ISSN: 0975-766X
Available Online through
Research Article
www.ijptonline.com

A COMPARATIVE STUDY OF *BRANDED* VERSUS *BRANDED GENERICS* IN INDIA

Girdhari Lal Singal and Arun Nanda*
Faculty of Pharmaceutical Sciences, M.D. University, Rohtak, Haryana, INDIA - 124 001.
Email: an_mdu@rediffmail.com

Received on 24-09-2010 *Accepted on 10-10-2010*

ABSTRACT

AIM: To nullify the notion that costly *branded* drugs are superior in quality to their cheaper *branded - generic* counterparts.

METHODS: Four batches of Restyl ® (*branded)* and Tranax ® *(branded - generic)* containing Alprazolam, 0.25 mg, manufactured by Cipla, were selected for carrying out the proposed study. The test samples were tested for assay, hardness, uniformity of weight and disintegration time, as per official methods.

RESULTS: The average assay values obtained after analysis of these four different batches of RESTYL TABLETS using HPLC method was 0.2535 mg per tablet against the claim of 0.25mg while it was 0.233 mg for TRANAX TABLETS. Other physical tests like hardness, uniformity of weight and disintegration time were also within the permissible limits for all the eight batches of the drugs.

CONCLUSION: From the present study it is deciphered that there is no difference in quality of branded versus branded - generic alprazolam, although huge difference exists in their price / profit margins.

Keywords: Alprazolam, branded, branded - generics, generics.

INTRODUCTION:

Availability of essential medicines and their affordability is yet a dream cum true. It poses a great challenge for the health care provider not only in a developing country like India but all over the world.

Despite India being the fourth largest producer of medicines in the world and exporter to over 200 countries, majority of its population lacks access to the essential medicines [1]. Making essential medicines available to the common man still remains a burning issue for the state, in spite of the tremendous growth of pharmaceutical industry in India during the past two decades. As a supplier of *generic* medicines India's status is well recognized in developing and developed countries but back in India the population is in want of *generic* essential medicines. In absence of such essential drugs the incidence of mortality, morbidity and disability has gradually gone up hinting towards introspection in the supply system of our medicines. The public health system in India is in a state of high despair as it is under funded and poorly managed. Due to the lack of insurance cover or any subsidies over 80 percent of India's health is borne by the patients [2]. Hence cost of medicines is a crucial determinant related to the health of the citizens. Inadequate and poor distribution of medicines also affects its availability in the public facilities. The patients visiting the public facilities are forced to purchase medicines from the market as the drugs are normally "out of stock". Consequently, a significant proportion of them drift to the private practitioners on whose rationality there is little control: a vicious circle of poverty, ill-health, poor planning and poorer regulations thus sets in which victimizes the ailing Indian population with malice. After dowry, medical care is the second major cause of rural indebtedness in India [3].

In a study in Haryana, India, it was reported that majority of the private doctors do not prescribe generics, being considered as of inferior to branded in quality. Those in public facilities, however, were found prescribing generics, may be, because of government policies on generics. Overall concern about the quality and therapeutic efficacy of generics was found perturbing the minds of physicians, while prescribing them [4].

In the open market the drugs are generally available in two forms – *generic* and *branded*. According to the US FDA "*generic* drugs are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties" (www.fda/cder/consumerinfo/generics_q&a.htm). Out of these *branded* drugs are costly as compared to the

generic counterpart. The concept of low cost *generic* medicines is gearing up to improve the availability and affordability of essential medicines throughout the world. Their popularity can be adjudged from the fact that as on day, more than half of the prescriptions filled in US are *generics* only [5]. In view of the high cost of patented medicines and the fact that most of the essential medicines are going off patent, *generic* medicines are replacing the patented ones, speedily throughout the world including the developed countries like US. Prescribing through the *generic* medicines would be patient pocket friendly and will not lead to error of drug compliance on account of high cost of patent drugs.

