



JOURNAL OF SCIENTIFIC RESEARCH IN ALLIED SCIENCES

Contents available at: www.jusres.com



Comparative Evaluation of Generic Local and Multinational Paracetamol Brands: Quality and Efficacy

Arjun Gupta, Shweta Gogate*, Shailesh Jain and Rita Mourya

SAM College of Pharmacy, SAM Global University, Raisen (M.P.) 462021

ARTICLE INFO

ABSTRACT

ORIGINAL RESEARCH ARTICLE

Article History

Received: January 2025

Accepted: March 2025

Keywords:

Tablet, Paracetamol, Evaluation Parameter, Disintegration Test, Dissolution Test.

*Corresponding Author:
Ms. Shweta Gogate

Paracetamol is an analgesic and antipyretic drug which are generally used in reducing fever and relief in pain. PCM is one of the popular OTC products among patients. In this time all the pharmaceutical companies produce various brands of paracetamol tablets by various technique and manufacturing process. The aim of the study is to compare and evaluate different brands of paracetamol tablets of 500mg. Three different brands of paracetamol 500mg were taken in this research work to check their quality control parameters like weight variation, hardness, friability, disintegration and dissolution test. These brands are manufactured by multinational companies and local companies. Acceptable & wearable Weight variation and friability are seen in all brands. The physical and chemical tests like in-vitro dissolution, disintegration, hardness etc. were found to be varying but within the specified limits. At the point of conclusion, local brands of Paracetamol are found to be safe enough and will use to achieve desired therapeutic effect.

2025, www.jusres.com

1.INTRODUCTION

Paracetamol, known as Acetaminophen is a non-steroidal anti-inflammatory drug (NSAID) and commonly used as analgesic and antipyretic agent in the relief of fever, headaches, other minor aches and pains.[1] In India, it has been more the 30 years paracetamol has been treated as an analgesic for domestic medication and it is also well established as a very effective treatment for the relief of fever and pain in adults and children. It is commonly used for severe pain condition such as cancer pain and pain after surgery in combination with opioid pain medication[2]. But, overdoses of paracetamol and prolonged duration of taking this drug can cause potentially fatal liver damage. Hepatotoxicity due to paracetamol

overdose leads to liver injury which is a common cause of poisoning worldwide as well as toxicity in kidney. Furthermore, DNA synthesis is also hindered by paracetamol that leads to promote genotoxicity and carcinogenicity².

It is better tolerated than aspirin in patients in whom excessive gastric acid secretion or prolongation of bleeding time may be a concern [5]. The Paracetamol are available without prescription in markets, and it has few anti-inflammatory effects in comparison to NSAIDs. However, aspirin, paracetamol and other NSAIDs all act by the same mechanism (inhibition of prostaglandin synthesis by inhibiting cyclooxygenase (COX)) and all show varying levels of analgesic, anti-inflammatory,

antipyretic and antiplatelet actions[6]. Several brands of paracetamol tablets are available in markets with different-different strength. Paracetamol is generally safe for human use at recommended dose. But overdoses of Paracetamol can cause potentially fatal liver damage and in rare individual, a normal dose can do the same. [7].

2. MATERIALS AND METHODS

Materials:All Chemicals and Reagent used are Laboratory Grade. All Chemicals, Reagents and

Logistical support are provided by an academic organisation. For working standard, United State Pharmacopeia & British Pharmacopoeia were used as a reference for the experimental Research work.

Two multinational brands & one generic or local brands of compressed tablets (TABLE 1) of Paracetamol were purchased and collected from a Pharmacy⁶.

Table1. Two Multinational Brands & One Generic or Local Brands Of Compressed Tablets Of Paracetamol

S.NO.	Brands	Labelled as
1.	Generic brand	Tablet A
2.	Multinational brand A	Tablet B
3.	Multinational brand B	Tablet C

Chemicals

1. Pure Paracetamol powder for standard solutions.

2. Three different brands of paracetamol tablets 500mg

3. Potassium dihydrogen orthophosphates for buffers solution.

4. Sodium Hydroxide

Glassware – Beakers, test tubes.

Volumetric flask, measuring cylinder, pipette, funnel, etc.

Instruments – Weighing balance,

Monsanto hardness tester, Vernier Caliper,

Disintegration machine, Dissolution machine, UV spectrophotometer etc.

Methods:

Weight Variation Test – Ten tablets from each brands of paracetamol were weighted individually with the mentioned analytical balance and average weight and the percent deviation was determined for each brand of paracetamol tablets [8]. The weight variation limits show in tablet 2.

