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Original Article

Comparative study of four different brands of acetaminophen available in Karachi

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ABSTRACT

Acetaminophen is used analgesic and available in several brands in the market which makes it difficult to select the safe and effective one. There for The aim of study to establish pharmaceutical equivalence of the different brands of acetaminophen tablets available in Karachi, Pakistan. Four different brands of acetaminophen tablets (500 mg) were included in study. The quality control parameters which are studied are weight variation test, hardness test, thickness, friability, disintegration and dissolution specified by BP/USP (British and United state Pharmacopoeia) .Weight variation and hardness value requirement was complied by all brands .Disintegration time for all brands was within 15 minutes also complying the BP/USP recommendation. All brands showed more than 80 % drug release within 45 minutes. The present findings suggest that almost all the brands of acetaminophen that are available in Karachi meet the BP/USP specification for quality control analysis.

Key words: acetaminophen, comparative study, available brands

INTRODUCTION

Paracetamol fig1 belong to non-steroidal anti-inflammatory drug (NSAID) and it is prescribed most frequently for pain relieve. It is also used as antipyretic agent with analgesic and in the relief of headaches, fever and other aches [1]. Chemically, it is 4-hydroxy acetanilide and it is generally safe for human use at the recommended doses. But when overdoses of paracetamol cause fatal liver damage and in rare individuals, with normal dose can do the same.[2] The safety and efficacy of a pharmaceutical dosage form depend on its quality.[3] The efficacy of pharmaceutical dosage forms generally depends on their formulation properties, and manufacturing methods, hence it is likely that the quality of dosage form may vary.[4-5] Dissolution test which is one of the *in vitro* tests usually used to assess the quality of oral pharmaceutical dosage forms such as tablets and capsules. *In vitro* dissolution tests can be used as a guide line for formulation developments, and also identify manufacturing variables, quality monitor formulation from batch to batch and also predict the *in vivo* performances and also important for bioavailability and bioequivalence.[6-7] Therefore, we have decided to carry out the comparative evaluation of qualities of various commercially available paracetamol tablet. Paracetamol tablets of 500 mg were selected for the study. Statistical assessment of various dissolution was also conducted to establish if there were any differences among them. The aim of this study is to investigate the physico-chemical parameters of commercially available four brands of paracetamol in Karachi,Pakistan.

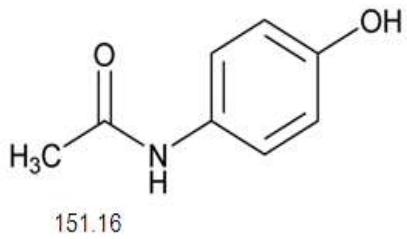

Figure 1:paracetamol

METHODOLOGY

In this Comparative study, quality control parameters between the commercially available four different tablet brands of paracetamol were studied in *Jinnah University for women Karachi, Pakistan* through the evaluation of average weight, weight variation, hardness, friability, disintegration time and dissolution profile. The four different brands were purchased from different Public medical store located in Karachi, Pakistan. All tablets of each brand have same batch number and were labeled to conatin Paracetamol B.P 500mg

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per tablet. All the four brands have 5 year shelf life.The serial number as identification mark of purchased brands are shown in Tabel 1.After identification marking the above mentioned tests were performed step by step.

Weight variation and average weight: Twenty tablets were selected from each of the brand and weighed individually using Electronic Balance FX-400.Note down the weight of each tablet on sheet in mg.Calculate average weight in mg.

Hardness: There is no official limit specified in USP,BP or any other Pharmacopeia.Hardness or crushing strength were checked on 10 tablets of each brand using Hardness Tester MH-1,Galveno Scientific.Place tablets one by one and when the device was started,gradually applied force onto the tablet until it split, and the force at which the tablet split was recorded in Newtons.

Thickness: During testing, thickness of ten tablets from each brand were determined by using Vernier Caliper. Place each tablet one by one in the Jaw and note the thickness reading in mm.

