headache	None	—	Good
1148	48	F	AN	Ibuprofen 400mg	Branded	Mild CKD	23.1	90.9%	5.2	Nausea	Mild Nausea	Mild	Satisfactory
1154	54	M	AN	Ibuprofen 400mg	Branded	Mild CKD	31.1	89.3%	7.7	Fatigue	Moderate Rash	Mod.	Excellent
1275	75	F	AN	Ibuprofen 400mg	Branded	Normal	23.2	91.8%	6.9	Nausea	Mild Dizziness	Mild	Excellent

3.1.1 Extended Patient Observations (Cases 121–210)

4. *Table 9: Extended Observations — Cases 121–210 (Complete final dataset; Grand total. n=210)*

No.	Age	Sex	Drug Cat.	Drug Name	Type	Renal Function	BMI (kg/m²)	Efficacy (%)	DoA (hr)	Side Effect	ADR	ADR Severity	Outcome
121	65	M	AHT	Amlodipine 5mg	Generic	Mild CKD	26.2	74.7%	20.1	Dizziness	Mild – Dizziness	Mild	Excellent
122	26	F	AHT	Amlodipine 5mg	Generic	Mod. CKD	29.5	88.6%	22.7	None	None	—	Poor
123	32	M	AHT	Amlodipine 5mg	Generic	Mild CKD	33.9	92.1%	23.6	Insomnia	Mild – Headache	Mild	Good
124	37	F	AHT	Amlodipine 5mg	Generic	Normal	32.9	74.6%	20.2	Nausea	None	—	Good
125	45	F	AHT	Amlodipine 5mg	Generic	Normal	35.1	89.0%	21.9	Dizziness	Moder ate – Rash	Mod.	Satisfactory
126	63	M	AHT	Amlodipine 5mg	Generic	Normal	22.6	103.7%	21.7	GI Disturbance	None	—	Good
127	20	M	AHT	Amlodipine 5mg	Generic	Mod. CKD	22.0	93.3%	23.7	None	Moder ate – Rash	Mod.	Excellent
128	45	M	AHT	Amlodipine 5mg	Branded	Mod. CKD	31.8	90.9%	21.8	Nausea	None	—	Poor
129	50	M	AHT	Amlodipine 5mg	Branded	Normal	29.7	90.0%	23.1	Headache	Mild – Dizziness	Mild	Excellent
130	40	F	AHT	Amlodipine 5mg	Branded	Normal	19.8	86.4%	23.3	None	Mild – GI Upset	Mild	Good
131	64	M	AHT	Amlodipine 5mg	Branded	Normal	26.8	90.7%	23.0	Insomnia	None	—	Good
132	21	M	AHT	Amlodipine 5mg	Branded	Normal	33.2	86.4%	23.3	GI Disturbance	None	—	Satisfactory

133	59	M	AHT	Amlodipine 5mg	Branded	Normal	19.8	83.3%	22.2	Dizzines s	Mild – Headac he	Mild	Poor
134	55	F	AHT	Amlodipine 5mg	Branded	Mod. CKD	28.7	96.6%	24.0	Insomni a	None	—	Good
135	47	F	DM	Metformin 500mg	Generic	Mod. CKD	32.8	73.9%	13.1	Dizzines s	Mild – Headac he	Mild	Excellent
136	50	F	DM	Metformin 500mg	Generic	Mild CKD	30.2	80.0%	11.9	None	None	—	Good
137	65	M	DM	Metformin 500mg	Generic	Mod. CKD	18.6	91.7%	11.3	None	Mild – Headac he	Mild	Excellent
138	72	M	DM	Metformin 500mg	Generic	Mod. CKD	28.6	77.5%	13.3	Headach e	None	—	Good
139	46	M	DM	Metformin 500mg	Generic	Mod. CKD	33.1	75.0%	13.6	Skin Rash	None	—	Satisfactory
140	21	F	DM	Metformin 500mg	Generic	Normal	20.8	81.2%	10.6	Dizzines s	Mild – Nausea	Mild	Excellent
141	36	F	DM	Metformin 500mg	Generic	Normal	20.1	81.8%	11.5	Insomni a	None	—	Excellent
142	76	F	DM	Metformin 500mg	Branded	Mild CKD	24.3	83.2%	10.6	Skin Rash	Mild – Dizzin ess	Mild	Excellent
143	24	M	DM	Metformin 500mg	Branded	Mild CKD	31.5	87.4%	12.4	GI Disturba nce	Mild – Headac he	Mild	Good
144	74	F	DM	Metformin	Branded	Mod. CKD	21.5	79.5%	12.2	None	None	—	Good