Table 2. Weight variation limits according IP/BP

IP/BP	Limits
80 mg or less	±10%
More than 80 mg or less than 250 mg	±7.5%
250 mg or more	±5%

Hardness Test – The tablet hardness was measured with a Monsanto hardness tester. The force to break the tablet was diametrically applied, by placing the tablet between the anvil and spindle of the tester, and the knurled knob turned until the tablet fits into space and adjusted to zero. The pressure was applied by

turning the knurled knob until the tablet breaks; the force (kg) was read and the mean of triplicate determinations of each brand was recorded [9]

Friability Test: 10 tablets of each brand of paracetamol tablets were weighed and placed in Roche friabilator that rotated at 25 rpm for 4

minutes. Then the tablets of paracetamol were dedusted and weighed again. The percentage of weight loss was calculated again, the percentage of weight loss was calculated using the formula [10].

$$\% \text{ friability} = [(W1-W2)100]/W1$$

W1 refers initial weight of tablet,

while W2 refers final weight of tablets.

Disintegration Test – Six tablets of each sample were placed in disintegration apparatus, where the volume of disintegration medium was 900 ml of water maintained at $37 \pm 1^\circ\text{C}$. The time taken to break each tablet into small particles and pass through the mesh was recorded and average time was calculated [11].

Dissolution Test: USP Type-1st (Basket) Apparatus is used to perform this Quality parameter. Tablets are immersed in 900 ml of dissolution medium maintained at temperature $37 \pm 0.20^\circ\text{C}$. The rotation speed of Basket was set at 50RPM. Pipette out the 1ml of the medium at 5, 10, 15, 20, 30, 45, 60 minutes. Replaced with the fresh dissolution medium i.e., Phosphate buffer (pH-5.8). Continue the procedure for the 60 minutes. Note down all the readings. Samples which are pipette out are

diluted to 10 ml by using the fresh dissolution medium i.e., Phosphate buffer (pH-5.8).

Assay Test: Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing about 0.15g of paracetamol add 50ml of 0.1 M sodium hydroxide, dilute with 100ml of water, shake for 15 minutes and add sufficient water to produce 200ml. Mix, filter and dilute 10 ml of the filtrate to 100ml with water. To 10 ml of the resulting solution add 10ml of 0.1M sodium hydroxide, dilute to 100ml with water and mix, Measure the absorbance of the resulting solution at the maximum at about 257nm Calculate the content of paracetamol taking 715 as the specific absorbance at 257nm[13].

3.RESULTS AND DISCUSSIONS

Weight Variation:

During the study, at first the weight variation which is the key to controlling crushing strength and friability of tablet was assessed. The test stated that ALL the samples of paracetamol brands A & B have passed the weight variation uniformity test as specified in the Indian Pharmacopoeia 2018 (not exceed 5% deviation). (Table 5)

Table 3 : Result of Weight Variation test.

S.N O	NAME OF BRAND =A	NAME OF BRAND =B	NAME OF BRAND = C
	Avg. weight of tablets= 0.6g	Avg. weight of tablets= 0.61g	Avg. weight of tablets = 0.59g
	Wt. of individual tablets(g)	Wt. of individual tablets(g)	Wt. of individual tablets (g)
1	0.60g	0.50g	0.70g
2	0.60g	0.70g	0.50g
3	0.60g	0.60g	0.60g
4	0.70g	0.60g	0.60g
5	0.60g	0.50g	0.50g
6	0.60g	0.60g	0.60g
7	0.60g	0.70g	0.60g

8	0.60g	0.70g	0.60g
9	0.60g	0.60g	0.60g
10	0.50g	0.60g	0.60g

Hardness test – Hardness always influence the friability and disintegration time. In this study the hardness result of all the different brand of paracetamol found satisfactory.

Table4: Result of Hardness Testing (kg/cm²)

S.NO.	TABLET A	TABLET B	TABLET C
1	3.5	6.5	4.8
2	3.7	6.5	5.0
3	3.6	5.0	4.9
4	5.1	6.8	4.0
5	5.3	7.0	5.0
6	7.1	6.3	4.5
7	4.8	8.0	4.5
8	6.1	7.8	4.9
9	5.8	7.0	4.5
10	5.0	6.5	4.5

Friability:

All the brands show acceptable results in terms of Friability. All brands possess exceptional value in terms of Friability. All the acceptable value of test in terms of Friability were ranged from 0.1-0.5% for Paracetamol according to the

Indian Pharmacopoeia. Friability values are Less than 1%, it means the tablets are mechanically stable (Table 5) and all the tablets are ensuring that they are mechanically stable and safe and should be considered for the rationale use of the tablets¹⁹.