Friability: Ten tablets for each brand were initially weighed and transferred into Friabilator FB-400 one by one. The friabilator was operated at 25 rpm for 4 minutes (up to 100 revolutions). The tablets were weighed again and the calculate the friability in %. NMT 1% is the official limit.

% Friability=Initial Weight(IW) - Final Weight(FW) / Initial Weight(IW)

Disintegration Test: Six tablets of each brand were selected and placed in six tubes of the basket and place a small disc over it. The time taken to break each tablet into small particles or granules and pass out through the mesh or no particles or granules left in the tube was recorded in sec or min or both. Disintegration Tester was Curro DS-0702.

Dissolution Profile: Dissolution test was performed on apparatus having model no GDT-7L of Galvano Scientific**.**Take 900ml distill water as a medium(due to unavailability of phosphate buffer) in four beakers,maintained at 37 ^{0}C using water bath.Place one tablet from each brand in the beaker separately. Allow the apparatus to run at 50rpm for 30min.Take 5ml sample from each beaker with the help of pipette at 10min,20min and 30min.After collection of samples,take absorbance at 243nm for each sample using UV-Spectrophotometer.Calculate the amount of dissolved paracetamol in 30min.

RESULTS

The physicochemical analysis of four Paracetamol Tablet brands show following results:The results of Average weight for ACP-01 is 607.2mg with 636.1-607.2mg upper & lower limit, ACP-02 is 614.5mg with 631.8-597.4mg upper& lower limit,ACP-03 is 555.1mg with 574.7-535.5mg upper & lower limit,ACP-04 is 593.8mg with 621.1-565.6mg upper & lower limit shown in Table The Results of Thickness(mm) for ACP-01 is 4.24 with 4.4-4.1 upper and lower limit,ACP-02 4.38 with 4.5-4.26 with upper and lower limits,ACP-03 is 4.38 with 4.5-4.26 upper and lower limit,ACP-04 is 4.22 with 4.34-4.1 upper and lower limit shown in Table 1,2. The results of Hardness(Newton) for ACP-01 is 78.2 with 92.2-63.2 upper & lower limit,ACP-02 is 95.5 with 95.5-51.7 with upper & lower limit, ACP-03 is 114.6 with 140.1-89.1 upper & lower limit,ACP-04 is 106.4 with 133.7-79.1 upper & lower limit shown in Table3,4. The results of Friability for ACP-01 & ACP-02 are same that is 0.02 %,ACP-03 is 0.08%,ACP-04 is 0.12% shown in Table 5. The Disintegration Test for ACP-01 is 40sec,ACP-02 is 2min & 35sec,ACP-03 is 1min& 35sec,ACP-04 is 1min & 30sec shown in Table 6.The results of Dissolution for ACP-01 is 100.09 % ,ACP-02 is 98.43%,ACP-03 is 99.36% shown is Table 7,8.

DISCUSSION

The purpose of this research work was to compare and evaluate the quality standards of commercially available four brands of Paracetamol Tablet in Karachi, Pakistan.Paracetamol Tablets (500mg) were evaluated comparatively for their physical and chemical parameters.Performed physical and chemical tests like in-vitro dissolution, disintegration, hardness, friability,weight variation and thickness. According to B.P Specification all the Paracetamol Tablets of four brands were predictable not to deviate by ± 5% of the average tablet weight. Auspiciously, there were no tablet of each four brands deviate from the specified limit and all tablets passed the Weight variation test. According to BP/USP Friability should not be more than 1% and ACP-04 have grater friability than other 3 brands but all testing results of all four brands came under the specified limit i.e NMT 1%.According to B.P the core tablet should not cross 15min duration during disintegration process and ACP-01 took less time to disintegrate i.e 40sec and ACP-03 & ACP-04 disintegrate within 2min where as ACP-02 took more time i.e more than 2min as compared to other three brands.The selected four brands for this study were not cross the time.According to U.S.P official limits for Paracetamol Tablet dissolved amount of

Paracetamol should not less than 80% (Q) of the labeled amount in 30 min and our results came under the specified limit.There is no official limit for Hardness and Thickness of Tablets.Analysis for thickness shows that all brands have almost similar thickness and for hardness,two brands ACP-03 & ACP-04 have more hardness than ACP-01 & ACP-02.Hence it is concluded that the results of each testing of selected brands of Paracetamol Tablet shows variation but these variation is in specified limit.