In India, the concept of *branded and generics* is not the same as it is worldwide. Strictly speaking, there are hardly any *branded* products in India, since there were almost no innovated pharmaceutical products in India. However, most of the drug products are marketed in India, under a *brand*, by major Indian / multinational companies, who incur a lot of expenditure on *brand* promotion. Thus, *branded* products in India are costly, and the vigorous promotional campaigns by pharmaceutical companies, involving medical representatives and doctors, rely on the common impression that "*costly branded products are better in quality (than their cheaper counterparts, viz., generics).* On the other hand, pharmaceutical companies do not invest anything in the marketing of *generics*, which are offered at a comparatively cheaper price, to the patients. However, a unique class of pharmaceutical products has also emerged in India, viz., *branded generics*. In fact, these are *generic* products (marketed by the same company) in the sense that the pharmaceutical companies do not invest anything on their marketing. These products (*branded generics*) are given a *brand* name, and since their actual cost is very less, these products are offered to the retailers at a very low PTR (Price to the Retailer). But the Maximum Retail Price (MRP) printed on these *branded generics* is almost the same, or slightly lower than their *branded* counterparts, although much higher than their *generic* counterparts. This huge difference in the PTR and MRP gives a very big profit margin to the retailers, who therefore willingly promote the sales of such (*branded generic*) products. In this whole process, both the pharmaceutical company and the retailers are benefitted; ultimately, the poor patients are befooled,

since they are made to pay heavily for a *branded-generic*, which is the same as a *branded* (or a *generic* product). The whole process of such sales relies upon the common psychology: costly, *branded* products are better in quality, than their cheaper counterparts (*generics*). It is very difficult for a common / ordinary consumer to know whether it is *branded* product or is a *branded generic* product because of lack of any distinguishing mark. The Indian drug laws do not have any such provisions to differentiate the *generic* product from its *branded* counterpart [6]. Under such circumstances, the consumer having no choice is left at the mercy of the dispensing chemist and the prescribing physician.

A comparative evaluation of prices for common *branded* and *branded - generic* products in India, is given in Table 1.

Table- 1: *Branded Generics*/*Branded* drug products and their trade margins.

Drug Name	Type	Brand Name /mfg. company	PTR	MRP	Tade Margins
Alprazolam Tab. 0.25 mg. (1x10 tab)	*Branded*	Restyl (Cipla/Protec)	Rs. 11.85	Rs.15.50	31 %
	Branded generic	Tranax (Cipla)	Rs. 2.20	Rs.11.34	420 %
Ciprofloxacin Tab. 500 mg. (1x10 tab)	*Branded*	Ciprobid (Cadila)	Rs. 54.84	Rs.68.56	25 %
	Branded generic	Ciprodac (Cadila)	Rs. 15.00	Rs.68.56	457 %
Cetrizine hcl Tab. 10 mg (1 X 10 tab)	*Branded*	Alerid (Cipla)	Rs. 27.16	Rs 35.31	30 %
	Branded generic	Cetcip (Cipla)	Rs. 2.24	Rs. 25.00	1016 %
Fluoxetine hcl 20 mg Cap.	*Branded*	Fludac (Cadila)	Rs. 29.80	Rs. 37.26	25 %
	Branded generic	Cadflo (Cadila)	Rs. 6.00	Rs. 28.00	367 %
Lansoprazole 30 mg Cap.	*Branded*	Lanzol - 30 (Cipla)	Rs. 42.36	Rs. 53.77	27 %
	Branded generic	Lansec - 30 (Cipla)	Rs. 15.68	Rs. 47.25	201 %

PTR –Price to the retailer MRP- Maximum retail price

As on date, the *branded - generics* have virtually replaced all the *generic* products in India. For example, most of the leading pharmaceutical companies in India do not manufacture any *generics* (although

many of such companies do market the *branded - generic).* Hence, it was realized that it is very essential to investigate whether *branded* products are superior in quality than their *branded generic* counterpart. For this purpose, the authors focused on alprazolam, which is a restricted product in India, i.e., it can be purchased in India only through a prescription.

METHODS:

In the present study, Alprazolam tablets, marketed and manufactured by M/S Cipla Ltd., Mumbai, under the *brand* name Restyl ® tablets, 0.25 mg, and *branded - generic* Tranax ® tablets, 0.25 mg, were selected. Four different batches of both the *branded* and *branded - generic* alprazolam, marketed by the same company, were procured and were tested for their assay, hardness, uniformity of weight and disintegration time, as per official method (Indian Pharmacopoeia, 2007) [7]. The details of drug products selected for this study are given in Table-2.

Table – 2: Details of the drug products selected for comparative analysis.

