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IN-VITRO QUALITY ANALYSIS OF DIFFERENT BRANDS OF PARACETAMOL TABLET AVAILABLE IN BANGLADESH

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ABSTRACT

Paracetamol is the most prescribed analgesic drug which is used in the treatment of mild to moderate pain relief. The aim of the present study is to examine the physio-chemical parameters of commercially available local brands of paracetamol tablets in Bangladesh. Five brands of paracetamol tablet were explored by testing various parameters according to in-vitro analytical methods. The study parameters were weight variation, friability, disintegration, dissolution and hardness. All brands were tested according to their pharmacopoeia claimed methods to find out their qualities. The requirements of weight variation and friability value were compiled for all brands. According to the BP/IP recommendation for uncoated tablets, fifteen minutes of disintegration time was also complied for all the brands. All brands demonstrated not less than 80% drug release in 45 minute as per BP and not less than 85% in 30 minute as per IP. In case of weight variation, content of each brand was found to be within the range of 95–105%. The hardness of all the brands was found to be in the range of 40-80 N. Again, all brands of paracetamol exhibited less than 1% friability. The findings of the present study suggest that every paracetamol brands which are available in Bangladeshi market supporting the IP/BP requirements. Therefore, as an over-the-counter drug, the consumption of paracetamol is safe and effective for human consumption.

KEYWORDS: Paracetamol; wet variation; hardness; friability; disintegration time; dissolution profile.

INTRODUCTION

Paracetamol which is also familiar as acetaminophen or APAP is the most prescribed analgesic drug.[1] It is usually used for treatment of mild to moderate pain relief. Paracetamol is also used for more severe pain such as cancer pain and pain after surgery in combination with opioid pain medication. Besides, paracetamol is administrated for reducing fever in people of all ages.[2] The World Health Organization recommends that paracetamol should be used to treat fever in children only if their temperature is higher than 38.5 °C (101.3 °F). Paracetamol is now globally administrated as antipyretic and analgesic drug.[3] Because of its being highly effective analgesic and antipyretic activity with minor adverse effect and non-carcinogenic effect at recommended dose, paracetamol has been occupying the market of phenacetin and its combination.[4] A body of researchers claimed that paracetamol may modify the lipid profile by rising the triglycerides and total cholesterol level and reducing high-density lipoprotein.[5] It is generally administrated either by mouth or rectally but is also available as intravenous formulation. The effect of paracetamol ranges between two and four hours.[2] So the quality parameters assessment of paracetamol is an important factor for ensuring its effectiveness.

The process of quality control is conducted to confirm an expected level of quality in a product. It includes the necessary actions, a business conceives, essential to provide for the control and verification of various parameter of a product.[6] Different quality parameters like weight variation, hardness, friability, disintegration time, dissolution profile etc. which play a significant effect on the drug product formulation.[7] As we know that paracetamol is an over-the-counter drug which is easily available in market and the effect of such drugs is directly related to the public health.[8] That is why every brand available in market should be well manufactured, genuine and well marketed. It is also mandatory that every brand in the market should pass its quality control parameters and the parameters should be ranged within the limits. Therefore, the present study was designed to evaluate various in vitro quality control parameters of paracetamol tablet brands available in Bangladesh.

MATERIALS AND METHODS

Study design

The study of in-vitro quality analysis of available paracetamol tablet brands in Bangladesh was studied by the evaluation of weight variation, hardness, friability, and disintegration time and dissolution profile. The study was performed by applying different standard test methods for evaluating the quality of tablets.

Sample collection and identification

Five paracetamol tablets of leading brand were purchased from the various retail pharmacies of Noakhali in Bangladesh which were 500 mg in weight. The samples were blindly leveled as PARA1, PARA2, PARA3, PARA4 and PARA5. Collected brands were stored under appropriate conditions until further study.

Analytical methods

In this study, following tests were conducted for the assessment of all the paracetamol tablet brands.

Weight variation test

Weight variation should not exceed 10% for tablets having average weight of 80 mg or less.[9] In this test, variation of weight from tablet to tablet can be discerned. The weight of the tablet is calculated physically by the diameter of the die and the weight adjustment cam on the tablet machine. It is carried out to ensure that, each of tablets contains the exact amount of drug. The test was executed by weighing the 20 tablets individually using analytical balance. Then the average weight was determined which was compared to the individual tablet weights to the average. The variation of the weight of the tablets from the average weight was calculated as the weight variation.[10] The following formula is used:

$$\text{Weight variation} = \frac{IW - AW}{AW} \times 100$$

Where,

IW= Individual weight of tablet

AW= Average weight of tablet

Hardness test

Hardness of randomly selected ten tablets was determined for all the brands in ‘Monsanto’ type hardness tester (Intech, Korea). Finally the mean strengths were determined using the following formula.[10]

$$\text{Hardness} = \frac{\text{Total hardness of all tablets}}{\text{number of tablet}}$$