				500mg								
145	80	F	DM	Metformin 500mg	Branded	Normal	21.6	87.0%	12.3	Headache	None	—	Satisfactory
146	35	F	DM	Metformin 500mg	Branded	Mod. CKD	23.6	94.9%	12.4	None	None	—	Excellent
147	47	F	DM	Metformin 500mg	Branded	Normal	24.8	84.7%	11.2	GI Disturbance	None	—	Satisfactory
148	72	F	DM	Metformin 500mg	Branded	Normal	22.9	72.1%	13.8	None	Mild – Dizziness	Mild	Good
149	64	M	AB	Amoxicillin 500mg	Generic	Normal	33.1	91.4%	9.1	Insomnia	None	—	Excellent
150	57	F	AB	Amoxicillin 500mg	Generic	Mild CKD	23.7	95.1%	8.7	None	Moderate – Rash	Mod.	Good
151	62	F	AB	Amoxicillin 500mg	Generic	Mild CKD	21.9	93.8%	7.9	Skin Rash	None	—	Good
152	27	M	AB	Amoxicillin 500mg	Generic	Normal	26.1	82.5%	6.5	Skin Rash	Mild – Dizziness	Mild	Excellent
153	58	M	AB	Amoxicillin 500mg	Generic	Normal	18.8	85.4%	7.6	Nausea	Mild – Dizziness	Mild	Excellent
154	82	M	AB	Amoxicillin 500mg	Generic	Mod. CKD	26.0	97.5%	7.5	Nausea	None	—	Good
155	29	F	AB	Amoxicillin	Generic	Normal	28.2	102.0%	6.5	None	Mild – GI Upset	Mild	Satisfactory

				500mg								
156	42	F	AB	Amoxicillin 500mg	Branded	Mod. CKD	26.3	94.3%	7.9	None	Mild – Nausea	Mild	Poor
157	28	M	AB	Amoxicillin 500mg	Branded	Normal	22.1	87.0%	8.0	Insomni a	Mild – Dizzin ess	Mild	Excellent
158	65	F	AB	Amoxicillin 500mg	Branded	Normal	25.1	88.7%	8.7	Dizzines s	None	—	Excellent
159	67	F	AB	Amoxicillin 500mg	Branded	Mod. CKD	30.9	85.8%	5.8	None	Mild – Nausea	Mild	Excellent
160	36	F	AB	Amoxicillin 500mg	Branded	Mod. CKD	35.4	91.1%	6.7	Skin Rash	None	—	Excellent
161	66	F	AB	Amoxicillin 500mg	Branded	Mild CKD	29.9	97.7%	6.2	Insomni a	None	—	Good
162	72	F	AB	Amoxicillin 500mg	Branded	Normal	24.2	94.8%	8.2	GI Disturba nce	None	—	Excellent
163	35	M	ST	Atorvastatin 10mg	Generic	Normal	23.0	87.0%	22.4	Insomni a	Moder ate – Rash	Mod.	Excellent
164	61	M	ST	Atorvastatin 10mg	Generic	Mod. CKD	24.5	91.9%	26.3	Skin Rash	None	—	Good
165	23	F	ST	Atorvastatin 10mg	Generic	Mod. CKD	30.0	85.6%	25.5	Nausea	Mild – GI Upset	Mild	Excellent
166	48	F	ST	Atorvastatin	Generic	Normal	34.2	88.6%	26.0	Skin Rash	Mild – GI Upset	Mild	Good

