OPEN ACCESS

Research Article

Quality Effectiveness Assessment Study On Diffrent Brands Of Paracetamol Tablet Available In Navsari Market

Bhavna Chandnani*[1], Vikram Pandya[2], Chaudhari Komal[3], Patel Bhoomi[4], Kapadia Krishna[5], Sheikh Fiza[6], Rajput Suraj[7]

[1-2]*Department Of Pharmaceutical Analysis, Tathya Pharmacy College, Chikhli, Gujarat.*
[3-6]*B. Pharm scholar Tathya Pharmacy College, Chikhli, Gujarat.*

ABSTRACT

Drugs are any substance either biological or chemical and when consumed affects the physiological function of the body. These drugs are classified as OTC drugs or Prescription drugs. Both OTC drugs and Prescription drugs are available as Generic drugs or Branded/Proprietary drugs. While Branded drugs are protected by a patent for a particular number of years, generic drugs are not. Generic drugs only have to meet the same bio-equivalence requirement as their branded counterparts. Also, Branded drugs take a lot of time to get approved while generic drugs take a much lesser time. Due to the time taken for the Branded drugs to get approved, the costs used in the development of the drug, branded drugs then to get very expensive in the market while generic drugs are cheaper. We use authorized generic products, which are identical in composition and appearance to brand name products but are marketed as generic, as a control group to address this bias in an evaluation aiming to compare the effectiveness of generic versus brand medication.

INTRODUCTION

Paracetamol called acetaminophen or 4-acetamidophenol, is a common pain reliever and fever reduction medicine1. Its chemical name is N-acetyl-p-aminophenol with a chemical formula C8H9NO2. Paracetamol was first prepared in 1878 by Harmon Northrop Morse an American chemist2. It is available as a generic medication with trade names including Tylenol and Panadol, among others3. It is often sold in the commercial markets with a major ingredient in many cold and flu remedial combination drugs. It is usually used either by mouth or rectally, but is also available intravenously1,4. Paracetamol is accessible in as a tablet, drops, capsules, injection, and syrup5. Paracetamol is usually safe at suggested doses.. The suggested maximum daily dosage for an adult is 3 or 4 grams7,8. Higher doses may result in

*Corresponding Author: Bhavna Chandnani

Address: *Department Of Pharmaceutical Analysis, Tathya Pharmacy College, Chikhli, Gujarat.*

Email ✉ : tathya.bhavna@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

toxicity, including liver disaster. Serious skin rashes may infrequently occur, and it appears to be secure during pregnancy and breastfeeding

OVER THE COUNTER DRUGS:

Over the Counter Drugs are also called Non-Prescription drugs are drugs that are usually sold over the counter without a doctor's prescription. Over the counter drugs can be analgesics, NSAIDs, decongestants, antacids, anti-fungal drugs, cough suppressants (e.g anti-tussives and expectorants), anti-acne drugs, some topical antibiotics (usually available in the form of creams, ointments, powder, sprays, etc.

GENERIC DRUGS

Generic drug refers to the chemical composition of a drug and not the innovator drug which has a brand name in which the chemical composition of the drug is sold. It is usually identical as a propietary drug in dose, potency, route of administration, quality, its action and does the same work as the drug was manufactured for. The term, generic, when used to describe household items implies that the item is cheaper and can be less effective and a duplicate version of a brand name product. But in the case of generic drugs, they are of the same quality and are as effective as that of the branded counterpart. The generic name is the name for the active pharmaceutical ingredient that is responsible for the therapeutic action and is found in the medicine that has been made. In other words, the generic name of a drug is the official name of a drug. It contains Active Pharmaceutical Ingredients same as the original brand name formulation.Generic drugs usually become available after the patent protection to the original developer of a drug expires. Phrmaceutical Ingredients such as demulscents, suspending agents, etc. That do not disturb the body to cure illnesses and may be different in physical appearance and shape. Paracetamol/ Acetaminophen is the non-proprietary name(generic name) of Paracetamol drug.

