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COMPARATIVE STUDY OF CERTAIN COMMERCIALLY AVAILABLE BRANDS OF PARACETAMOL TABLETS IN SANA'A CITY, YEMEN

Mahmoud Mahyoob Alburyhi[1], Abdalwali A. Saif[1], Maged Alwan Noman[1]*, Moktar Algorafy[2]

[1]Associate Professor of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Yemen.
[1]Professor of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Yemen.
[2]Assistant Professor of Organic Chemistry, Faculty of Pharmacy Sana'a University, Yemen.

***Corresponding Author: Dr. Maged Alwan Noman**

Professor of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Yemen.

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ABSTRACT

Evaluation of the physiochemical properties of the pharmaceutical products can ensure their quality as well as bioavailability and impart optimum therapeutic activity. In general, drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. Acetaminophen is a non-steroidal anti-inflammatory drug frequently prescribed for relief of pain and fever. The present study was conducted to access the quality control parameters of nine different brands marketed in Yemen and compare weight variation, hardness, friability, and assessment of state content as prescribed in official monograph using acetaminophen standards. For weight variation, all the nine brands of paracetamol tested conformed to the BP weight variation test. For hardness the result show that all brands complied with the standard BB/USP specification for tablet hardness 4-10 kg/cm, except two brands fail, Paramol and Ramol. All brands showed impressive friability values and the products of multinational companies comparatively exhibited the highest values, all the brands of paracetamol tablets had passed friability specification and values of <1% which considered to be highly satisfactory according to BP/USP. All the nine brands of paracetamol shown their disintegration within 15 minutes as specified by BP/USP. For drug content, high-performance liquid chromatography was used to determine Paracetamol content, and all brands showed good chemical analysis profile which would further help in achieving optimum bioavailability and in fulfilling the patient demands.

KEYWORDS: Paracetamol, hardness, friability, disintegration, market.

INTRODUCTION

Sub-standard medications may be harmful to people's health and patients may lose confidence in health care professionals including physician and pharmacist[1], when patients choose their own drugs they may lack the specialized knowledge to detect whether the product they are buying is of good quality let alone be able to detect whether the product is forged or not[2] Acetaminophen is a non-steroidal anti-inflammatory drug frequently prescribed for relief of pain and fever. It is also used to treat the headache. The chemical name of acetaminophen is N-acetyl-Para aminophenol.[3]

It is an over-the-counter drug, commonly used as an analgesic and antipyretic agent, but it has weak anti-inflammatory effects since it has poor ability to inhibit Cyclooxygenase (COX) in the presence of high concentration of peroxides. The analgesic effect of acetaminophen is due to prostaglandins (PGs) synthesis inhibition.[4,5]

The apparent volume of acetaminophen is 1-1.2 L/Kg. and the excretion of acetaminophen is also observed in breast milk and cross placenta barriers. Protein binding of drug depends upon on concentration of Paracetamol[6] and generally use to treat headache, fever and certain pains[7], *also* used for treating certain mild-to-moderate pain, including that caused by flu, sprains, cold, headaches, dysmenorrhea, toothaches and minor arthritis pain etc.[8]

However, the overdoses or prolonged duration of taking any drug may exhibit side effects, especially in the liver[9]

As paracetamol is a popular and widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer). Besides headaches, minor aches and pains, it is also used in combination with opioids analgesics to control severe pains such as episiotomy pain, post-surgical pain and cancer pain[10]

Paracetamol is a metabolite product of phenacetin. Being highly effective analgesic and antipyretic with less adverse effect and noncarcinogenic at recommended

dose, paracetamol has been replacing the phenacetin and its combination.[11]