Friability test

In this study, friability conducted by using Electrolab EF-2 Friabilator (USP) and the values of friability were revealed in percentage (%). Ten tablets from each brand were individually weighed and transferred into friabilator which was run at 25 rpm and carried out up to 4 minutes (100 revolutions). After that, the tablets weights were taken again and the percent (%) of friability was calculated using following formula.[10,11]

$$\%\ \text{of Friability} = \frac{\text{weight before test} - \text{weight after test}}{\text{weight before test}} \times 100$$

Disintegration time test

The disintegration test was conducted using disintegration tester –USP; (Electro lab EF 2L; United Kingdom) with disc in distilled water medium. To determine disintegration time, three tablets of each brand were placed in each tube and the basket rack is positioned in a 1 liter beaker of water at 37 ± 0.5 ^{0}C. The time required to break of each tablet into small particles and pass out through the mesh was recorded. Then, the mean disintegration time was calculated for each brands tablet.[12]

Dissolution test

The dissolution test was carried out using Dissolution Tester – USP Apparatus-1 (Basket type). Three tablets of each brand were placed in 3 different beakers in dissolution medium containing 900 ml of 0.1N HCl buffer (pH 7.4). The apparatus was rotated at a speed of 100 rpm by maintaining temperature at 37 ± 1 ºC in each test. Then 5 ml sample was withdrawn at a regular interval of 10 minutes and this was carried out up to 30 minutes by adding equal quantity of fresh dissolution medium. The filtered samples were analyzed by using UV Spectrophotometer (SHIMADZU UV Spectrophotometer: UV-1800-240V) at 260 nm for paracetamol and percentage (%) of drug release was calculated by measuring the absorbance.[13,14]

Statistical analysis

The data were assayed by using the above mentioned mathematical formula and MS Excel®, 2007.

RESULTS AND DISCUSSION

Weight variation

The weights of different brands of paracetamol tablets shown in Table 1. According to the BP[9] and IP[14,15] specifications, it was determined that weight variation should not be more than ±5% deviation for tablets above 250 mg (Table 1). All the paracetamol tablets of five brands were found not deviated by ± 5% of the average tablet weight according to IP/BP specifications.

Table 1: Observation of weight variation for different brands.

Brands	Minimum weight (mg)	Maximum weight (mg)	Average weight (mg)	Weight variation (%)
PARA1	552.51	581.15	563.7	1.60
PARA2	569.81	576.90	573.8	0.34
PARA3	547.08	556.84	552.9	0.48
PARA4	595.06	614.79	604.0	0.80
PARA5	636.74	626.40	629.8	0.62

Hardness test

All the brands exhibited satisfactory hardness which is required for safe handling and transportation. According to USP, the hardness of tablet should be lying in 40-80 N. All the brands of paracetamol showed hardness within the USP specified range.

Table 2: Observation of hardness for different brands.

Brands	Hardness (N)	USP specification	Deviation from official limit
PARA1	69.6		Pass
PARA2	66.6		Pass
PARA3	70.5	40-80 N	Pass
PARA4	54.8		Pass
PARA5	72.4		Pass

Friability test

The results of friability were noted in table 3. According to BP/IP the friability should be less than 1%. All brands of paracetamol showed friability less than 1%. Brand PARA1 had minimum friability of 0.52% while brand PARA3 had maximum friability of 0.90% and both were within the limit of specification.

Table 3: Observation of friability for different brands.

Brands	Initial weight (g)	Final weight (g)	Result (%)	IP/BP specification	Deviation from official limit
PARA 1	2.29	2.28	0.52	Not more than 1 %	Pass
PARA 2	3.40	3.37	0.81		Pass
PARA 3	3.31	3.28	0.90		Pass
PARA 4	3.77	3.74	0.75		Pass
PARA 5	3.62	3.59	0.66		Pass

Disintegration time (Dt) Test

The results of disintegration time were exhibited in table 4. According to the BP, uncoated tablets should disintegrate within 15 min and film coated tablets in 30 min whereas the USP noted that both uncoated and film coated tablets should disintegrate within 30 min. In our study, all brands of paracetamol disintegrated within the BP and USP mentioned time boundary where PARA3 showed minimum disintegration time and PARA5 showed maximum disintegration time.

Table 4: Observation of disintegration time for different brands.

Brands	Disintegration time (min)	IP/BP specification	Deviation from official limit
PARA1	1.10	Not more than 15 min	Pass
PARA2	0.47		Pass
PARA3	0.41		Pass
PARA4	0.58		Pass
PARA5	1.40		Pass

Dissolution profile

The results of dissolution were noted in table 5. The dissolution test is used to determine the amount of the drug released into the dissolution medium with time. According to the standard limits of IP, more than 85% drug should be released in 30 min whereas in case of BP it is more than 80% in 45 min. All of our brands of paracetamol got dissolved in specified range of BP and USP.

Table 5: Observation of dissolution rate for different brands.