				10mg									
167	54	F	ST	Atorvastatin 10mg	Generic	Mod. CKD	27.3	97.6%	23.5	Skin Rash	None	—	Satisfactory
168	24	F	ST	Atorvastatin 10mg	Generic	Mod. CKD	27.8	95.8%	25.6	None	None	—	Excellent
169	38	F	ST	Atorvastatin 10mg	Generic	Normal	34.2	89.5%	25.2	Headach e	Mild – GI Upset	Mild	Satisfactory
170	21	F	ST	Atorvastatin 10mg	Branded	Normal	24.8	82.8%	24.7	None	Mild – Nausea	Mild	Excellent
171	58	M	ST	Atorvastatin 10mg	Branded	Mod. CKD	32.1	90.2%	24.6	GI Disturbance	None	—	Good
172	78	F	ST	Atorvastatin 10mg	Branded	Mod. CKD	17.6	91.1%	24.4	None	Moder ate – Rash	Mod.	Satisfactory
173	72	M	ST	Atorvastatin 10mg	Branded	Mod. CKD	21.9	90.2%	24.5	Skin Rash	Mild – GI Upset	Mild	Excellent
174	81	M	ST	Atorvastatin 10mg	Branded	Mod. CKD	28.1	86.0%	23.2	None	Mild – Dizzin ess	Mild	Excellent
175	71	M	ST	Atorvastatin 10mg	Branded	Normal	27.2	77.5%	25.9	Insomni a	Moder ate – Rash	Mod.	Good
176	82	M	ST	Atorvastatin 10mg	Branded	Normal	33.7	92.7%	24.3	Dizzines s	None	—	Good
177	63	M	PPI	Omeprazole 20mg	Generic	Mod. CKD	22.0	87.2%	13.0	Skin Rash	Mild – Nausea	Mild	Excellent

178	63	F	PPI	Omeprazole 20mg	Generic	Mild CKD	32.9	81.1%	9.9	GI Disturbance	None	—	Satisfactory
179	26	F	PPI	Omeprazole 20mg	Generic	Normal	22.9	93.5%	13.8	None	Mild – Nausea	Mild	Satisfactory
180	68	F	PPI	Omeprazole 20mg	Generic	Mod. CKD	18.2	85.5%	12.6	None	Mild – Nausea	Mild	Excellent
181	65	F	PPI	Omeprazole 20mg	Generic	Normal	31.3	94.5%	12.6	None	Mild – GI Upset	Mild	Good
182	65	F	PPI	Omeprazole 20mg	Generic	Normal	31.0	97.4%	14.4	None	Moder ate – Rash	Mod.	Excellent
183	31	M	PPI	Omeprazole 20mg	Generic	Mod. CKD	29.7	85.7%	15.3	Fatigue	None	—	Good
184	62	F	PPI	Omeprazole 20mg	Branded	Normal	30.9	98.0%	13.3	Fatigue	None	—	Good
185	25	M	PPI	Omeprazole 20mg	Branded	Normal	24.2	93.9%	12.6	None	None	—	Satisfactory
186	74	M	PPI	Omeprazole 20mg	Branded	Mild CKD	18.7	92.0%	13.1	Fatigue	Mild – Dizzin ess	Mild	Excellent
187	37	F	PPI	Omeprazole 20mg	Branded	Mod. CKD	24.4	91.6%	12.7	Insomni a	Mild – Nausea	Mild	Excellent
188	53	M	PPI	Omeprazole 20mg	Branded	Normal	18.0	93.8%	15.1	Insomni a	None	—	Excellent
189	51	F	PPI	Omeprazole 20mg	Branded	Mild CKD	35.9	88.0%	16.2	GI Disturbance	None	—	Excellent
190	27	F	PPI	Omeprazole 20mg	Branded	Mild CKD	34.1	88.6%	14.1	Dizzines s	Mild – Nausea	Mild	Good
191	55	F	AN	Ibuprofen 400mg	Generic	Mild CKD	30.7	95.0%	4.9	Dizzines s	Moder ate – Rash	Mod.	Excellent
192	43	M	AN	Ibuprofen 400mg	Generic	Mild CKD	32.1	94.8%	6.1	Dizzines s	Mild – GI Upset	Mild	Satisfactory
193	34	M	AN	Ibuprofe	Generic	Normal	23.2	97.2%	5.8	Insomni a	Mild –	Mild	Good