Table 6. Percentage friability of our brands of paracetamol 500 mg tablet

BRAND	Initial Average Weight of Tablet	Final Average Weight of Tablet	% FRIABILITY
A	0.604	0.602	0.33
B	0.612	0.610	0.32
C	0.586	0.585	0.17

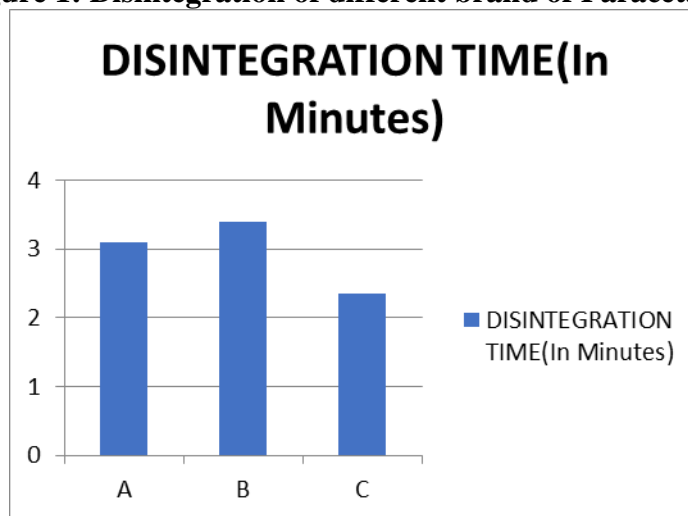
Disintegration -

According to IP the uncoated tablet disintegration time is within 15 minutes. In this study all the tablets of different brand of

paracetamol was completely disintegrated within 15 minutes which is show by the graph (figure 2).

Table7:Disintegration of different brand of Paracetamol

S.NO.	BRAND	DISINTEGRATION TIME(In Minutes)
1	A	3.10
2	B	3.40
3	C	2.35

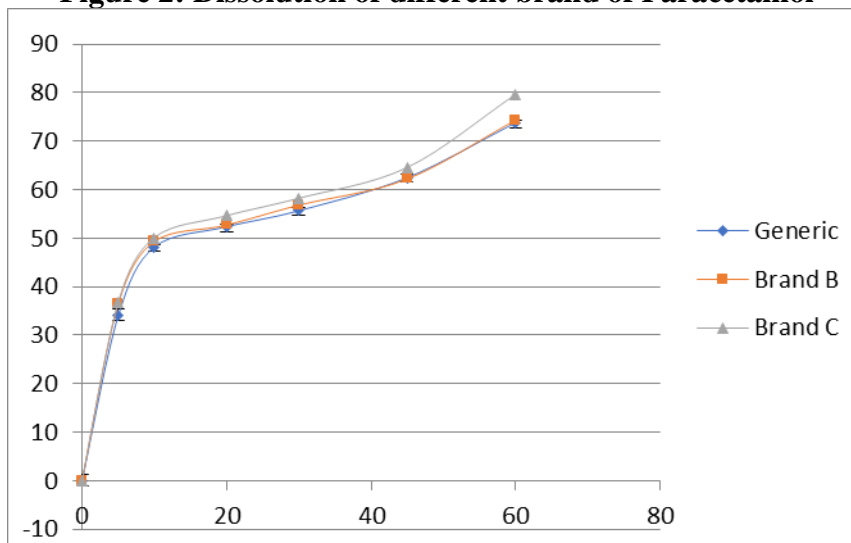
Figure 1: Disintegration of different brand of Paracetamol**Dissolution:**

Dissolution is another very important quality control parameters that is directly interconnected to the absorption and bioavailability of drug [22]. The present study exposed that at different time intervals drug release rate is better in paracetamol tablet

brands comparing with the paracetamol alone. After 10 minutes, the release rate of tablet brands of paracetamol was 40.81% to 56.28%. Finally after 30 minutes, the release rate of tablet all brands of paracetamol also showed more than 90% drug release after 30 minute.

Table7: Result of Dissolution Test

TABLET	% Drug Release					
	(5 mins)	(10 mins)	(20 mins)	(30 mins)	(45 mins)	(60 mins)
A	34.0	48.2	52.4	55.7	62.5	73.8
B	36.5	49.4	52.8	56.9	62.3	74.4
C	36.7	50.1	54.6	58.2	64.5	79.5

Figure 2: Dissolution of different brand of Paracetamol

3. CONCLUSION

This study evaluated the quality of 3 brands of paracetamol tablets using Pharmacopoeia and tests. The study revealed that most of the brands conformed to the specifications for the percentage of active content, hardness, friability and the uniformity of dosage units as stated by the IP. From the obtained result we were conclude that each and every branded tablet taken for comparative evaluation gives almost same results but no one crosses the limits given in official books.