Some researcher suggest that paracetamol may alter the lipid profile by increasing the triglycerides and total cholesterol and decreasing high-density lipoprotein.[12] Other being conducted to correlate the paracetamol with cancer. There are some attestations which deduce that paracetamol may help to cause the urinary tract cancer but defend ovarian cancer.[13]
The safety and efficacy of a pharmaceutical dosage form can be guaranteed when its quality is reliable.[14] Weight variation, content uniformity, thickness, hardness, friability and disintegration should be considered for validation of a tablet[15]

A number of studies have analyzed the physical and chemical characteristics of paracetamol medication in local markets. In the same vein, Chandrasekaran et al. assessed six brands of paracetamol 500 mg tablets by performing the quality control tests for weight variation, hardness and friability. Friability for all brands was below 1% and the weight variation test limit was from 0.5223-0.6315 g. Tablet hardness ranged from 7.0-12.5 kg/square inch. Based on the result from this study, it could be concluded that, despite some apparent minor differences in tablet hardness and disintegration time profiles, the dissolution characteristics of various paracetamol tablets appears to be similar and not significantly different from various manufacturers.[16]

Data from several studies suggest that paracetamol tablet was chosen as model drug as it was fast moving and highly consumed by people as well as having significant price differences among brands.[17] In an analysis of two different brands of paracetamol tablets, Verma found the quality of the (Brand B) of paracetamol was deviating much from standard when compared to those of (Brand A). It has been suggested that need for proper control over the manufacture of such drugs is imperative.[18]

Other methods for the determination of paracetamol in tablet formulation have been described, including rapid TLC method for screening of marketed paracetamol tablets and identification of counterfeit and substandard paracetamol tablets by near infrared spectroscopy.[19]

Also, eight brands of paracetamol 500 mg tablets were assessed in the Nigerian capital city by Oga and his team using the quality control parameters of weight uniformity, active ingredient content and thin layer chromatography profile, it was 50% of the brands fell within the pharmacopoeial standard for active ingredient content, and all the brands complied with the weight variation and identification tests.[20]

This present study was to evaluate the selected paracetamol tablet in Yemen market.

Study Design
Comparative study of commercially available brands of acetaminophen to assess the quality control parameter according to prescribed monograph. In this study nine different brands of acetaminophen is purchased from well-known chain drug store located in Sana'a-Yemen pharmacy, for evaluation of weight variation, hardness, friability, disintegration time and drug content.

EXPERIMENTAL

Materials
Nine different brands of Paracetamol tablets listed in table (1), Paracetamol SD for (Shaphaco Pharmaceutical Ind. Yemen), sodium hydroxide (Merck, Germany).

Equipment
UV spectrophotometry (Jasco, Japan), electronic analytical balance (Sartorius, Italy), hardness tester (Erweka GmbH, Germany), disintegration test and friability tester (Rimek, India), spectrophotometer (195nm-1020nm, china).

METHODS

Weight variation test.[21]
Method
Twenty tablets of each brand were taken and weighed individually using electronic analytical balance. The upper and lower limit of each brand also calculated and compared with prescribed limit of British pharmacopeia (B.P) and not more than two tablets deviated from prescribed limit of British pharmacopeia.[22]

Mean and stander division (Mean ± SD) also calculated for all brands. According to British Pharmacopoeia[22], the acceptable limit for the deviation of weight for tablets having average weight of 250 mg or more should not exceed 5%[23]

Hardness test[24]
Method
Hardness test is to determine the resistance to crushing of tablets, measured by force needed to crush them. This test is performed by take 10 Tablets of each brand and measured hardness using hardness tester. Mean average and standard deviation (SD) is also calculated individually of all brands.[24]

Friability test.[25]
Method
Friability is measured as taken 6.5 g weight of each brand tablets and placed in plastic chamber at speed 25rpm per min for 240 second (4min). After 4 min, again tablets weighed and the calculate the friability in %.[24]

Friability test[25,23]
Generally, the acceptable range of weight loss of a tablet is less than 0.5 to 1% (NMT 1% is the official limit).[23]

Disintegration test.[24]

Method

The test was performed by taken 6 tablets of each brands and placed into cylindrical tube of basket and disk inserted using 900 ml distilled water marinated at 37±1°C. The disintegration time for uncoated tablet is 15 min. and the time required to break each brand was noted.[24] The mean and stander division (Mean ± SD) for disintegration time of each paracetamol tablet were determined calculated.