BRANDED DRUGS/PROPIETARY DRUGS:

Proprietary drug is a drug that has a trade name and is protected by a patent(means that a drug can be manufactured and sold by the innovator company). A patent is given because pharmaceutical organisation spends lots of money and resources to make, develop and discover a new drug substance and hence they are given the exclusive rights to make and dispense the medicine for a particular duration. At the time of the patent protection, only the innovator company can make the drug and this is the reason a lot of people trust and know the proprietary

METHODOLOGY

Procedure:

- Weigh and powder 20 tablets.
- Take a quantity of the powder equivalent to 0.15 g of paracetamol 20 tablets 0.5g paracetamol wt 0.15 g paracetamol $\rightarrow$ X
- Place in a volumetric flask (200ml)
- Add 50 ml 0.1 M NaOH (using a burette)
- Dilute with 100 ml of water, shake for 15 minutes, and add sufficient water to produce 200 ml. Mix, and filter.
- Dilute 10 ml of the filtrate to 100 ml with water (in a volumetric flask 100ml).
- Add 10ml of the resulting solution to 10 ml of 0.1 M NaOH, dilute to 100 ml with
- water (in a volumetric flask 100ml)
- Measure the absorbance of the resulting solution at max257 nm taking 0.715 as the value of Ers

Blank:

- Take 20 ml of 0.1 M NaOH and complete to 100 ml with water
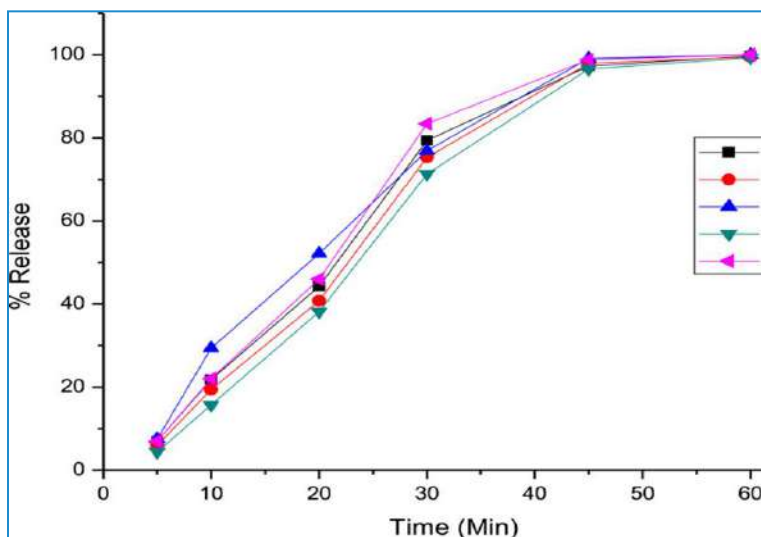
Limit:

Content: 95-105% of the prescribed (labeled) amount.

RESULT

Brand	Batch no.	Price/10tab
Dolo	B1542	10.59
Calpol	5427	10.26
Cipla	1128	9.55
Generic	D25	7.45
API	--	--

Code	Name	Dosage	Manufacturer
01	Dolo	500 Mg	Micro
02	Calpol	500mg	Gsk
03	Paracip	500mg	Cipla
04	Generic	500mg	Jan Ausadhi
05	API	Q.S	-

ASSAY OF PCM

Name	Sample	Absorbance	Percentage Purity	Lambda
Dolo	A	0.262	101%	257nm
Calpol	B	0.263	100.9%	257nm
Cipla	C	0.279	101.7%	257nm
Generic	D	0.246	99.5%	257nm
API	E	0.279	101.2%	257nm

PARACETAMOL CALIBRATION CURVE

Paracetamol Calibration Curve

$$y = 0.0802x + 0.0158$$
$$R^2 = 0.9971$$

Chart: x-axis "Concentration (g/L)" (0 to 12), y-axis "Absorbance" (0 to 0.9)
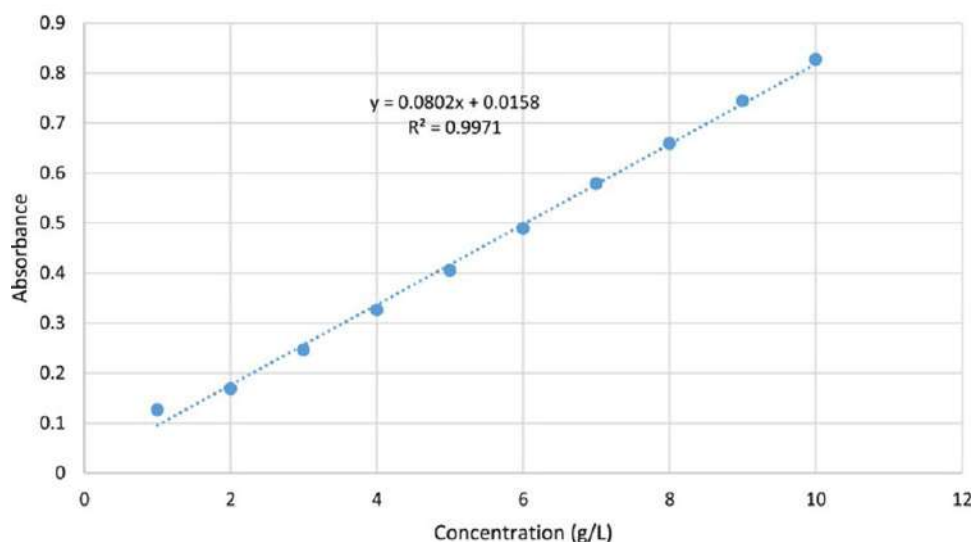
CONCLUSION:

