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Research Article

**COMPARATIVE STUDY OF PERCENTAGE PURITY AND
COST OF SOME GENERIC AND BRANDED MARKETED
TABLETS OF DIFFERENT CLASSES****M.Gayathri Devi*, M.Savitri, P.Uma Devi, P.V.Madhavi Latha, B. Nagamani,
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Abstract:

The present work describes about the comparative study of percentage purity and cost of some generic and branded marketed tablets of different categories like Anti-diabetic , Diuretic, Anti-pyretic and Vitamin B formulations. Branded formulations are at high cost, so that the poor can't afford them. Therapeutic efficacy of Generics is almost identical to that of branded drugs. But one of the major differences is Generics are 80% cheaper on average when compared to branded drugs. In fact FDA estimates that 50% of generic drug production is by brand-name companies. So the consumption of generic and branded medicines depends on this un-popularized fact. Therefore the generic drugs of various pharmaceutical companies are sold at low cost .The present study is about comparison of Percentage purity and cost of the different generics and branded formulations. Our experimental results of generic and branded tablets were compared by statistical analysis which gave an important conclusion that the percentage purity of both generic and branded drugs are similar whereas the cost of branded drugs is more.

Key Words: *Branded drugs, Generic drugs, Percentage purity, T-value .***Corresponding author:****M.Gayathri Devi,**Viswanadha Institute of Pharmaceutical Sciences,
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INTRODUCTION:

Objective: The objective of present study is to compare the percentage purity and cost of some generic and branded marketed tablets of different categories like Anti-diabetic, Diuretic, Anti-pyretic and Vitamin B.

Branded vs Generics: The difference between a brand-name product and a generic one is designed to be transparent. Once the patent life expires on a brand-name drug product, it is eligible to be made into a "generic drug." To do this, the generic drug manufacturer must ensure that the drug they are producing contains the same active ingredient(s) as the brand-name product, in the same dosage form, at the same dose or concentration, and for the same route of administration. The drug may differ in color, shape, taste, inactive ingredients, preservatives and packaging, however. Because of these differences, the generic drug manufacturers are required to submit additional paperwork to the FDA to prove that their

product is manufactured in accordance with good manufacturing practices (GMPs), and is as pure and stable as the brand-name product. Additionally, the generic needs to meet pharmacokinetic parameters in the body, which means it, must dissolve at the same rate and to the same extent as the original which ensures that there are bioequivalent and behave the same inside the body [1-3].

MATERIALS AND METHODS:

We have selected some generic and branded formulations of different classes like Anti- diabetic, Diuretic, Anti-pyretic and Vitamin-B in order to check the percentage purity and cost of the formulations. In the present scenario diabetes and hypertension are more prevailing so we selected the anti- diabetic and diuretic drugs and in regular use antipyretic and vitamin-B are used and hence these are used for the study.

Table 1: Generic formulation

DRUGS	GENERIC	COST PER STRIP (rs)	MANUFACTURER
Metformin Hydrochloride	Okamet (500mg)	10/-	Cipla.LTD.
	Metfor (500mg)	12/-	Cipla.LTD.
	Elecphase (500mg)	8/-	Elder pharmaceuticals limited
Furosemide	Lasix (40mg)	8/-	Sanofi Aventis.LTD RS 10/-
	Fruselac (40mg)	22/-	Lupin.LTD
Paracetamol	Paracip (500mg)	10/-	Cipla.LTD.
	Parakym (500mg)	8/-	Mankind.LTD
	Welset (500mg)	8/-	Shivek.LTD
Riboflavin	Riboflavin (10mg)	2/-	Cortex.LTD.
	RiboflavinB2(10mg)	6/-	Shreyas.Life Sciences

Note: The cost and manufacturer of the generic formulations of different class of drugs