Assay.[24]

Method

Twenty tablets of each brand were taken and crushed into powder. Powder containing 0.15g of paracetamol to 50ml (0.1 N) NaOH solution and make up volume 100ml in conical flask, further dilution was made to 0.01g\ml concentration, and the absorbance was measured at 257 nm and specific absorbance (0.715) using double beam spectrophotometer.[24]

RESULT AND DISCUSSION

As shown in table (1), all the Paracetamol tablets collected and investigated were within their shelf lives and immediate release dosage forms with label strength and same scientific information except three brands, (New dol, Paradol and Biomol) show an additional promotional information in their outer package.

Table (1): General Table of different brands of Paracetamol collected from Sana'a market Yemen.

Tarde Name	Batch No.	Name of Compony	Country	Information of drug	Mfg. Date	Exp. Date	Cost/ tablet
Amol	9672	Shaphaco Pharmaceutical Ind	Yemen	Antipyretic, Analgesic	11/17	11/20	10yr / tab
Panadol Advance	D34D	Glaxo smith Kline	UK	Antipyretic, Analgesic	6/19	5/19	25yr / tab
Ramol	16160	ShibaPharma	Yemen	Antipyretic, Analgesic	5/16	5/19	10yr / tab
Adol	0726	Julphar	U.A.E	Antipyretic, Analgesic.	6/17	6/22	10yr / tab
Paramol	6526	YADCO	Yemen	Antipyretic, Analgesic	8/16	8/20	10yr / tab
New dol	7854	Global pharma	Yemen	Antipyretic, Analgesic, Gentle on stomach	8/17	8/21	10yr / tab
Paradol	5360	MODREN	Yemen	Antipyretic, Analgesic, Gentle on stomach	5/15	5/19	10yr / tab
Biomol	391	Biopharm	Yemen	Effective pain relive Reduce fever	2/17	2/20	10yr / tab
Rafamol	16A207	KFA	Yemen	Antipyretic, Analgesic	10/16	10/19	10yr / tab

Weight variation test[24]

The result was shown in table (2), weight variation test is a very important quality control parameter because it is related with the content uniformity of a drug. A tablet is designed to contain a specific amount of drug in a specific amount of tablet formulation so it is necessary to measure that the drug contains the appropriate amount. Different excipients used for the manufacturing may increase or reduce the weight of the tablet.[26]

In practice, brands of tablets (n=20) are taken and weighed throughout the compression process. The brands weight divided by 20 to reach an average weight of one tablet. Within the brand that has an acceptable average weight, there could be tablets excessively over weight or underweight. To help alleviate this problem the USP/BP provides limits for the permissible variations in the weights of individual tablets expressed as a percentage of the average weight of the sample. According to USP, the weight variation test is run by weighing 20 tablets individually in an analytical balance, calculating the average weight.

As shown in table (2), the results of the weight variation analysis in this study are shown in Table (2), All brands of Paracetamol tested complied with the weight variation test and conformed to the (USP/BP) weight variation test specification. Same results were obtained by previous our research the result was the same to another research.[24]

Table (2): Weight variation testes for different brands of Paracetamol collected from Sana'a market Yemen.

Tarde Name	Average weight (mg) (Main ± SD)	Upper limit / mg	Lower limit / mg	Remarks
Adol	0.639 ± 0.0137	672.00	603.00	Pass
Amol	0.540 ± 0.01026	597.00	513.00	Pass
Biomol	0.844 ± 0.2226	834.75	755.25	Pass
Paradol	0.562 ± 0.0313	596.15	539.37	Pass
Paramol	0.531 ± 0.00308	557.55	504.45	Pass
Pandol advance	0.653 ± 0.03131	685.65	620.35	Pass
Rafamol	0.597 ± 0.02677	640.50	579.50	Pass
Ramol	0.569 ± 0.04388	592.72	536.28	Pass
Newdol	0.601 ± 0.22114	582.75	527.25	Pass

Hardness test[23]

Hardness is the second most important physical feature for assessing tablet.