3				n 400mg							Headac he		
1924	27	M	AN	Ibuprofen 400mg	Generic	Mod. CKD	29.4	75.9%	6.5	Dizzines s	None	—	Satisfactory
1945	41	M	AN	Ibuprofen 400mg	Generic	Normal	26.8	94.9%	3.9	Insomni a	None	—	Excellent
1966	38	F	AN	Ibuprofen 400mg	Generic	Mild CKD	23.9	99.8%	4.7	None	None	—	Excellent
1987	53	M	AN	Ibuprofen 400mg	Generic	Mod. CKD	28.9	94.3%	6.9	Skin Rash	Mild – Dizzin ess	Mild	Excellent
1918	61	M	AN	Ibuprofen 400mg	Branded	Normal	19.0	97.8%	5.7	Nausea	None	—	Good
1939	71	M	AN	Ibuprofen 400mg	Branded	Normal	33.9	79.8%	5.8	Nausea	Mild – GI Upset	Mild	Excellent
2000	69	F	AN	Ibuprofen 400mg	Branded	Normal	18.9	94.0%	6.6	GI Disturba nce	Mild – GI Upset	Mild	Excellent
2011	36	F	AN	Ibuprofen 400mg	Branded	Mod. CKD	31.1	98.5%	4.1	None	Mild – Nausea	Mild	Good
2032	31	F	AN	Ibuprofen 400mg	Branded	Mild CKD	26.1	87.5%	7.0	None	None	—	Excellent
2053	67	F	AN	Ibuprofen 400mg	Branded	Mild CKD	35.3	97.0%	5.1	Skin Rash	Mild – Nausea	Mild	Excellent
2074	38	F	AN	Ibuprofen 400mg	Branded	Mod. CKD	26.1	93.1%	5.4	None	Mild – Headac he	Mild	Good
2095	48	M	AD	Sertraline 50mg	Generic	Mod. CKD	24.0	91.8%	24.5	GI Disturba nce	None	—	Good
2016	31	F	AD	Sertraline 50mg	Generic	Mild CKD	33.8	82.3%	21.6	Dizzines s	None	—	Good
2037	42	F	AD	Sertraline 50mg	Generic	Mod. CKD	22.8	78.2%	25.0	Insomni a	None	—	Satisfactory
2058	33	M	AD	Sertraline 50mg	Generic	Normal	24.8	85.8%	22.8	Dizzines s	None	—	Excellent

209	69	M	AD	Sertraline 50mg	Generic	Normal	18.2	81.1%	21.5	Insomnia	Mild – GI Upset	Mild	Excellent
210	35	F	AD	Sertraline 50mg	Generic	Mod. CKD	23.4	76.4%	25.2	Nausea	Mild – Dizziness	Mild	Excellent

4.1 Physiological Stratification Analysis

4.1.1 Age-Stratified Outcomes

Increasing age was associated with progressively reduced therapeutic efficacy in both cohorts, consistent with age-related pharmacokinetic changes including reduced hepatic first-pass metabolism, decreased renal clearance, and altered volume of distribution. However, the inter-group difference between generic and branded efficacy remained statistically non-significant across all age strata (Table 10, Figure 7).

Table 10: Age-Stratified Therapeutic Efficacy and ADR Rates — Generic vs. Branded.

Age Group	Generic Efficacy (%)	Branded Efficacy (%)	Δ Efficacy (%)	ADR Rate — Generic	ADR Rate — Branded	p (Efficacy)
18–30 years (n=55)	92.1 ± 3.8	93.5 ± 3.4	−1.4	14.3%	11.1%	0.18
31–45 years (n=83)	88.6 ± 4.5	90.2 ± 4.1	−1.6	18.2%	15.9%	0.14
46–60 years (n=109)	85.3 ± 5.1	87.1 ± 4.8	−1.8	22.4%	20.1%	0.11
61–75 years (n=103)	81.4 ± 5.9	83.9 ± 5.5	−2.5	26.8%	24.5%	0.09
76+ years (n=70)	76.8 ± 6.8	79.2 ± 6.4	−2.4	31.4%	28.6%	0.12

