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A comparative analysis on generic product vs branded product of prednisolone tablet

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Abstract

The main aim and objective of present research work is to evaluate and compare the standard concerning quality of generic and branded anti-inflammatory drug. The drug are evaluated and research showed that branded and generic meet the Pharmacopoeial specification. All tablet passed for the test of weight variation, hardness, thickness, friability, disintegration, dissolution as per pharmacopeia. Hence, we can say that branded and nonbranded drugs of anti-inflammatory are equal. So, healthcare professionals are suggested to prescribe generic drugs so that everyone can reach the cost of drugs and maintain health.

Keywords: Prednisolone; *In-vitro* studies; Physio chemical test; Anti-inflammatory drug

1. Introduction

In recent years, colon targeted delivery systems have been the focus point of formulation laboratories because the colon is considered as a suitable site for delivery of both conventional and labile molecules, and it is also a site for some specific diseases, such as, ulcerative colitis, Crohn's disease, bowel cancer, some infections, and constipation, which require local delivery of drug. Chemically equivalent drugs are those drug products that are identical in their active ingredient, strength, concentration, and dosage concentration form. Prednisolone (PD) is the drug of choice prescribed in moderate to severe conditions of ulcerative colitis though it has number of side effects. PD is rapidly absorbed from stomach. The biological t1/2 for PD is 2.5 h, but pharmacokinetics of the drug reportedly follows a nonlinear pattern and the biological absorption is influenced by multiple factors including food intake throughout the GIT. In systemic circulation, PD remains predominantly protein bound leading to series of side effects.

2. Materials and Methods

2.1. Chemicals and reagents

The prednisolone tablets were taken from one of the reputed pharmaceutical stores as well as taken from the Government hospital pharmaceutical store.

2.2. Methodology

Various analytical methods and tests are important for the development and manufacture of pharmaceutical formulations. Prednisolone tablets were evaluated as per Indian pharmacopoeial standards.

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2.3. Evaluation Tests for Tablets

2.3.1. Weight variation

The USP weight variation test was performed by taking 20 tablets. Then 20 tablet, were weighed and the average weight is taken. Then each tablet was weighed individually. The percentage deviation can be determined by using the formula

%Deviation= [(Average weight – Individual weight)/Average weight] X 100

Table 1: Labeling contents of Prednisolone

Tablets	Cost of drug(per 10 tab)	Batch no	Mfg date	Expiry date
Brand	18.82Rs/-	GT6930	Jan.2023	Dec.2024
Generic	8.00Rs/-	01123	May.2023	April.2025

2.3.2. Hardness Test

Six tablets were randomly selected from each brand for hardness test using hardness tester.Each tablet was held between a fixed jaw and moving jaw of the tester. The pressure applied to the edge of the tablet increased gradually by moving the screw knob until the tablet broke. The pressure required to break the tablet was noted from the scale. The average and standard deviation were calculated for each brand

2.3.3. Friability Test

Based on USP method, the initial weight (W1) of 10 tablets selected randomly from each brand was determined and placed in a friabilator tester, 25 rpm for 4 min, after which the tablets were dusted and weighed (W2). The percent friability (F) was calculated using the equation:

$F = [(W1 – W2) / (W1 \times W2)] \times 100.$

2.3.4. Disintegration Test

The disintegration test was performed according to USP (28). A disintegration apparatus was used with 600 mL distilled water maintained at 37 ± 2 °C as the medium. Tablets from each batch (a total of 6) were taken randomly for the test. The disintegration time was recorded as how long it took for the tablet to break into pieces small enough to pass through the basket mesh into the medium.