4. REFERENCES

1. Graham G G, Scott KF, 2005. Mechanism of action of paracetamol, American Journal of Therapeutics, 12(1):46-55.
2. Rang HP, Dale MM, Ritter JM, Moore PK. 2003. Pharmacology. 5th Ed. London: Churchill Livingstone, 251-252.
3. Brune K. 1986. Comparative pharmacology of 'non-opioid' analgesics. Med Toxicol, 1:1-9.
4. Nayak AK. 2010. Comparative in vitro dissolution assessment of some commercially available paracetamol tablets. Int J Pharm Sci Rev Res. 2:29-30
5. Khan, A. 2019. Comparative quality evaluation of two brands of paracetamol tablets obtained from the market. International Journal of Pharmaceutical Education and Research (Ijper), 1(1), 14-18
6. Mathur N and Kumar R. 2015. Evaluation of quality control parameters on various brands of paracetamol tablet formulation. World J Pharm Pharm Sci. 4: 976-984.
7. Thakuri GMS and Yadav KK, Chhetri RR. 2016. Comparative in-vitro analysis of different brands of paracetamol tablets available in Nepal. J Coast Life Med. 4: 645- 648.
8. Teklu L, Adugna E, Ashenef A. 2014. Quality Evaluation of Paracetamol Tablets obtained from the Common Shops (Kiosks) in Addis Ababa, Ethiopia. International Journal of Pharmaceutical Sciences and Research. 5(8): 3502-3510.
9. The Indian Pharmacopoeia, 1996. Government of India, Ministry of Health and Family Welfare, Controller of publication, New Delhi, 1:556.
10. Mosharraf Z. Determination of the quality control parameters of paracetamol tablets in Bangladesh pharma market [bachelor's thesis]
11. Paracetamol Information Centre, 2000. Paracetamol Chemistry.

12. Oscier CD and Milner QJ. 2009, Peri-operative use of paracetamol. *Anaesthesia*. 64:65-72.
13. Amit Kumar Nayak. Comparative In Vitro Dissolution Assessment of Some Commercially Available Paracetamol Tablets.
14. International Journal of Pharmaceutical Sciences Review and Research. 2010 May – June ; 2(1) ; 29-30
15. Bertolini A and Ferrari A. 2006. Paracetamol: New vistas of an old drug. *CNS Drug Rev*. 12:250-275:
16. S. S. Dahiwal, S. G. Bhokare. In-Vitro Evaluation of Marketed Brands of Paracetamol Tablets in India Using Quality Control Tests.
17. International Journal of Pharmacy and Pharmaceutical Research. 2017 August ; 10(1) ; 182-192
18. Ad Khan, Pk Baranwal, Ali Ma, S Kumar, S Sharma. Comparative Quality Evaluation of Two Brands of Paracetamol Tablets Obtained From The Market. *International Journal of Pharmaceutical Education And Research*. 2019 ; 1(1) ; 14-18
19. Palash Karmakar, Md. Golam Kibria: In-vitro comparative evaluation of quality control parameters between paracetamol and paracetamol/caffeine tablets available in Bangladesh. *International Current Pharmaceutical Journal* 2012; 1(5):103-109.
20. Haritha B, A Review on Evaluation of Tablets. *Journal of Formulation Science and Bioavailability*. 2017; 1(1):1-5
21. Syed Anees Ahmed, Niharika Pal, Garima Verma And Arvind Singh. Comparative In Vitro Release Study of Some Commercially Available Paracetamol Tablets. *Pelagia Research Library*. 2012 ; 3(5) ; 1075-1077
22. Srivastava P, Malviya R, Kulkarni GT. 2010. Formulation and evaluation of Paracetamol tablets to assess binding property of orange peel pectin. *International Journal of Pharmaceutical Sciences Review and Research*. 3(1):30-34.
23. Indian Pharmacopoeia , Government of India, Ministry of Health & Family Welfare, Ghaziabad. 2004 ; 3 ; 902 – 903
24. Manoj Kumar Sarangi, Dr. K.A Chowdary. Ankush Sundriyal. Formulation Development And Evaluation of Bilayer Tablets Containing Paracetamol SR And Tizanidine. *Journal of Applied Pharmacy*. 2014 October ; 6(4) ; 347 – 359
25. S. Belay Sahle, A. Tesfaye Ayane, N. Tajure Wabe, Comparative quality evaluation of paracetamol tablet marketed in Somali region of Ethiopia, *IJPSR* 3 (2)(2012) 545. –50. Available from: www.ijpsr.com. (Accessed 17 August 2023)