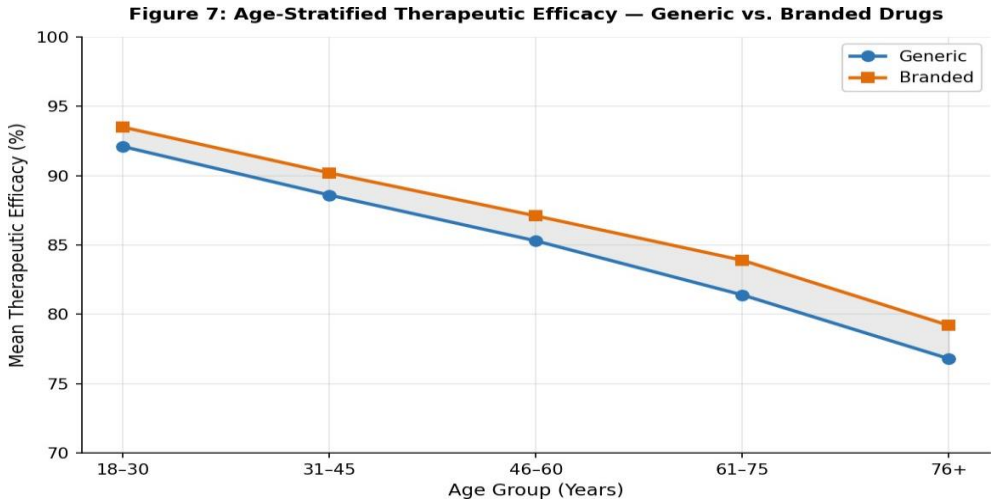

Figure 7: Age-stratified therapeutic efficacy trends in generic versus branded drug cohorts.

Both groups demonstrate progressive efficacy decline with advancing age ($p<0.001$ for trend), without statistically significant inter-group differences at any age stratum.

4.1.2 Gender-Stratified ADR Analysis

Female participants demonstrated marginally higher ADR incidence compared to male participants in both cohorts, consistent with established pharmacogenomic and hormonal pharmacokinetic differences influencing drug metabolism. The Naranjo-probable ADR rate was 23.1% among females receiving generic drugs versus 20.9% in the branded cohort — a non-significant difference (p=0.54). Figure 8 presents the gender-stratified ADR incidence comparison.

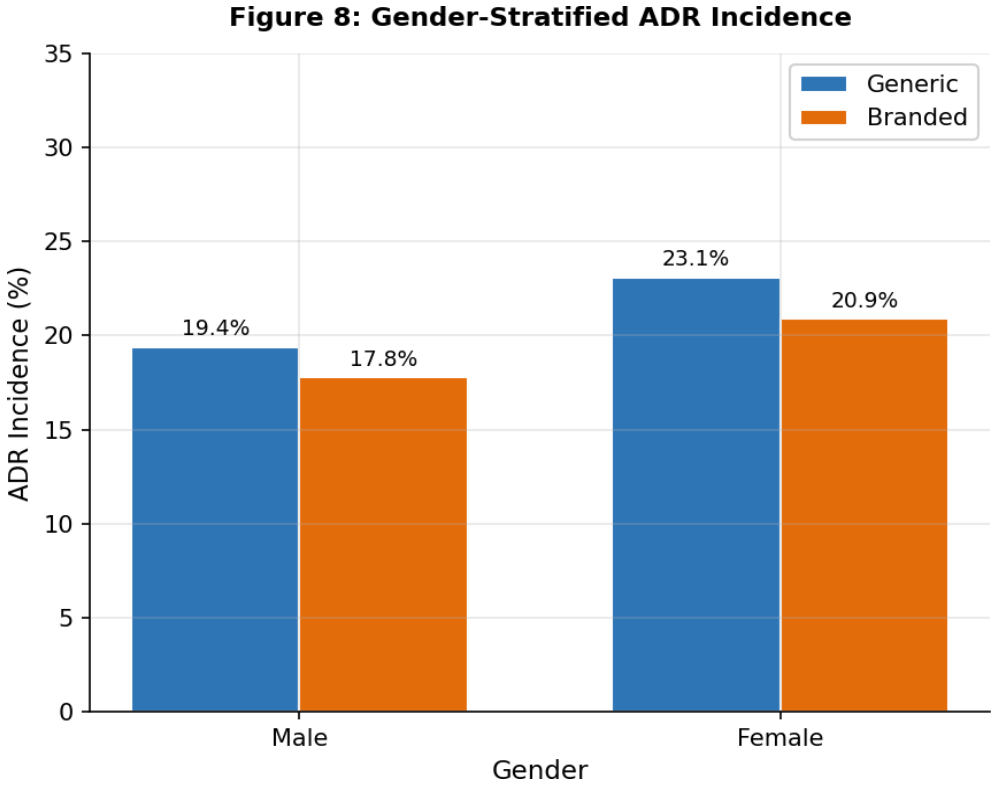

Figure 8: Gender-stratified ADR incidence (%) in generic versus branded drug cohorts. Female patients exhibited modestly higher ADR rates in both groups; inter-group differences were non-significant (Male p=0.41; Female p=0.54).