This study showed the consumers general view and the reality of locally manufactured paracetamol tablet effectiveness. As the finding of the current study, consumers hold a negative view of the local paracetamol and tend to use the expensive brand paracetamol even though the laboratory specifications of the paracetamol tablet have met the standard. This study will be a benchmark for future studies, and further knowledge research should be done to access the knowledge and attitude of consumers and healthcare professionals on generic medicines to unveil the consumers practice and healthcare professional attitude.In the comparative analysis of generic drugs over the proprietary drugs, the analysis were made based on how they were developed. Proprietary drugs take lots of time to get approved as the new substance drug undergoes lots of testings (pre clinical as well as clinical testings). Also, the analysis was made based on the costs. Branded drugs are more expensive as seen in the cost estimate above. Generic drugs are cheaper option especially for long term treatments.

REFERENCES:

1. Anonymous (2015). Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. WHO Regional Ofce for Europe. 159405. Accessed 12 Dec 2020.

2. Dunne SS, Dunne CP. What do people really think of generic medicines A systematic review and critical appraisal of literature on stakeholder perceptions of generic drugs. BMC Med. 2015;13:173. https://doi.org/10.1186/s12916-015-0415-3.

3. Toverud E-L, Hartmann K, Håkonsen H. A systematic review of physicians' and pharmacists' perspectives on generic drug use: what are the global challenges Appl Health Econ Health Policy. 2015;13(Suppl 1):35–45. https://doi.org/10.1007/s40258-014-0145-2.

4. Saudi Food and Drug Authority.. aspx. Accessed 12 Dec 2020.

5. Anand O, Yu LX, Conner DP, Davit BM. Dissolution testing for generic drugs: an FDA perspective. AAPS J. 2011;13(3):328–35.

6. Anonymous (2015). Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. WHO Regional Ofce for Europe. 159405. Accessed 12 Dec 2020.

7. Dunne SS, Dunne CP. What do people really think of generic medicines A systematic review and critical appraisal of literature on stakeholder Perceptions of generic drugs. BMC Med. 2015;13:173..1186/s12916-015-0415-3.

8. Toverud E-L, Hartmann K, Håkonsen H. A systematic review of physicians' And pharmacists' perspectives on generic drug use: what are the global Challenges? Appl Health Econ Health Policy. 2015;13(Suppl 1):35–45.

9. Saudi Food and Drug Authority..Aspx. Accessed 12 Dec 2020.

10. Anand O, Yu LX, Conner DP, Davit BM. Dissolution testing for generic Drugs: an FDA perspective. AAPS J. 2011;13(3):328–35..1208/s12248-011-9272-y.

11. Rahman Md. M, Akther Md. T, TalukdarS J, AfrozT , Azad A.K. In-Vitro Study Of Formulated Paracetamol Plus Caffeine Tablet With Different Brands Available In Bangladesh. Article in Pharmacologyonline, Newsletter 2019; vol.2: 94-104.

12. Fattouh R M. Physicians' compliance with The Palestinianessential drug list in primary Health care in Gaza strip.Unpublished Master's thesis, 2005; Al-Quds University, Jerusalem, Palestine.

13. Banker G S,Rhodes C T. Drug Products: Their role in the treatment of disease, their Quality and their status and future as drug-Delivery systems. Modern pharmaceutics,2002; New York: Marcel Dekker,Inc. 1-21.

14. The International Pharmacopoeia, Ninth Edition (2019)..Int/phint/en/p/docf/. Accessed 12 Dec 2020.

15. 15.Pharmacopeiaonline.USP32. Data/v32270/usp32nf27s0_m200.html. Accessed 12 Dec 2020.

16. Zaid A, Rinno T, Jaradat N, Jodeh S, Khammash S. Interchangeability Between paracetamol tablets marketed in Palastine. Is there a quality Reason for a higher price? EMHJ. 2013;19(6):542–6.

17. Ukwueze SE, Uzochukwu IC, Ngonebu EJ. Comparative quality assess-Ment and in vitro dissolution profle of some paracetamol tablet generics Marketed in Nigeria. Port Harcourt Med J. 2008;3:85–90.

