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A comparative study of generic (Jan Aushadhi)and ethical glimepiride

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Abstract

Whole of the study tries to evaluate and compare the quality of generic glimepiride with their ethical product as per Indian Pharmacopoeial standards and other validated methods on commonly used type II diabetes drug (Glimepiride). Studies were performed as per Indian Pharmacopoeia 2007. The tests performed for evaluation includes uniformity of weight, In vitro dissolution, disintegration, friability, assay, hardness, thickness. The study revealed that ethical as well as generic glimepiride tablets comply with the standards provide in IP 2007.

Key- words: Glimepiride, Jan aushadhi, IPS

Introduction

A baguette brand bag costs more because of its good quality as compared to a non-branded bag, although it is not the same in the case of quality of low cost generics or non-branded medicines when compared to their branded counterparts. Generic medicines are equally effective and safe in terms of quality to their costly branded counterpart. A study reported by USFDA of the evaluation of the results of 38 published clinical trials that compared cardiovascular generic medicines to their branded counterparts revealed no evidence that brand-name heart drugs worked any better than generic heart drugs[1]. According to World Health Organization (W.H.O.) "a generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights"[15]. When it comes to prescribing a generic medicine most of the doctors in India and several other countries are found to be reluctant in prescribing generic medicine due to cynical about the quality, safety and efficacy of generic medicine. Medical Council of India, Code of Ethics Regulations regardingthe use of Generic names of drugs says "Every physician should, as far as possible, prescribe drugs with generic names and he / she shall ensure that there is a rational prescription and use of drugs"[16].

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Prescribing medicine with generic name was also recommended by Parliamentary Standing Committee (PSC) for Health and Family Welfare to the 'Rajya Sabha' on August 4, 2010 . Several studies conducted worldwide raise the issue of myths and prejudice regarding the 'quality' of generic medicine in the minds of patients, healthcare professionals and even the medical specialists. A study conducted to evaluate perceptions of physician about generic medicine in USA in 2011 revealed that out of 506 physicians surveyed more than 23% of physicians expressed negative perceptions about efficacy of generic drugs, almost 50% reported negative perceptions about quality of generic medications and more than one quarter do not choose to use generics as first-line medications for themselves or for their families . Similarly a study in Malaysia revealed that majority of physicians was positive about generics substitution but doubtful about their quality in terms of efficacy and safety for some drug categories. According to a survey report conducted on 500 doctors in Haryana, India reveals that 40% of doctors in private as well as in public facilities never prescribe a generic medicine. There are describe the misconception in minds of physician as well as patient about the quality of generic medicine. A generic medicine costs less from that branded medicine because a brand name medicine has to go through 10-15 years of research and testing in animals and clinical trials in proving that it is safe and effective before it can be sold to the public. The testing can cost over $1 billion. Once the new drug is approved, the company that made and tested it files for patent protection and as it receives a patent, that company is only the sole manufacturer of that

medicine. When a patent for a brand name medicine expires, any other company can copy the medicine and sell a generic version. These other companies are required to only prove that their product is the same as the brand name medicine through Bioavailability/Bioequivalence studies . This means that generic drug companies do not have to spend as much time and money because they do not have to conduct clinical trials. Since there are ample of companies manufacturing the generic medicine, due to competition the price is lowered even farther. Skyrocketing cost of medicine has always been a matter of great concern to the health authorities providing health care to mankind. Efforts are made globally to provide quality medicine at affordable price. Generic medicines provide the same medical benefits to the suffering mankind as these are certified to be perfect substitute for the innovator branded product and its use can reduce the healthcare expenditure to a great extent. The effective use of generic products saved the U.S. health system nearly $1.5 trillion over the past 10 years (2004-2013) as per the IMS Institute for Healthcare Informatics[17]. As per US-FDA data nearly 8 in 10 prescriptions filled in the United States are for generic drugs (2014)[18]. In India due to the prejudice in the minds of physicians regarding the safety and efficacy of generics, their use is hindered and further as per law pharmacist cannot substitute the brand name with generic , so consumer has to buy costly brandedmedicine even though the equivalent low cost generic medicines are available. With a view to adjudge and compare the quality of generic medicines with that of their costly branded counterparts, a comparative quality evaluation study was undertaken on commonly used drug for type 2 diabetes i.e. Glimepiride. India has more diabetics than any other country in the world, as per the International Diabetes Foundation the estimate of the actual number of diabetics in India is around 40 million (2014) [1].