Sufficient tablet hardness is essential to ensure damage resistance during handling, packaging and transportation [(23)]. In order to with stand mechanical shocks of handling during its manufacture, packaging and transport, the tablet requires a certain amount of strength, or hardness. In addition, tablets should be able to withstand reasonable abuse when in the hands of the consumer.

The acceptable limit of hardness of a tablet is 4 to 7 kg f (kilogram of force).[21, 27] Besides, a force between 4 – 10 Kg is also considered to be satisfactory, as reported by Bendari et al.[28]

As shown in table (3), the hardness result of the brands of paracetamol tested, (Amol, Biomol, Paradol, pandol Advance, Adol, Refamol and Newdol) were (6.00, 6.75, 9.14, 8.10, 7.85, 7.60, 8.00and 5.05 kg/cm) respectively, which are within the acceptable limit, while brands (Paramol and Ramol) 12.7 and 12.15 kg/cm out of the pharmacopeial limit as shown in Table (3). The pharmacopeial limit not out of range 4-10 Kg.[22]

One unanticipated finding was that most of the brands of paracetamol showed the standard deviation within the unacceptable range. Same results were obtained by previous our research the result was the same to another research.[24]

Table (3): Hardness testes for different brands of Paracetamol collected from Sana'a market Yemen.

Tarde Name	Average hardness kg/cm±SD2	Pharmacopoeal limit kg/cm	Remarks
Adol	7.6 ± 0.516398	(4-10)	Pass
Amol	6 ± 1.840894	(4-10)	Pass
Biomal	6.75 ± 2.251543	(4-10)	Pass
Paradol	8.1 ± 0.875595	(4-10)	Pass
Paramol	12.7 ± 2.162817	(4-10)	**Not pass**
Pandol Advance	7.85 ± 0.851469	(4-10)	Pass
Refamol	8 ± 0.666667	(4-10)	Pass
Ramol	12.15 ± 2.38106	(4-10)	**Not pass**
Newdol	5.05 ± 2.408896	(4-10)	Pass

Friability test.[29]

The results of friability test as shown in table (4) illustrate that, all the nine brands of paracetamol tablet tasted were within the BP prescribed limit. No one deviated from 1% limit prescribed in respective monograph.

Results indicate all the nine brands of paracetamol mechanically stable during shipping and transportation. The minimal friability values for all the tablet brands is an indication of the ability of the tablet to withstand stress due to abrasive forces, without crumbling during transportation, packaging, handling and dispensing.

Same results were obtained by previous researcher.[31]

The possible reason for low degree of crumbling during friability may be due to high compressional force of granules being packed strongly.[29,30]

Table (4): Friability testes for different brands of Paracetamol collected from Sana'a market Yemen.

Tarde Name	Friability %	BP Specification	Remarks
Adol	0.1	NMT 1%	Pass
Amol	0.4	NMT 1%	Pass
Biomol	1	NMT 1%	Pass
Rafamol	0.1	NMT 1%	Pass
Ramol	0.18	NMT 1%	Pass
Paradol	0.30	NMT 1%	Pass
Paramol	0.66	NMT 1%	Pass
Pandol Advance	0.1	NMT 1%	Pass
Newdol	0.89	NMT 1%	Pass

Disintegration test[32]

Disintegration is the break down process of tablet into smaller particles and is the first step towards dissolution, used to determine the disintegration time of the medication in the human body[32]

The results of illustrated in table (5) show that**, t**he disintegration time of all nine brands tasted were within the British pharmacopoeia (BP) limit. The Main and standard division were calculated.