18. Khuluza F. In vitro evaluation of the quality of paracetamol and co-Trimoxazole tablets used in Malawi based on pharmaceutical standards. Malawi Med J. 2014;26(2):38–41.

19. Lockyer M, Al-Dgither S, AlGaai E, Yusuf A, Hammami MM. Bioequivalence Of two oral formulations of nizatidine capsules in healthy male volun-teers. Biopharm Drug Dispos. 2005;26(3):117–20.

20. Lockyer M, Al-Dgither S, AlGaai E, Hammami MM. Bioequivalence of two Oral formulations of gatifoxacin tablets in healthy male volunteers. J Appl Res. 2005;5(1):73–9.

21. AlGaai E, Lockyer M, Al-Dgither S, Hammami MM. Bioequivalence evalua-Tion of two formulations of fuconazole 150 mg capsules in healthy Arab Men. Biopharm Drug Dispos. 2005;26(4):143–6.

22. AlGaai E, Al-Dgither S, Lockyer M, Hammami MM. Bioequivalence study of Two amoxicillin formulations. Drug Research. 2006;56(1):48–55.

23. Yusuf A, Al Gaai E, Hammami MM. Bioequivalence evaluation of two Rosiglitazone tablet formulations. Drug Research. 2006;56(11):740–3.

24. Hussein R, Lockyer M, Yousuf A, AlGaai E, Abdelgaleel A, Hammami MM. Bioequivalence assessment of two domperidone tablet formulations. Drug Research. 2007;57:269–73.

25. Hussein RF, Lockyer M, Hammami MM. Bioequivalence assessment of Two capsule

formulations of omeprazole in healthy volunteers. Drug Res. 2007;57(2):101–5.

26. AlHawari S, AlGaai E, Yousuf A, Abdelgaleel A, Hammami MM. Bio-Equivalence study of two metformin tablet formulations. Drug Res. 2007;57(4):192–5.

27. Hammami MM, De Padua SJS, Hussein R, Al Gaai E, Khodr NA, Al-Swayeh R, Alvi SN, Binhashim N. Generic-reference and generic-generic Bioequivalence of forty-two, randomly-selected, on-market generic products of fourteen immediate-release oral drugs. BMC Pharmacol Toxicol. 2017;18:78.

28. Anonymous (2015). Access to new medicines in Europe: technical review Of policy initiatives and opportunities for collaboration and research. WHO Regional Ofce for Europe. 159405. Accessed 12 Dec 2020.

29. Dunne SS, Dunne CP. What do people really think of generic medicines A systematic review and critical appraisal of literature on stakeholder Perceptions of generic drugs. BMC Med. 2015;13:173..1186/s12916-015-0415-3.

30. Toverud E-L, Hartmann K, Håkonsen H. A systematic review of physicians' And pharmacists' perspectives on generic drug use: what are the global Challenges Appl Health Econ Health Policy. 2015;13(Suppl 1):35–45..

31. Saudi Food and Drug Authority..Aspx. Accessed 12 Dec 2020.

32. Anand O, Yu LX, Conner DP, Davit BM. Dissolution testing for generic Drugs: an FDA perspective. AAPS J. 2011;13(3):328–35..1208/s12248-011-9272-y.

33. Rahman Md. M, Akther Md. T, TalukdarS J, AfrozT , Azad A.K. In-Vitro Study Of Formulated Paracetamol Plus Caffeine Tablet With Different Brands Available In Bangladesh. Article in Pharmacologyonline, Newsletter 2019; vol.2: 94-104.

34. Fattouh R M. Physicians' compliance with The Palestinianessential drug list in primary Health care in Gaza strip.Unpublished Master's thesis, 2005; Al-Quds University, Jerusalem, Palestine.

35. Banker G S,Rhodes C T. Drug Products: Their role in the treatment of disease, their Quality and their status and future as drug-Delivery systems. Modern pharmaceutics,2002; New York: Marcel Dekker,Inc. 1-21.

36. AwofisayoS O, AwofisayoO A, Eyen N, and UdohI E. Comparative Assessment of theQuality Control Measurements of Multisource Ofloxacin Tablets Marketed in Nigeria. ResearchGate; Article in Dissolution Technologies, May 2010.

37. Nwodo N, Uzochukwu I, Omeje E O. Quality control assessment and the possibility of interchangeability between multisourcednorfloxacin tablets marketed in Nigeria. Scientific Research and Essay. 2007; 2 (8): 348-352.