Brands	Disintegration rate (%)	IP/BP specification	Deviation from official limit
PARA1	102.0	>80	Pass
PARA2	98.5	>80	Pass
PARA3	99.1	>85	Pass
PARA4	95.4	>85	Pass
PARA5	104.4	>80	Pass

The objective of this research was to demonstrate the physico-chemical parameters of commercially available local brands of paracetamol tablets in Bangladesh. Five different brands which are available in Bangladesh pharma market were assessed regarding their quality standards. In-vitro examination such as weight variation, friability, disintegration, dissolution and hardness were performed. All brands of paracetamol tablets were found not deviated by ± 5% of the average tablet weight according to IP/BP specification. Even though all brands of paracetamol also fulfill the specification mentioned in BP and USP in case of hardness, friability, disintegration time and dissolution. As all brands of paracetamol fulfill the criteria specified in BP and USP, we can claim that pharmaceutical company of Bangladesh manufacture the paracetamol of standard quality.

CONCLUSION

The result of present study of wet variation, hardness, friability, disintegration time and dissolution profile of paracetamol available in Bangladesh support its standard quality. From the study, it is concluded that all brands of paracetamol in Bangladesh are manufactured following the guidelines mentioned in BP and USP for maintaining standard quality. As a result, the users get desired therapeutic effect because quality ensures better medicine. So, as an over-the-counter drug, the consumption of different brands of paracetamol in Bangladesh is safe and effective for human.

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ABBREVIATION

USP: United States Pharmacopeia, BP: British Pharmacopeia, IP: Indian Pharmacopeia, PARA: Paracetamol, Dt: disintegration time, APAP: Acetaminophen.

Author contributions

Concept-M.G.U; Design-M.S.U.; Supervision-M.S.U.; Resources-M.F., M.A.J., M.S.M.; Data collection and processing-M.G.U, M.F., M.A.J. S.A.S; Analysis-M.G.U., M.F. M.A.J., S.A.S.; Literature search-M.G.U.; M.S.I.; Writing-S.A.S.; M.S.U.; Critical Reviews-M.G.U., M.F., M.A.J., M.S.M., S.A.S., M.S.I., M.S.U.

Consent for publication

All authors gave their written consent to publish the manuscript.

Competing interests

The authors declare that they have no competing interests.

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REFERENCES

1. Pape E, Collin C, Camelot F, Javot L, Petitpain N, Puskarczyk E, Anastasio D, Gerard E, Gambier N, Scala-Bertola J, Clement C. Paracetamol misuse and dental pain: results from the french observational DANtaLor study. J Oral Facial Pain Headache, 2009; 1(33): 123–129.
2. The American Society of Health-System Pharmacists. Archived from the original on 5 June 2016. Retrieved 16 September 2016.
3. Jozwiak-Bebenista M, Nowak JZ. Paracetamol: mechanism of action, applications and safety concern. Acta Pol Pharm, 2014; 71(1): 11-23.
4. Zyoud SH, Al-jabi SW, Sweileh WM. World-wide research productivity of paracetamol (acetaminophen) poisoning: a bibliometric analysis. Hum Exp Toxicol, 2015; 34(1): 12-23.
5. AL-Harbi MS. Ameliorative effects of silymarin and Nigella sativa extract on paracetamol induced hyperlipidemia and oxidative stress in heart tissues in male mice. J Chem Pharm Res., 2015; 7: 925-33.
6. Dewan SMR, Alam A, Ahamed SK. A comparative quality control study on conventional ibuprofen tablets available in Bangladeshi pharma market. Int Res J Pharm, 2013; 4: 96-98.
7. Karmakar P, Kibria MG. In-vitro comparative evaluation of quality control parameters between paracetamol and paracetamol/caffeine tablets available in Bangladesh. Int Curr Pharm J., 2012; 1: 103-109.
8. Kar A, Amin MN, Hossain MS, Mukul MEH, Rashed MSU, Ibrahim M. Quality analysis of different marketed brands of paracetamol available in Bangladesh. Int Curr Pharm J., 2015; 4: 432-35.
9. British Pharmacopoeia. 2005; 4, Appendix XII H A273, Table: 2.9.5-1.

10. Uddin MS, Millat MS, Siddiqui SA. Formulation and evaluation studies of Atorvastatin calcium sustained release tablet. Pharma Tutor, 2019; 7(9): 1-5.
11. Kalakuntla R, Veerlapati U, Chepuri M, Raparla R. Effect of various super disintegrants on hardness, disintegration and dissolution of drug from dosage form. J Adv Sci Res., 2010; 1: 15-19.
12. Gangwar S, Singh S, Garg G, Garg V, Sharma PK. To compare the disintegrating property of papaya starch and sago starch in paracetamol tablets. Int J Pharm Sci., 2010; 2: 148-151.
13. Kumar KA, Mohanakrishna A, Sudheer M, Rajesh KS, Ramalingam P. UV-Spectrophotometric method for the estimation of Alprazolam in tablet dosage Form. Int J Chem Tech Res., 2011; 3: 161-164.
14. Kumar S, Shashikant, Agnihotri R. In-vitro evaluation of two marketed brands of paracetamol tablets using quality control tests. Int J Pharm Sci Res., 2012; 3(9): 3337-3341.
15. The Indian Pharmacopoeia, Govt. of India Ministry of Health and Family Welfare, Controller of Publication New Delhi, 1996; I & II.