2.3.5. Dissolution Test

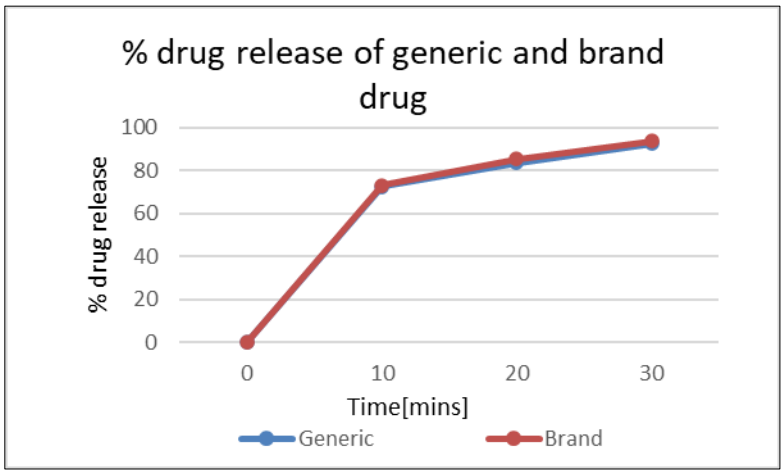

Figure 1 Dissolution profile of generic and branded tablet of Prednisolone

The dissolution test was performed according to USP.A tablet was placed in a single-station dissolution apparatus with 900 mL of distilled water maintained at 37 ± 0.5 °C and rotated at 50 rpm. After 30 min, a 10-mL sample was withdrawn, filtered, and analyzed using the UV/VIS spectrophotometer at 246 nm. Readings were taken in triplicate.

2.4. Assay

The spectroscopic method (uv visible) is chosen for ascertaining the percentage purity of samples they are UV Method

2.4.1. Preparation of working Solution

Prednisolone (5 mg) reference powder was weighed accurately using an analytical balance and dissolved in sufficient ethanol to produce 100.0ml. Dilute 2.0 mL of this solution to 100.0ml with ethanol. Measure the absorbance of the resulting solution at the Maximum at about 243.5nm. Calculated the content of $C_{21}H_{28}O_5$ taking 415 as the specific absorbance at 243.5nm.

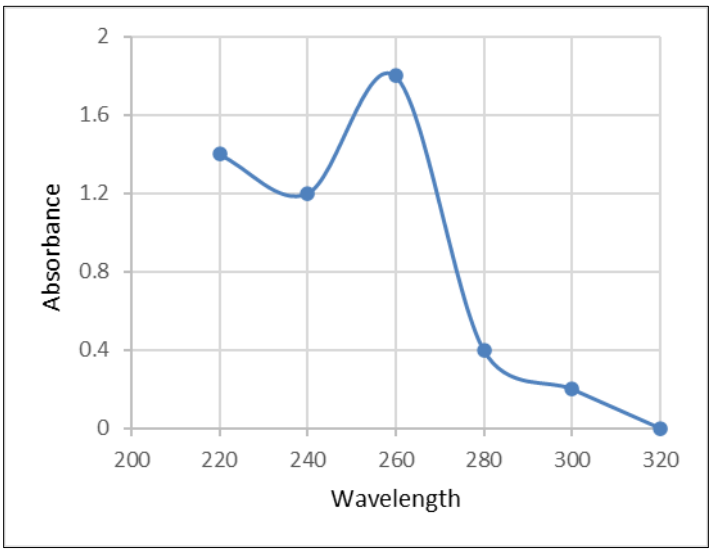

Figure 2 UV spectrum of Prednisolone

Table 2 Evaluation test for Prednisolone

SI.No	Tablet Name	Weight Variation	Hardness Test	Friability Test	Thickness Test	Disintegration Test	Dissolution Test	Assay
	Standard as per IP	<7.5%for>300mg	3-10kg/cm^2	1	5%	Not Less than 70%	30min	90-100
1	Brand	±4.7025%	5.7	0.38%	±2.02	78.35%	50sec	91%
2	Generic	±3.308%	6.1	0.18%	±2.1	79.55%	58sec	98%

3. Result and Discussion

The results of our research work conducted on generic and two different brands of anti-inflammatory Prednisolone tablets, met the IP requirements of quality control tests within specified limits. It is carried out in an *in vitro* study. The various physical parameters of tablets like weight variation, hardness, thickness, friability, dissolution, assay and disintegration time are accessed were within the Pharmacopoeial specifications. Disintegration time of the entire branded and generic tablet was found in the Pharmacopoeial limit while generic tablet showing little higher disintegration. Hence, it can be concluded that tablets were all found to be as per pharmaceutical specifications.

4. Conclusion

Finally, study suggests that generic and branded (non-generic drugs) shown equal results. Hence generic form of the drug should be widely prescribed to reduce the medication cost and make the treatment economical. So that general people can also meet the medication cost.