S. No.	Product Name	Name	Batch No/Manufacturing date//Expiry Date				Mfd. by
			I	II	III	IV	
1.	Alprazolam Tablets 0.25 mg.	Restyl ® (*Branded*)	D83972 Mfd:10/08; Exp: 9/11	D83973 Mfd:10/08; Exp:9/11	D83974 Mfd:10/08; Exp:9/11	D83975 Mfd:10/08; Exp:9/11	Cipla
2.	Alprazolam Tablets 0.25 mg	Tranax ® (*Branded generic*)	DP8265 Mfd:7/08; Exp:6/11	DP8401 Mfd:8/08; Exp:7/11	DP8494 Mfd:9/08; Exp:8/11	DP8499 Mfd:9/08 Exp:8/11	Cipla

The test samples were procured from the licensed authorized chemist dealers through valid purchase invoice. The sample size comprised 10x10 tablets; each of four different batches of the said both types of drug product. Efforts were made to procure these test samples having almost identical dates of manufacturing to rule out the possibility of difference in assay of the samples bearing different dates of manufacturing. The test samples were subjected to quantitative analysis for their assay as well as other tests using alternate methods of analysis for purposes of the validation of analytical method. The analytical methods prescribed in the latest edition of Indian Pharmacopoeia, 2007, were followed for carrying out the said study [7].

RESULTS:

The average assay value obtained after analysis of these four different batches of drug product RESTYL TABLETS using HPLC method was 0.2535 mg per tablet against the claim of 0.25mg while it was 0.233 mg for its counterpart *branded generic* versions i.e., TRANAX TABLETS (limits : 0.225 to 0.275 mg). Thus, both the *branded* and *branded - generic* alprazolam tablets passed the assay. Other physical tests like hardness, uniformity of weight and disintegration time were also within the permissible limits for all the eight batches of the drugs. The results obtained during the study are detailed in the Table- 3.

Table-3: Comparative analytical profile of *generic / branded* Alprazolam tablets.

S. No.	Name of the product	Batch No.	Assay (HPLC)	Hardness (Kg/cm)	Uniformity of Weight	Disintegration Time (sec.)
1.	RESTYL	D83972	0.248 mg	3.5	+1.71% to -1.90%	30
2.	RESTYL	D83973	0.259 mg	3.0	+2.18% to -2.04%	22
3.	RESTYL	D83974	0.253 mg	2.5	+2.18% to 2.04%	24
4.	RESTYL	D83975	0.254 mg	2.5	+1.80% to -1.98%	26
5.	TRANAX	DP8265	0.225 mg	3.5	+2.19% to -3.08%	32
6.	TRANAX	DP8401	0.240 mg	4.0	+6.69% to -4.01%	48
7.	TRANAX	DP8494	0.229 mg	3.5	+3.84% to -4.45%	40
8.	TRANAX	DP8499	0.238 mg	4.0	+3.27% to -2.86%	25
	Permissible Limits		0.225 to 0.275 mg.	Up to 5 kg.	+7.5% to -7.5%	Up to 15 minutes

DISCUSSION:

It is deciphered from the present study that the *branded generic* product, TRANAX TABLETS, 0.25 mg, as well as its counterpart, *branded* product, RESTYL TABLETS 0.25 mg, both manufactured and marketed by M/S Cipla (I) Limited, Mumbai, conform to the statutory quality standards laid down under the Indian laws [Drugs and Cosmetics Act, 1940 and Rules, 1945] [6]. There is no compromise in their quality although they carry different price tags and the manufacturing company adopts different strategies to market

them. The present study is suggestive that the price tag does not have any bearing on the quality of this product. Thus the prevalent notion that costly *branded* drugs are of better quality does not hold true.

The results are in conformity with the definition of the *generic* drug which states that *generic* medicine is copy of its innovator/ *branded* counterpart and is identical in dose, strength, intended use, etc. to the *branded* counterpart. These results further suggest that both kinds of these products are processed utilizing similar / identical manufacturing facilities and further subjected to similar quality control tests involving almost similar production expenses. Therefore, both these versions must exhibit comparable therapeutic efficacy.