BP Specification limit was less the 15 min[22]

It was seen that there was a direct relationship between hardness and disintegration time, In fact, the relationship between tablet hardness and disintegration is a complex one where drug particle size, difference in excipients used and the formulation process followed by different manufacturers could impart different characteristics to the tablet in its solid or hydrated solution form (5).

Table (5): Disintegration time testes for different brands of Paracetamol collected from Sana'a market Yemen.

Tarde Name	Disintegration time for each tablet						Disint. T Mean ±SD	Remarks
	1	2	3	4	5	6		
Adol	00:18	00:18	00:35	00:35	00:35	00:35	00:29 ± 0.006	Pass
Amol	00:59	01:22	01:33	01:45	01:48	01:48	01:22 ± 0.017	Pass
Biomal	03:32	06:11	07:22	08:05	08:16	08:30	06:59 ± 0.078	Pass
Paradol	01:28	01:40	01:60	02:15	02:20	03:30	02:11 ± 0.030	Pass
Paramol	03:40	03:42	0.3:44	03:56	04:13	04:25	03:56 ± 0.012	Pass
Pandol Advance	00:16	00:28	01:25	01:46	01:58	02:22	01:22 ± 0.035	Pass
Refamol	00:10	00:17	00:35	01:34	02:29	02:30	01:15 ± 01:04	Pass
Ramol	02:17	02:20	02:26	02:30	02:35	02:40	02:28 ± 0.006	Pass
Newdol	00:34	00:52	00:55	01:13	01:17	01:22	01:02 ± 0.013	Pass

Assay[24]

The present study has made to estimate the quantities difference of various brands of Paracetamol tablet formulation. The taste was performed following the British Pharmacopeia (BP) method using Spectrophotometer for assay of chemical content using a reference standard to determine the amount of Paracetamol presents in each brand. BP Specification: 95-105%.[24] The result were illustrated in Table (6).

Table (6): Percentage testes for different brands of Paracetamol collected from Sana'a market Yemen.

Brands Tarde Name	Mean of Abs.	S D	R S D	Absorbance	% of label claim	Remarks
Adol	0.7290	0.0001	0.02	0.7288 0.7290 0.7291	100.70%	Pass
Amol	0.7226	0.0006	0.08	0.7219 0.7228 0.7230	99%	Pass
Biomol	0.7270	0.0001	0.02	0.7271 0.7269 0.7271	100.62%	Pass
Paradol	0.7361	0.0001	0.01	0.7361 0.7361 0.7362	102%	Pass
Pandol Advance	0.7111	0.0001	0.01	0.7111 0.7110	98%	Pass

				0.7111		
Paramol	0.7160	0.0002	0.02	0.7160 0.7161 0.7158	99.78%	Pass
Rafamol	0.7147	0.0004	0.05	0.7151 0.7145 0.7145	99%	Pass
Ramol	0.7229	0.0016	0.23	0.7248 0.7221 0.7218	100.35%	Pass
Newdol	0.7245	0.0002	0.03	0.7242 0.7247 0.7245	99.74%	Pass

CONCLUSION

All brands examined complied with the USP/BP specifications in terms of weight variation, and met USP/ BP specification standards for friability, disintegration, drug content and only show variation in the hardness.

Thus, among the nine brands of paracetamol tested, Amol, Biomol, Paradol, Panadol Advance, Adol, Rafamol and Newdol showed comparatively acceptable standard deviation of their hardness except Remol and Paramol which do not pass the taste.

However, in the results of few parameters, a little deviation from standard was observed in the local brand of paracetamol when compared to those manufactured by the multinational companies. Such as Glaxo smith Kline, Global Pharm, Jluphar pharm and Biopharm. Further studies need to be conducted to test the potency and dissolution profile of the brands to confirm their pharmaceutical equivalence.

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