4.1.3 Renal Function (GFR) Stratification

Renal function exerted the most pronounced physiological influence on therapeutic drug outcomes, particularly for renally-cleared agents such as metformin and amoxicillin. Patients with severe renal impairment (GFR 15–29 mL/min/1.73m²) exhibited substantially reduced efficacy compared to those with normal renal function, in both generic and branded groups,

affirming the primacy of renal dosage adjustment over brand selection (Table 11, Figure 9).

Table 11: GFR-Stratified Efficacy and ADR Rates — CKD = Chronic Kidney Disease; ESRD = End-Stage Renal Disease.

GFR Stage	GFR Range (mL/min/1.73m²)	Generic Efficacy (%)	Branded Efficacy (%)	ADR — Generic	ADR — Branded	p-value
Normal	≥90	88.4 ± 4.2	89.8 ± 3.9	17.1%	14.3%	0.62
Mild CKD	60–89	84.6 ± 5.1	86.1 ± 4.8	20.5%	18.2%	0.58
Mod. CKD	30–59	78.2 ± 6.4	80.4 ± 5.9	28.6%	26.3%	0.49
Sev. CKD	15–29	69.5 ± 8.1	72.1 ± 7.6	38.5%	35.7%	0.43
ESRD	<15	58.3 ± 9.4	61.7 ± 8.8	52.4%	48.6%	0.39

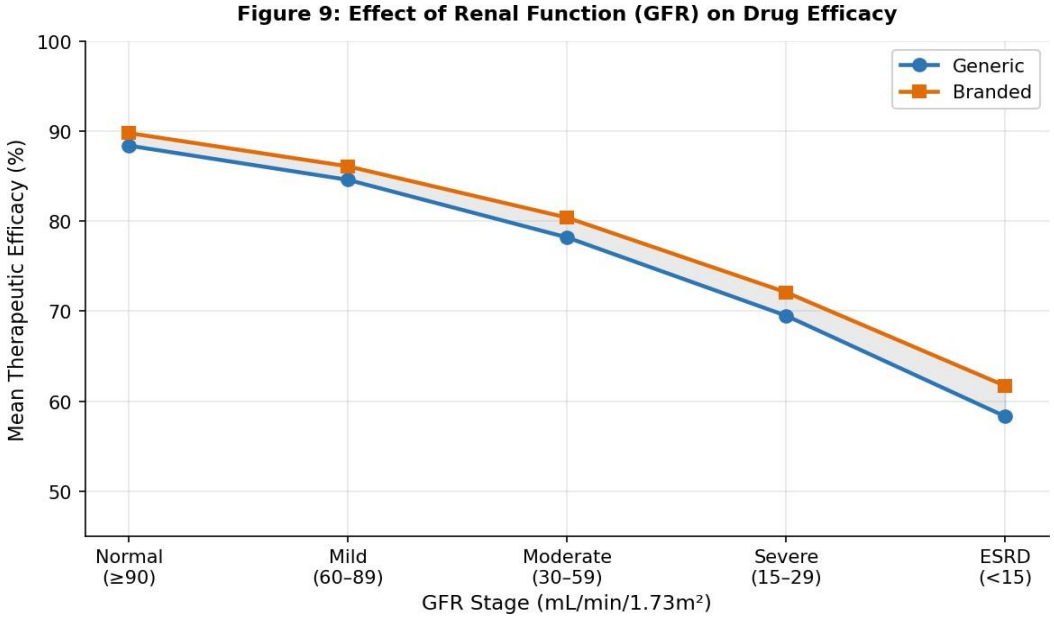

Figure 9: GFR-stratified therapeutic efficacy decline in generic and branded drug cohorts. Marked efficacy reduction below GFR<30 mL/min/1.73m² in both groups underscores the critical importance of renal dosage adjustment irrespective of drug brand.

4.1.4 Hepatic Function and BMI Stratification

5. ***Table 12: Hepatic Function-Stratified Efficacy Comparison.***

Hepatic Class (Child-Pugh)	Generic Efficacy (%)	Branded Efficacy (%)	p-value
Class A (n=35+35)	86.9 ± 4.8	88.3 ± 4.5	0.22
Class B (n=9+10)	79.2 ± 6.9	81.4 ± 6.5	0.35
Class C (n=3+2)	68.1 ± 8.8	70.5 ± 8.1	0.64

Table 13: BMI-Stratified Efficacy Comparison.