Compliance with ethical standards

Acknowledgement

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Indian Pharmacopoeia pg;2982

[2] Vignesh E. *Formulation and Evaluation of Colon Targated Prednisolone Compression Coated Tablet* (Doctoral dissertation, CL Baid Metha College of Pharmacy, Chennai.).

[3] Dhole AR, Shendage GG, Pethkar S, Magdum CS, Mohite SK. Drug used in inflammatory bowel disease (IBD)-Brief review. Research Journal of Pharmacology and Pharmacodynamics. 2014;6(3):153-61.

[4] York P. Design of dosage forms. Aulton's Pharmaceutics the Design and Manufacture of Medicines, 6th ed.; Aulton, ME, Taylor, KMG, Eds. 2013 Jul 29:1-2.

[5] Berends SE, Strik AS, Löwenberg M, D'Haens GR, Mathôt RA. Clinical pharmacokinetic and pharmacodynamic considerations in the treatment of ulcerative colitis. Clinical Pharmacokinetics. 2019 Jan 17;58:15-37.

[6] Jones AW. Pharmacokinetics of ethanol–issues of forensic importance. Forensic Sci Rev. 2011 Jul 1;23(2):91-136.

[7] De AK, Bhattacharya P, Datta S, Mukherjee A. Evaluation of in vivo efficacy and toxicity of prednisolone-loaded hydrogel-based drug delivery device. International Journal of Pharmaceutical Investigation. 2013 Oct;3(4):225.

[8] Scott NR, Chakraborty J, Marks V. Determination of prednisolone, prednisone, and cortisol in human plasma by high-performance liquid chromatography. Analytical Biochemistry. 1980 Nov 1;108(2):266-8.

[9] Bhusnure OG, Gholve S, Manoj B, Todkar V, Giram PS. Analytical method development and validation of prednisolone sodium phosphate by qbd approach. IOSR J. Pharm. Biol. Sci. 2015;10:64-75.

[10] Santhanamariammal C. *Formulation and Evaluation of Prednisolone Retention Enema as Dispersible Tablet with Vehicle* (Doctoral dissertation, Sankaralingam Bhuvaneswari College of Pharmacy, Sivakasi).

[11] Isaac JA, Hayatu GI, John JE, Ekere KE, Daburi A, Omachoko SO, Buiders PF. Quality Assessment of Brands of Prednisolone (5 Mg) Tablets Marketed in Abuja Metropolis of Nigeria. Dissolution Technologies. 2021 Feb 1;28(1):24-+.

[12] Krishnaswamy R. *Development of BioresponsiveChronopharmaceutical Drug Delivery System in Treatment of Asthma &Copd Using Colon Targeted Mucoadhesive Tablets in Capsule System* (Doctoral dissertation, JKK Nattraja College of Pharmacy, Kumarapalayam).

[13] PACKIARAJ J. *FORMULATION AND EVALUATION OF CONTROLLED-RELEASE DOSAGE FORM OF CLARITHROMYCIN & PREDNISONE AS MODEL DRUGS* (Doctoral dissertation, ANNAMALAI UNIVERSITY).

[14] Spireas S, Sadu S. Enhancement of prednisolone dissolution properties using liquisolid compacts. International Journal of Pharmaceutics. 1998 May 18;166(2):177-88.

[15] Watson DG. Pharmaceutical analysis E-book: a textbook for pharmacy students and pharmaceutical chemists. Elsevier Health Sciences; 2020 Jun 10.

[16] Amegadzie JE. *The Use of Surrogate Reference Standards in Quantitative HPLC* (Doctoral dissertation).

[17] Gøtzsche PC, Johansen HK. Meta-analysis of short term low dose prednisolone versus placebo and non-steroidal anti-inflammatory drugs in rheumatoid arthritis. Bmj. 1998 Mar 14;316(7134):811-8.

[18] Basu B, Aviya KR, Bhattacharya A. Development and characterization of mouth dissolving tablets of prednisolone. Journal of Pharmaceutical Investigation. 2014 Apr;44(2):79-102.

[19] Gerlag DM, Haringman JJ, Smeets TJ, Zwinderman AH, Kraan MC, Laud PJ, Morgan S, Nash AF, Tak PP. Effects of oral prednisolone on biomarkers in synovial tissue and clinical improvement in rheumatoid arthritis. Arthritis & Rheumatism. 2004 Dec;50(12):3783-91.

[20] Martindale (2014) 39thedition , Alison Brayfield.