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Original article

Physical and Chemical Evaluation of Different Brands of Paracetamol Tablets

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ABSTRACT

Paracetamol is considered as one of the most Over-The-Counter (OTC) analgesic and antipyretic drug used. Therefore, assessment of its chemical content as well as physical tests is important to ensure its therapeutic effectiveness. This work included evaluation of three different brands of paracetamol tablets collected from different community pharmacies in Tripoli-Libya as a part of post-marketing evaluation. The physical tests included weight variation, hardness, disintegration, where chemical test included content uniformity of each brand. Physical tests were varying due to different considerations of manufacturing. Test for content of each product showed that the (A) product was of highest percentage content followed by (B)Panadol with small difference where Panadol from (C) had the lowest value; 92%. The results showed the failure of code (C) drug to comply with pharmacopoeia standards for uniformity of contents.

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INTRODUCTION

Paracetamol; acetaminophen is commonly prescribed as analgesic and antipyretic Over-The-Counter (OTC) drug. It is an important component of cold and flu remedies. It has weak anti- inflammatory effect compared to non-steroidal anti-inflammatory drugs (NSAIDs) [1]. Chemically, it is N-(4-hydroxyphenyl) acetamide;(acetaminophen), figure (1) [1].

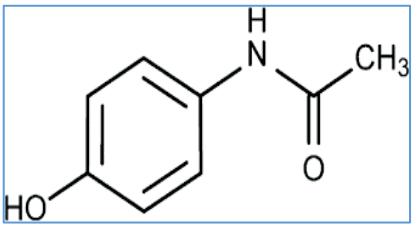

Figure 1. Structural formula of Paracetamol

Paracetamol tablet is one of solid dosage form produced by application of compression force to compact powdered materials into a solid unit. Additives of tablets namely binders and lubricants along with the active ingredient will determine the different properties of the tablet [2]. Formulation variables like compression pressure and manufacturing methods could also affect mechanical strength of the tablets [3,4].

Although paracetamol is considered a safe drug at the recommended doses, it is one of the most commonly overdosed drugs inducing life-threatening toxicity and death [5]. In this study quality control of paracetamol tablets from three different manufacturers marketed in Libyan pharmacies was assessed by official and non-official tests.

METHODS

The three different brands selected were tested for evaluation of chemical and physical properties. The different brands were given a letter for each as shown in table 1.

Table1. Code, brand, dosage, origin and batch number.

Brand	Dosage	Origin	Batch number
A	500 mg	Tunisia	19033
B	500 mg	Ireland	MF 4P
C	500 mg	UAE	922

Physical tests

Friability test cannot be performed because the tablets were all film-coated so there would be no loss in weight. Therefore, other tests were performed, weight variation, hardness and disintegration.

Materials

Sodium hydroxide AR from Riedel-de Haen, Germany; balance from Sartorius, Germany; hardness tester from PHARMA Test PTB, Germany; disintegration test apparatus from PHARMA TEST PTZ-AUTO, Germany; and 6505 UV/Vis Spectrophotometer from Jenway, UK.

Hardness test

Ten tablets were tested for each company according to EP and results for diameter and hardness. Results were tabulated [6].

Disintegration test

6 tablets of each company were tested using water as disintegration medium. The procedure is followed as in European Pharmacopoeia 6 where the 6 tablets must have disintegrated. Maximum and minimum time for each test of tablets is recorded [6].

Uniformity of mass

About 20 tablets of each company taken at random and were individually weighed. The average mass is determined. Conditions for the test are applied according to European Pharmacopeia 6, where it stated that not more than 2 tablets deviate from the average mass by more the percentage deviation of 5%. Results were listed and compared for each company.

Uniformity of content

20 tablets were weighed and powdered. A quantity of powder containing 0.15g of paracetamol is placed in 200ml-volumetric flask. 50ml of 0.1M sodium hydroxide is added to the powder and also 100ml of water. The contents were shaken for 15 min. The volume was completed to 200 ml with distilled water. Mix and filter and 10 ml of filtrate was transferred into 100ml-volumetric flask and volume completed with water. From the final preparation, 10ml were transferred into a 100 ml – volumetric flask and 10 ml of 0.1M NaOH and volume completed with water and absorbance was measured at 257nm taking 715 as the value of A (1%, 1cm) at the maximum at 257nm. The content was calculated and compared to the range stated in the monograph of paracetamol tablets in BP 2009 (95% - 105%) [7].

RESULTS

The study included three most dispensed brands of paracetamol. The physical tests included hardness and disintegration. Friability was not conducted as all were film-coated tablets [6,7]. The results showed that code B had the highest hardness but lowest time for disintegration, figure 2 (A,B). Assay provided percentage of drug content ranging from 92.8-98.4 % where code C had lowest % content of the drug, figure 2(D).

Table2. Results of hardness, disintegration, weight variation and assay.

Code	Hardness Kg/cm² n=10	Disintegration (min) n=6	%Weight variation n=20	% Drug content n=3
A	6.51 (±14.64)	5.88	0.63 (±0.91)	98.4%
B	10.04 (±16)	3.55	0.65 (±0.80)	97.33%
C	4.47 (±14.2)	7.33	0.77 (±1.03)	92.8%

In this study different quality control parameters were evaluated. Weight variation of all brands as shown in table 2; fell below accepted value of 5% [6]. Weight variation is important for assessment of friability and hardness of tablet dosage forms.