The results are also in comformity with an earlier study, in which comparative evaluation branded and branded - generic versions of Cetrizine, was carried out, manufactured by same company. In this study, both the branded and branded - generic versions of Cetrizine, were found to be within official limits. [8]

It is pertinent to investigate why is there so much difference in the price of *branded* and *branded generic* medicines. The pharmaceutical companies spend a lot on the promotion of their *branded* products. The sales of such *branded* products are promoted through medical representatives, distribution of free samples to medical professionals, incentives to the retailers, wholesalers/distributors and expiry / breakage replacement policies. These companies also incur heavy expenses on their advertisements with a view to make their brand popular among masses so as to attract its general acceptability and ultimately sales. The pharmaceutical companies even suffer lot of expenses in arranging workshops, seminars, training camps and free gifts to the medical professionals which add to the cost of their *branded* products. According to a recent report published in a medical journal, even in US, “many US faculty members on institutional review boards have ties with the industry” [9]. Industry invests heavily in inducing prescribers to make use of its products, and there is ample evidence that prescribers are sensitive to these promotional efforts which often lead to extravagant prescribing [10]. For example, it has been reported that an Indian pharmaceutical giant, Ranbaxy Laboratories (name now changed) sponsored visit of about 400 doctors to Bangkok. Similarly, another

pharmaceutical company Johnson & Johnson was reported to sponsor 300 kidney specialists to visit Singapore for three days. [18] In India, drugs companies are known to give costly gifts including refrigerators, air conditioners and even cars to promote their *branded* products. Unethical promotional practices by the pharmaceutical companies in India make the drugs market "unique" [11]. Only the Indian Academy of Pediatrics, amongst the professional bodies, has taken a principled stand on this matter by banning drug company sponsored conferences of its meetings. No such sales promotion strategies are undertaken for promoting *generics* / *branded generics* products by pharmaceutical companies which are usually promoted by the retailers exclusively. Sales of *generic* and *branded generics* is therefore exclusively left to the traders, who retains the maximum profit in the chain.

CONCLUSIONS:

The study highlight that *branded - generic* alprazolam is as good in quality as the *branded* alprazolam, and thus further substantiates the findings [9], which stress that branded drugs are not superior in quality to the *branded - generics* or *generics*.

REFERENCES:

1. A. Creese, A. Kotwani, J. Kutzin, A. Pillay. Evaluating pharmaceuticals for health policy in low and middle income country settings. In: Evaluating pharmaceuticals for health policy and reimbursement (eds. Freemantle N, Hill S) Blackwell Publishing (in collaboration with WHO, Geneva), Massachusetts, U.S.A, 2000; 227-43.
2. National Sample Survey (NSS) 60th Round, Morbidity, Health Care and Condition of the Aged Report No. *507*:2006 March; p 32.
3. Focus on health care delivery. *IDMA Bulletin XL* (3) Aug. 14, 2009; 60.
4. G.L. Singal and A. Nanda. Evaluating general practitioner's perceptions & practices on generics and branded medicines. *The Pharma Review, Vol. 8, No. 44*, March April 210, 140 - 144.

5. A. Kotwani, E. Margaret, D. Dey, P.K. Lakshmi, A. Patel, K. Raman. Prices & availability of common medicines at six sites in India using a standard methodology. *Indian J. Med. Res.* 2007 May; *125*: 645-654.

6. V. Malik. Laws relating to Drugs and Cosmetics.19th ed. Lucknow, (India) Eastern Book Company; 2007. p. 145-153.

7. Indian Pharmacopoeia 2007 volume II p 697, Govt. of India, Ministry of Health & Family Welfare. Published by The Indian Pharmacopoeia Commission, Ghaziabad.

8. N. Pahwa, G.L. Singal and A. Nanda. Quality of generics versus branded products for Cetrizine hcl tablets : A case study. *The Indian Pharmacist*, March 2010, 16 - 22.

9. J. Clark. A hot flush for Big Pharma. *Br. Med. J*. Aug 2003; 327:400.

10. A. Wazana. Physicians and the pharmaceutical industry. *JAMA* 2000; 283: 373-380.

11. C.M. Gulhati. Marketing of medicines in India. Informing, inducing or influencing. *Br. Med. J*. 2004; 328: 778-779 (3 April).

Corresponding Author:

Prof. Arun Nanda*,
HOD and Dean,
Faculty of Pharmaceutical Sciences,
Maharshi Dayanand University, Rohtak,
Haryana, INDIA - 124 001.
Email: *an_mdu@rediffmail.com*