Table 2: Branded formulations

DRUGS	BRANDED	COST PER STRIP (RS)	MANUFACTURED BY
Metformin Hydrochloride	Gluformin (500mg)	20/-	Sun.pharma.ltd
	Glyciphase (500mg)	30/-	Franco-indian Pharmaceuticals PVT.LTD
	Glycomet (500mg)	36/-	USV.LTD
Furosemide	Amifru (40mg)	10/-	Torrent.Pharmaceuticals.LTD.
	Frusimen (40mg)	12/-	Torrent.Pharmaceuticals.LTD.
Paracetamol	P-500 (500mg)	15/-	Apex.LTD
	Calpol (500mg)	16/-	Glaxosmithkline.LTD
	Realifast (500mg)	10/-	Regardia.LTD
Riboflavin	Riboflavin (10mg)	08/-	Shreyas. Life Sciences
	B2 400 (10mg)	08/-	Shreyas. Life Sciences.

Note: The cost and manufacturer of the branded formulations of different class of drugs

Metformin hydrochloride[4]

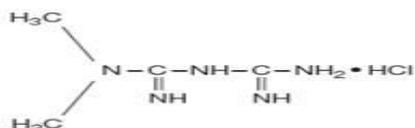


Fig 1: Structure of Metformin hydrochloride

Mechanism of action: It decreases hyperglycemia primarily by suppressing glucose production by the liver. Inhibition of the mitochondrial respiratory chain (complex I), activation of AMP-activated kinase (AMPK), inhibition of glucagon-induced elevation of cyclic adenosine monophosphate (cAMP) with reduced activation of protein kinase A (PKA), inhibition of mitochondrial glycerophosphate dehydrogenase.

Furosemide^[5]

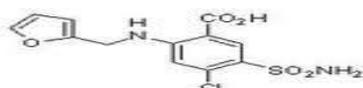


Fig 2: Structure of Furosemide

Mechanism of action: It acts by inhibiting NKCC2, the luminal Na-K-2Cl symporter in the thick

ascending limb of the loop of Henle. The action on the distal tubules is independent of any inhibitory effect on carbonic anhydrase or aldosterone; it also abolishes the cortico-medullary osmotic gradient and blocks negative, as well as positive, free water clearance. Because of the large NaCl absorptive capacity of the loop of Henle, diuresis is not limited by development of acidosis, as it is with the carbonic anhydrase inhibitors.

Paracetamol [6]

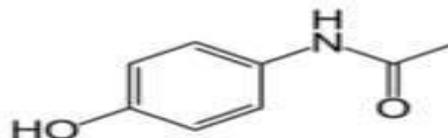
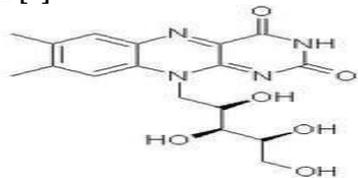


Fig 3: Structure of Paracetamol

Mechanism of action: It causes the inhibition of cyclooxygenase (COX), and it is highly selective for COX-2. Because of its selectivity for COX-2 it does not significantly inhibit the production of the pro-clotting thromboxanes. It has analgesic and antipyretic properties comparable to those of aspirin or other NSAIDs.

Riboflavin [7]**Fig 4: Structure of Riboflavin**

Mechanism of action: It binds to riboflavin hydrogenase, riboflavin kinase, and riboflavin synthase. It is the precursor of flavin mononucleotide (FMN, riboflavin monophosphate) and flavin adenine dinucleotide (FAD). The antioxidant activity of riboflavin is principally derived from its role as a precursor of FAD and the role of this cofactor in the production of the antioxidant reduced glutathione.

METHODOLOGY:

The percentage purity of these formulations was determined by using Systronics UV Visible Spectrophotometer ⁽⁸⁾ and was analyzed by using statistics.

Procedure for the preparation of drug solutions (As per IP)[9-12]**Procedure for the assay of Metformin Hydrochloride tablets:**

20 tablets were weighed and powdered in a clean mortar and pestle. Required quantity of powder equivalent to 0.1g of Metformin Hydrochloride was weighed accurately and transferred to a volumetric flask containing 70 ml of distilled water. The volumetric flask was shaken for 15 mins for complete solubility of drug. The volume was further made upto 100ml with distilled water and filtered. From the filtrate 10ml was taken diluted to 100 ml with water and absorbance of solution was measured at 232nm. The percentage purity was calculated taking 798 as specific absorbance.