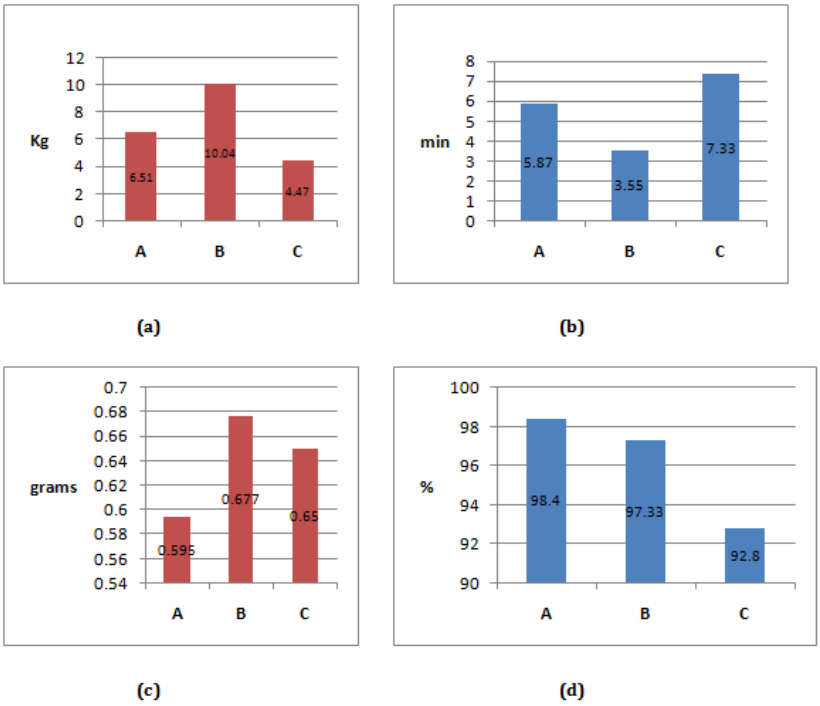

Figure 2. Different results for a: Hardness, b: disintegration, c: weight variation and d: content uniformity.

DISCUSSION

In this study different quality control parameters were evaluated. Weight variation of all brands fell below accepted value of 5% [6]. Weight variation is important for assessment of friability and hardness of tablet dosage forms. In this study hardness results should be acceptable and not too high to affect dissolution and disintegration of the tablets and hence release of the drug. Also, must be enough to withstand breakage, crumbling during conditions of storage, transportation and handling [8,9].

It is supposed that high values of hardness would result in high values of disintegration time which was not found in this study may be due to different formulations. Code B showed to have higher hardness value compared to lowest disintegration times where it has paracetamol with OPTIZORB formulation which releases its active ingredient up to 5 times faster than standard paracetamol. The Optizorb technology uses excipients like Alginic acid and calcium carbonate as disintegrant in varied concentrations. Alginic acid absorbs lot of water, swells and leads to decay of tablet whereas calcium carbonate reacts with the stomach acid leading to release the active ingredient in about 3 minutes [10,11].

Although physical parameters are of very importance, uniformity of content is the most important test for accepting or rejecting a batch of a drug. From figure 3; the results for percent content of the three drugs showed that code C drug had the lowest content that is out of the acceptable range of BP2009 which suggested urgent need for further tests to evaluate its impurities as well [12]. Similar studies conducted by Zaid *et al.* to evaluate the quality of 10 paracetamol products in the Palestinian market and found out that effectiveness of generic products is often in-vitro comparable to the brand product s [13]. Comparable conclusion was reached by Alswayeh*et al.* after studying nine 500mg brands of paracetamol tablets marketed in Saudia Arabia [14]. Such results would suggest the importance of establishment of post marketing evaluation of most drugs.

CONCLUSION

Because of failure of drug code C to fulfil pharmacopoeia requirements; this study assures on the need of practicing post marketing quality control as one of the worldwide quality assurance procedures to ensure safety and effectiveness of different generic drugs.

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Conflict of interest. The authors declare no conflicts of interest.

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التقييم الفيزيائي والكيميائي للعلامات التجارية المختلفة لأقراص الباراسيتامول

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المستخلص

يعتبر الباراسيتامول واحدًا من أكثر الأدوية المسكنة وخافضات الحرارة المتاحة دون وصفة طبية (OTC) استخدامًا. ولذلك، فإن تقييم محتواه الكيميائي وكذلك الاختبارات الفيزيائية أمر مهم للتأكد من فعاليته العلاجية. تضمن هذا العمل تقييم ثلاث علامات تجارية مختلفة من أقراص الباراسيتامول تم جمعها من صيدليات مجتمعية مختلفة في طرابلس-ليبيا كجزء من تقييم ما بعد التسويق. وتضمنت الاختبارات الفيزيائية اختلاف الوزن والصلابة والتفكك، حيث تضمن الاختبار الكيميائي تجانس محتوى كل علامة تجارية. كانت الاختبارات الفيزيائية متفاوتة بسبب اعتبارات التصنيع المختلفة. أظهر اختبار محتوى كل منتج أن المنتج (أ) كان ذو أعلى نسبة محتوى يليه (ب) البنادول مع اختلاف بسيط حيث كان البنادول من (ج) أقل قيمة؛ 92%. أظهرت النتائج عدم توافق الدواء ذو الرمز (ج) مع معايير دستور الأدوية لتوحيد المحتويات.

الكلمات الدالة. الباراسيتامول، الفحص، الفيزيائي، توحيد المحتوى.