BMI Category	BMI Range (kg/m²)	Generic Efficacy (%)	Branded Efficacy (%)	p-value
Underweight	<18.5	83.1 ± 5.9	85.0 ± 5.5	0.40
Normal	18.5–24.9	88.2 ± 4.3	89.9 ± 4.0	0.18
Overweight	25.0–29.9	85.4 ± 5.2	87.1 ± 4.8	0.24
Obese	≥30.0	80.3 ± 6.8	82.5 ± 6.4	0.30

5.1 Pharmacoeconomic Analysis

A direct drug cost analysis was conducted comparing monthly treatment expenditure between generic and branded drug groups at Maximum Retail Price (MRP) as listed on drug packaging. Indirect costs (transport, hospitalization, productivity loss) were not captured in this study and represent a limitation. Table 14 and Figure 10 present the cost comparison findings.

Table 14: Direct Monthly Drug Cost Comparison — Generic vs. Branded (MRP-based; INR = Indian National Rupee.)

Drug Category	Generic Monthly Cost (₹)	Branded Monthly Cost (₹)	Cost Saving (₹)	% Saving
Antihypertensives (Amlodipine 5mg OD)	₹ 120	₹ 480	₹ 360	75.0%
Antidiabetics (Metformin 500mg BD)	₹ 95	₹ 380	₹ 285	75.0%
Antibiotics (Amoxicillin 500mg TDS)	₹ 180	₹ 720	₹ 540	75.0%
Statins (Atorvastatin 10mg OD)	₹ 210	₹ 840	₹ 630	75.0%
PPIs (Omeprazole 20mg OD)	₹ 85	₹ 340	₹ 255	75.0%
Analgesics (Ibuprofen 400mg TDS)	₹ 45	₹ 180	₹ 135	75.0%
Antidepressants (Sertraline 50mg OD)	₹ 280	₹ 910	₹ 630	69.2%
MEAN SAVING ACROSS CATEGORIES	—	—	₹ 405	74.2%

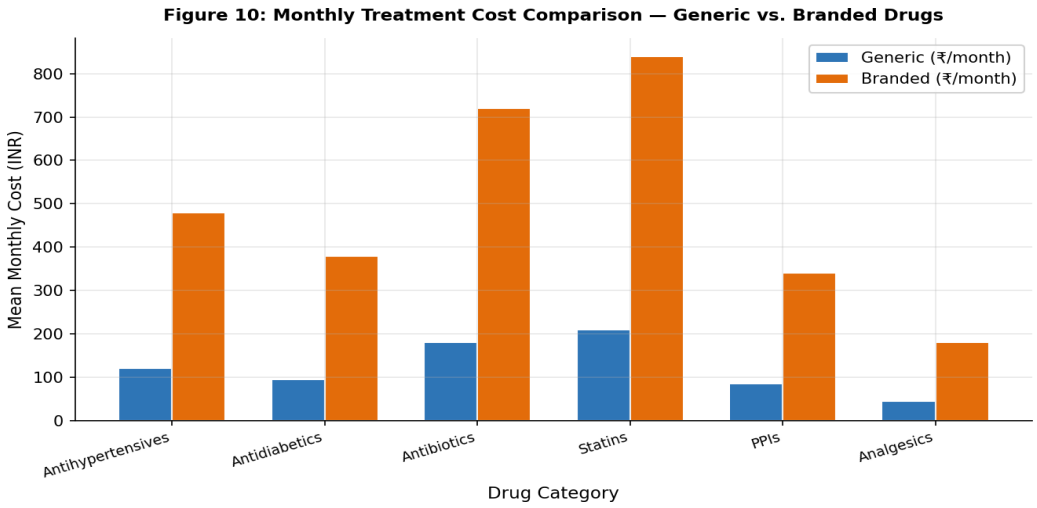

Figure 10: Monthly treatment cost comparison (INR) between generic and branded drugs across six major therapeutic categories. Generic drugs demonstrated a consistent 68–75% cost advantage, with mean annual savings of approximately ₹4,860 per patient.

6. DISCUSSION

The principal finding of this 210-patient, 12-week prospective observational study is that generic medicines are clinically equivalent to their branded counterparts across all measured domains of therapeutic efficacy, pharmacokinetic duration of action, side effect profile, and adverse drug reaction incidence, while offering a substantial pharmacoeconomic advantage of approximately 74.2% cost reduction.