Table 1: General Table

No.	Brand Name	Serial No.	Code No.	Batch No.
1	Disprol	Para-1	1657	3146
2	Calpol	Para-2	1612	CCDHP
3	Febrol	Para-3	23530	A2695
4	Panadol	Para-4	817	AL65

Table 2:Statistical Weight Variation

No.	Serial No.	Batch No.	Average weight (X) mg	Standard Deviation (S)	UpperLimit (UCL=X+3S)	Lower Limit (LCL=X-3S)
1	Para-1	3146	600.1	17.36	652.18	548.02
2	Para-2	CCDHP	616.6	5.54	633.22	599.98
3	Para-3	A2695	591.85	37.29	703.72	479.98
4	Para-4	AL65	555.1	38.79	671.47	438.73

Table 3:Statistical Hardness Variation

No.	Serial No.	Batch No.	Average Hardness (X) Newton	Standard Deviation (S)	Upper Limit (UCL=X+3S)	Lower Limit (LCL=X-3S)
1	Para-1	3146	78.2	5.0	93.2	63.2
2	Para-2	CCDHP	73.6	7.3	95.5	51.7
3	Para-3	A2695	114.6	8.5	140.1	89.1
4	Para-4	AL65	106.4	9.1	133.7	79.1

Table 4:Statistical Thickness Variation

No.	Serial No.	Batch No.	Average Thickness (mm)	Standard Deviation (S)	UpperLimit (UCL=X+3S)	LowerLimit (LCL=X-3S)
1	Para-1	3146	4.24	0.05	4.4	4.1
2	Para-2	CCDHP	4.38	0.04	4.5	4.26
3	Para-3	A2695	4.38	0.04	4.5	4.26
4	Para-4	AL65	4.22	0.04	4.37	4.1

Table 5:Statistical Friability Variation

Serial No.	**Code No.**	**Batch No.**	**Result (%)**	**B.P/USP Spec.**	**Deviation From BP/USP**
Para-1	1657	3146	0.02	NMT 1%	Pass
Para-2	1612	CCDHP	0.02	NMT 1%	Pass
Para-3	23530	A2695	0.08	NMT 1%	Pass
Para-4	817	AL65	0.12	NMT 1%	Pass

Table 5: Disintegration Test

Serial No.	**Code No.**	**Batch No.**	**Result**	**B.P/USP Spec.**	**Deviation From BP/USP**
Para-1	1657	3146	40sec	NMT 15min	Pass
Para-2	1612	CCDHP	2min 27sec	NMT 15min	Pass
Para-3	23530	A2695	1min 35sec	NMT 15min	Pass
Para-4	817	AL65	1min 30sec	NMT 15min	Pass

Table 6: Dissolution Test

Serial #	**Absorbance nm**		
	10min	20min	30min
Para-01	3.329	3.255	3.255
Para-02	3.329	3.159	3.201
Para-03	3.26	3.193	3.24
Para-04	3.303	3.284	3.252

Table 7: Dissolution Test

Serial No.	Code No	Batch No	Result	USP Spec.	Deviation From Official Limit
Para-1	1657	3146	100.09%	Not Less than 80%	Pass
Para-2	1612	CCDHP	98.43%		Pass
Para-3	23530	A2695	99.63%		Pass
Para-4	817	AL65	100.0%		Pass

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