Procedure for the assay of Furosemide tablets:

20 tablets were weighed and powdered in a clean mortar and pestle. Required quantity of powder equivalent to 0.1g of Furosemide was weighed accurately and transferred to a volumetric flask containing 150ml of 0.1M NaOH. The volumetric flask was shaken for 10 mins for complete solubility of drug and further sufficient 0.1M NaOH was added to produce a volume of 250 ml and filtered. From the filtrate 5 ml was taken and diluted to

200ml with 0.1M NaOH and absorbance of solution was measured at 271nm. The percentage purity was calculated taking 580 as specific absorbance.

Procedure for the assay of Paracetamol tablets:

20 tablets were weighed and powdered in a clean mortar and pestle. Required quantity of powder equivalent to 0.15g of Paracetamol was weighed accurately and transferred to a volumetric flask containing 50ml of 0.1M NaOH, this solution was diluted to 100 ml with distilled water. The volumetric flask was shaken for 15 mins, further sufficient distilled water was added to produce 200 ml, mixed and filtered, from the filtrate 10 ml was taken and diluted to 100 ml with distilled water. From the above solution 10ml was taken and 10 ml of 0.1M NaOH was added and diluted to 100 ml with distilled water and mixed, the absorbance of the resulting solution was measured at 257nm and the percentage purity was calculated taking 715 as specific absorbance.

Procedure for the assay of Riboflavin tablets:

20 tablets were weighed and powdered in a clean mortar and pestle. Required quantity of powder equivalent to 10mg of riboflavin was weighed accurately and transferred to a volumetric flask containing 5ml of glacial acetic acid and 100 ml of distilled water. The solution was heated on a water bath for 1hour with occasional shaking. An aliquot of 50 ml of distilled water was added and diluted, the solution was cooled, and 30ml of 1M NaOH was added with continuous stirring, further sufficient distilled water was added to produce 100ml, mixed, and filtered. From the filtrate first few ml was discarded and absorbance of the resulting solution was measured at 444nm, and the percentage purity was calculated taking 328 as specific absorbance.

Calculations: Weight of 20 tablets = x gms

Average weight of tablets = x/20 gms

Weight to be taken = Average weight/amount claimed * equivalent weight

= -----gms

Amount = absorbance/ $A_{1\%}^{1\text{cm}}$ * dilution factor * conversion factor * Average weight

= -----mg

Percentage purity = Amount / Label claimed * 100



5a



5b



5c



5d



5e



5f



5g

Fig 5: Different generic and branded formulations available in the market

5a –Metfor 500mg, 5b –Glyciphage 500mg, 5c –Paracip 500mg, 5d –P-500, 5e –Lasix-40, 5f –Riboflavin-10mg, 5g–Riboflavin vitamin B₂.

RESULTS AND DISCUSSION:

The percentage purity of generic and branded formulations of Anti-diabetic, Diuretic, Anti-pyretic, Vitamin –B was compared with the labeled claim.

Table 3: Percentage purity of Generic marketed drugs

Drug	Generic	Label claim	Amount	Percentage purity
Metformin Hydrochloride	Okamet	500mg	478.9mg	96.80%
	Metfor	500mg	499.9mg	99.98%
	Elecephase	500mg	499.9mg	99.98%
Furosemide	Lasix	40mg	39.7mg	99.25%
	Frucilac	40mg	39.8mg	99.50%
Paracetamol	Paracip	500mg	499.2mg	98.5%
	Parakym	500mg	499.1mg	99.62%
	Welset	500mg	498.2mg	99.60%
Riboflavin	Riboflavin (cortex)	10mg	9.8mg	98%
	Riboflavin B ₂	10mg	9.6mg	96%