Material and Methods

Branded marketed formulation of Glimepiride was purchased from authorized dealer (GP-3®) and generic version was obtained from *Jan Aushadhi* store, Budhwariya, Ujjain. All of the samples purchased were containing 3mg of Glimepiride and all of them were in tablet dosage form. The 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.

Evaluation Tests

1. Uniformity of weight: 20 tablets selected randomly weighed individually 20 units and average weight was calculated.

2. Dissolution: Dissolution study was performed using the IP Apparatus 1 in 900 ml phosphate buffer pH 6.8, maintained at 37±0.5°C with paddle speed at 100 rpm for 45 minutes. 5 milliliters of samples were withdrawn at specified time intervals. The volume of dissolution fluid was adjusted to 900 ml, by replacing each 5 ml aliquot withdrawn with 5 ml of phosphate buffer pH 6.8, pre-warmed at 37±0.5°C. Samples withdrawn were filtered through whatmann filter paper (no.41), suitably diluted with phosphate buffer pH 6.8, and analyzed at 226 nm, using UV-Visible spectrophotometer.

3. Disintegration Test: Disintegration was performed using basket rack assembly (IP 2007) maintained at 37±2°C. One tablet was introduced into each of 6 tubes and, a disc was added oneach tube. The assembly was suspended in the beaker containing distilled water and operated for the specified time.

4. Assay: 20 tablets of Glimepiride were weighed, powdered andweight equivalent to 10mg was taken and transferred intoa 100ml volumetric flask then 20 ml of chloroform wasadded and kept for 15 min with frequent shaking and the volume was made upto mark with chloroform.The solution was then filtered through whatmann filter paperand the absorbance was measured against blank.The amount of Glimepiride was computed by using theequation referring to the calibration curve.

5. Friability: A sample of whole tablets (37 tablets) corresponding to about 6.5 g weight was taken. The tablets were placed in drum and rotated it 100 times at 25 rpm. Tablets were removed and any loose dust from them also discarded and weighed. Dedusted the tablets carefully and weighed accurately.

6. Hardness : Hardness was tested using Monsanto Hardness Tester. The tablet was placed between the jaw and compressed and the value of the hardness is measured (kg/cm^2). The jaw should be fixed before compression.

7. Thickness : Thickness was measured using Vernier Caliper. Randomly selected tablet fixed between the external jaws ,with the help of locking screw. then readings from both the scales (vernier scale and Main scale) are taken. Thickness is Calculated using Formula :Main scale + Vernier scale.

Results and Discussion

In this research work, the quality of generic Glimepiride (Jan Aushadhi Store) was compared to that of branded Glimepiride (GP-3®), using pharmacopoeial and other tests. It was found that the generic Glimepiride was of "similar" pharmacopoeial standards, as that of branded Glimepiride, although the generic Glimepiride was much cheaper than the branded Glimepiride. The branded and generic variant showed comparable results. The assay was found to be more than 95% and less than 105% as per IP 2007, of all the branded (101.45%) and generic medicine (99.85%). (The results of the entire tests performed is depicted in Table 1 (a)) Hence, the general notion and doubt regarding the quality of the generic version of medicines needs to be expunged and government must campaign to promote generics about their quality and efficacy.