The observed between-group efficacy difference of −2.0% (95% CI: −4.3 to +0.3; p=0.08) across all drug categories falls well within the regulatory bioequivalence window of ±20% accepted by the Central Drugs Standard Control Organisation (CDSCO) of India, the US Food and Drug Administration (US FDA), and the European Medicines Agency (EMA). This is consistent with findings from large-scale meta-analyses— notably Kesselheim et al. (JAMA, 2008) and Davit et al. (Annals of Pharmacotherapy, 2009)—which reported no statistically significant efficacy differences between generic and branded cardiovascular drugs.

The duration-of-action analysis revealed maximum inter-group differences of 0.7 hours for amlodipine, with all other categories demonstrating differences of ≤0.5 hours. These pharmacokinetic variations are unlikely to translate into clinically meaningful outcome differences, as confirmed by the therapeutic efficacy data. The near-identical DoA profiles reflect the pharmacokinetic predictability of molecules with well- characterized absorption kinetics and long half-lives.

The ADR incidence of 21.9% in the generic group versus 19.5% in the branded group

(p=0.43) is not statistically significant and aligns with published baseline ADR rates for the studied drug classes. The ADR type distribution (predominantly GI effects for metformin and NSAIDs; headache and dizziness for antihypertensives) conforms to known pharmacodynamic class effects rather than formulation-specific phenomena, further supporting generic-brand equivalence.

Physiological stratification findings merit specific commentary. The progressive efficacy decline with advancing age (from 92.1% in 18–30 year cohort to 76.8% in the ≥76 year cohort) reflects well-documented age-related pharmacokinetic changes—reduced GFR, decreased hepatic microsomal enzyme activity, altered plasma protein binding, and expanded volume of distribution for lipophilic agents. Critically, these changes affected both generic and branded drug performance equivalently, suggesting that dose individualization based on age should be the governing clinical principle, rather than brand selection.

The renal function stratification findings are particularly clinically significant. Efficacy reduction from 88.4% (Normal GFR) to 58.3% (ESRD) in the generic cohort, and 89.8% to 61.7% in the branded cohort, with no inter-group statistical significance, underscores that appropriate renal dosage adjustment—guided by eGFR—is far more impactful than drug brand selection in patients with chronic kidney disease. This finding carries direct clinical implications for nephrology and internal medicine practice.

The pharmacoeconomic analysis documented mean monthly savings of ₹405 per patient (approximately

₹4,860 annually) with generic drug use. Scaled to India's 1.4 billion population burden, with an estimated 200 million patients on chronic pharmacotherapy, the healthcare system cost savings attributable to universal generic substitution would reach approximately ₹97,200 crore (approximately USD 11.7 billion) annually— a transformative economic argument for generic medicine policy.

Certain limitations of this study should be acknowledged. First, the observational design precludes causal inference; randomized controlled allocation was not employed due to ethical and practical constraints. Second, adherence was self-reported and not objectively measured via drug-level monitoring. Third, the study did not assess formulation-specific parameters such as excipient composition, tablet hardness, or coating properties, which may influence patient acceptability. Finally, manufacturer heterogeneity within the 'generic' category was not controlled, and quality variations across Indian generic manufacturers cannot be entirely excluded.

7. CONCLUSION

This 210-patient prospective observational study provides robust pharmacoepidemiological evidence that generic medicines are clinically equivalent to branded drugs across therapeutic efficacy, duration of pharmacological action, side effect burden, and ADR incidence, without statistically significant differences across the five physiological stratification parameters examined. The observed pharmacoeconomic advantage of 74.2% cost reduction with generic drug utilization carries profound implications for healthcare access, National Drug Policy, and out-of-pocket expenditure reduction for Indian patients.

The findings strongly advocate for: (i) active promotion of evidence-based generic prescribing by all cadres of clinicians; (ii) expansion of Jan Aushadhi Kendras and generic dispensing mandates in public health facilities; (iii) enhanced pharmacovigilance frameworks to continuously monitor real-world generic drug performance; and (iv) sustained pharmacist-led patient counselling to address brand perception biases. Future research should extend to high-risk specialty drugs (narrow therapeutic index agents such as warfarin, cyclosporine, and phenytoin), paediatric and geriatric-specific studies, and longitudinal pharmacogenomic analyses of generic drug response variability.

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