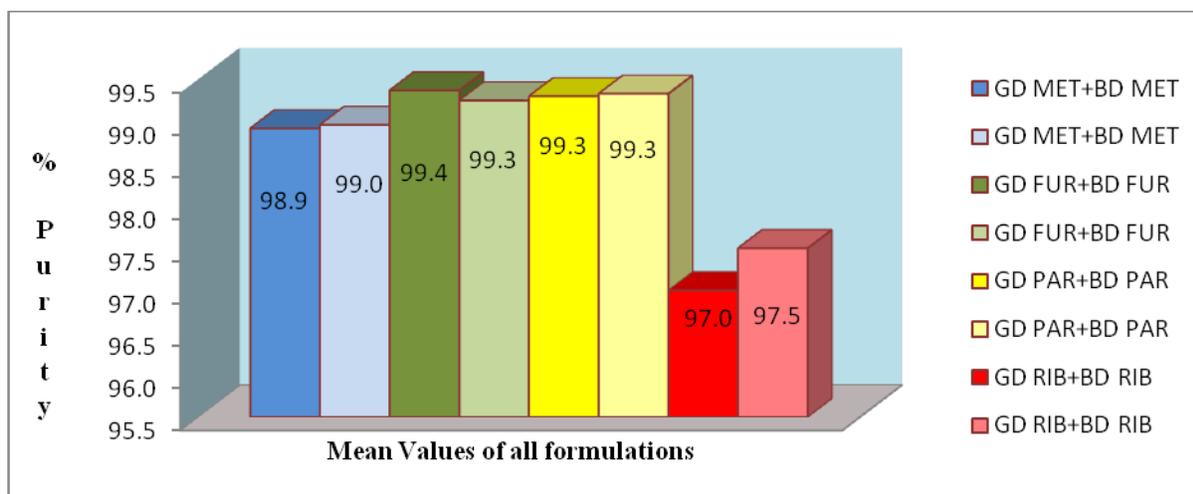
Table 4: Percentage purity of Branded marketed drugs

Drug	Branded	Label claim	Amount	Percentage purity
Metformin Hydrochloride	Gluformin	500mg	499.1mg	99.82%
	Glyciphase	500mg	499.9mg	99.98%
	Glycomet	500mg	478.9mg	96.8%
Furosemide	Amifru	40mg	39.8mg	99.5%
	Frusimen	40mg	39.6mg	99.0%
Paracetamol	P-500	500mg	499.1mg	99.82%
	Calpol	500mg	498.4mg	99.68mg%
	Realifast	500mg	492.7mg	98.50mg%
Riboflavin	Riboflavin	10mg	9.85mg	98.5%
	Riboflavin B2 400	10mg	9.70mg	97%

Statistical analysis: Statistical analysis was performed by using Statistica Version 7.0 software. Student T-test was performed with 0.1 level of significance at (n-1) degrees of freedom, to compare the statistical difference between percentage purity values of generic and branded tablets.

Table 5: Statistical data of Different Generic and Branded marketed tablets

Drug	No.of Generic	No.of Branded	Mean of Generic	Mean of Branded	S.D of Generic	S.D of Branded	T-value	Decision
Metformin Hydrochloride	3	3	96.80	98.92	1.835	1.791	0.972	NS*
Furosemide	2	2	99.37	99.25	0.176	0.35	0.698	NS*
Paracetamol	3	3	99.30	99.33	0.707	0.725	0.965	NS*
Riboflavin	2	2	97	97.5	1.41	1.06	0.609	NS*

**Fig. 6: Statistical comparison of mean values of percentage purity of different Generic and Branded tablets.**

GD MET- Generic Metformin Hydrochloride tablets. BD MET- Branded Metformin Hydrochloride tablets.
 GD FUR- Generic Furosemide tablets. BD FUR- Branded Furosemide tablets.
 GD PAR- Generic Paracetamol tablets. BD PAR- Branded Paracetamol tablets.
 GD RIB- Generic Riboflavin tablets. BD RIB- Branded Riboflavin tablets.

CONCLUSION:

From the above results, we had concluded that the percentage purity of both generic and branded tablets showed yields that are in acceptance within the Indian Pharmacopoeia limits. Also the generic drugs are as good as branded drugs in quality, purity and strength.

So as a pharmacist we can make use of generic drugs than branded forms as they are cost effective and also equally active as branded drugs.

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