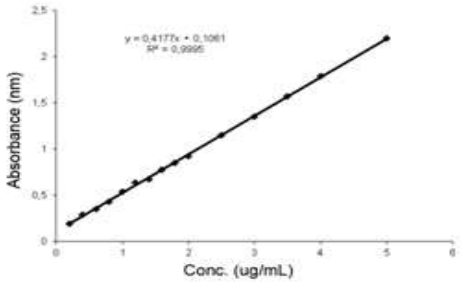

Fig 1.1 Standard curve

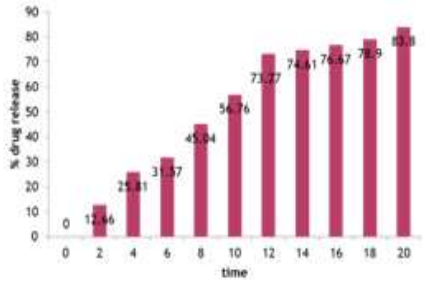

Fig1.2 Graph shows % cumulative drug release of Branded Glimepiride

Fig 1.1 Standard curve

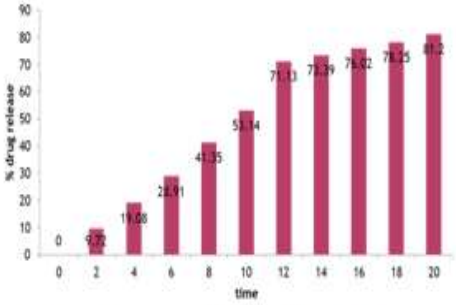

Fig 1.3 shows % cumulative drug release of Generic Glimepiride

Table 1 (a): Results of tests performed

TRADE NAME / TEST		GP-3®	GENERIC-GLIMEPIRIDE
Uniformity of Weight	Observations (Average weight of 20 tablets in mg)	181.5	180.5
	Limits (As per I.P. 2007)	167.88-195.11	166.96-194.03
	Results	All the 20 tablets comply with the test and were found within the above range	
In vitro Dissolution	Observations (% Amount of Drug Release after 20 minutes)	83.80%	81.20%
	Limits (As per I.P. 2007)	Not less than 70% of the label claimed	
	Results	Complies	
Disintegration	Observations (Average time of 6 tablets on minutes)	6.11	7.13
	Limits (As per I.P. 2007)	Not more than 15 minutes	
	Results	Complies	
Assay	Observations (% of drug content)	101.45%	99.85%
	Limits (As per I.P. 2007)	Not less than 95% and not more than 105%	
	Results	Complies	
Friability	Observations (% weight lost after friability)	0.17	0.22
	Limits (As per I.P. 2007)	Not more than 1%	
	Results	Complies	
Hardness Test	Observations	5.9 kg/cm^2	7.4 kg/cm^2
	Limits	5-10 kg/cm^2	
	Results	Complies	
Thickness	Observations	0.42 mm	0.84 mm
	Results	Complies	

Table 1(b): Branded (Ethical) and Generic Glimepiride

Trade Name	Company	IIN Name and Strength	Price (Rupees)	Packing	Price/ Tab (Rupees)
GP-3®	USV	Glimepiride-3mg	104.00	1*10	10.40
Glimepiride	Jan Aushadhi	Glimepiride-3mg	5.00	1*10	0.50

Conclusion

Ethical (Branded) and Generic (Jan Aushadhi) tablets were evaluated and compared as per the Indian Pharmacopoeia. Study justified that generic (JanAushadhi) product of Glimepiride is effective as their Ethical (Branded) product.Both the variant of Glimepiride tablets confirmed with the limits provided in IP 2007, in term of Uniformity of weight, Disintegration, Dissolution, Assay and Friability. This confirms that the generic medications are of equivalent and comparable quality of the costlier branded medicines available in the market. The government should therefore expand the scheme of opening Jan Aushadhistores and promoting generics throughout the country to provide quality medicine at affordable prices to larger section of its population. There is also dire necessity of expanding the scope of the study to entire range of generic medicines available at different centers to eradicate the myth aboutquality and safety of generic medicines. Creating public awareness by advertisements in print as well as electronic media to instill confidence in the minds of patients and physician regarding quality and efficacy of such drugs and also to propagate that patient ask their doctors to prescribe medicines in generic name rather than the brand name /trade name through which the benefit of the scheme can be finally beavailed. This data suggest that switching the prescription from branded to generic drug can result to a huge amount cost saving and cutting down the health care expenditure without compromising with the safety, quality and efficacy of medicinal product.

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