38. Wiffen PJ, Knaggs R, Derry S, Cole P, Phillips T, Moore RA (December 2016). "Paracetamol (acetaminophen) with or without codeine or dihydrocodeine for neuropathic pain in adults". Cochrane Database Syst Rev. 12 (5): CD012227.

39. "Acetaminophen". Health Canada. 11 October 2012. from the original on 3 November 2022. Retrieved 22 September 2022.

40. Southey ER, Soares-Weiser K, Kleijnen J (September 2009). "Systematic review and meta-analysis of the clinical safety and tolerability of ibuprofen compared with paracetamol in paediatric pain and fever". Current Medical Research and Opinion. 25 (9): 2207–2222. from the original on 3 January 2023. Retrieved 2 December 2022.

41. Drugs.com. Archived from the original on 19 February 2023. Retrieved 22 September 2022.

42. Moore RA, Moore N (July 2016). "Paracetamol and pain: the kiloton problem". European Journal of Hospital Pharmacy. 23 (4): 187–188.

43. Conaghan PG, Arden N, Avouac B, Migliore A, Rizzoli R (April 2019). "Safety of Paracetamol in Osteoarthritis: What Does the Literature Say?". Drugs Aging. 36 (Suppl 1): 7–45.

44. Roberts E, Delgado Nunes V, Buckner S, Latchem S, Constanti M, Miller P, Doherty M, Zhang W, Birrell F, Porcheret M, Dziedzic K, Bernstein I, Wise E, Conaghan PG (March 2016). "Paracetamol: not as safe as we thought? A systematic literature review of observational studies". Ann Rheum Dis. 75 (3): 552–9.

45. Alchin J, Dhar A, Siddiqui K, Christo PJ (May 2022). "Why paracetamol (acetaminophen) is a suitable first choice for treating mild to moderate acute pain in adults with liver, kidney or cardiovascular disease, gastrointestinal disorders, asthma, or who are older". Current Medical Research and Opinion. 38 (5): 811–825.

46. Leopoldino AO, Machado GC, Ferreira PH, Pinheiro MB, Day R, McLachlan AJ, Hunter DJ, Ferreira ML (February 2019). "Paracetamol versus placebo for knee and hip osteoarthritis". Cochrane Database Syst Rev. 2 (8): CD013273.

47. choueiri TK, Je Y, Cho E (January 2014). "Analgesic use and the risk of kidney cancer: a meta-analysis of epidemiologic studies". Int J Cancer. 134 (2): 384–96.

48. McCrae JC, Morrison EE, MacIntyre IM, Dear JW, Webb DJ (October 2018). "Long-term adverse effects of paracetamol – a review". Br J Clin Pharmacol. 84 (10): 2218–2230.

49. MacIntyre IM, Turtle EJ, Farrah TE, Graham C, Dear JW, Webb DJ (February 2022). "Regular Acetaminophen Use and Blood Pressure in People With Hypertension: The PATH-BP Trial". Circulation. 145 (6): 416–423

50. Bauer AZ, Kriebel D, Herbert MR, Bornehag CG, Swan SH (May 2018). "Prenatal paracetamol exposure and child neurodevelopment: A review". Horm Behav. 101: 125–147.

51. Gou X, Wang Y, Tang Y, Qu Y, Tang J, Shi J, Xiao D, Mu D (March 2019). "Association of maternal prenatal acetaminophen use with the risk of attention deficit/hyperactivity disorder in offspring: A meta-analysis". Aust N Z J Psychiatry. 53 (3): 195–206.

52. "Acetaminophen". The American Society of Health-System Pharmacists. Archived from the original on 5 June 2016. Retrieved 16 September 2016.

53. Daly FF, Fountain JS, Murray L, Graudins A, Buckley NA (March 2008). "Guidelines for the management of paracetamol poisoning in Australia and New Zealand—explanation and elaboration. A consensus statement from clinical toxicologists consulting to the Australasian poisons information centres". The Medical Journal of Australia. 188 (5): 296–301.

54. Hawkins LC, Edwards JN, Dargan PI (2007). "Impact of restricting paracetamol pack sizes on paracetamol poisoning in the United Kingdom: a review of the literature". Drug Saf. 30 (6): 465–79.

55. .Larson AM, Polson J, Fontana RJ, Davern TJ, Lalani E, Hynan LS, et al. (2005). "Acetaminophen-induced acute liver failure: results of a United States multicenter, prospective study". Hepatology. 42 (6): 1364–72..

56. Mangus BC, Miller MG (2005). Pharmacology application in athletic training. Philadelphia, Pennsylvania: F.A. Davis. p. 39.

ISBN 9780803620278. Archived from the original on 8 September 2017. Retrieved 7 September 2017.