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DETERMINATION OF THE QUALITY CONTROL PARAMETERS OF PARACETAMOL TABLETS IN INDIAN PHARMACEUTICAL MARKET

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ABSTRACT

As drugs have to be marketed as safe and therapeutically active formulations with consistent and predictable outcomes, the quality of any pharmaceutical product is very important. Assessment of the physiochemical properties of pharmaceutical products will ensure the quality and bioavailability of pharmaceutical products and provide maximum therapeutic effectiveness. Paracetamol tablets were selected for this comparative study because they are widely used worldwide to treat moderate to severe pain and fever. This is one of several Indian pharmaceutical firms that typically manufacture and distribute medications. The study aims to compare the different physical parameters for quality assessment and tablet characterization of five different brands of Indian pharmaceutical companies, including weight variation, stiffness, friability, and time of disintegration. The indicated compendial approach was adopted for their assessment test.

KEYWORDS: Paracetamol, Weight variation, Hardness, Friability, disintegration time

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INTRODUCTION

Paracetamol (**Figure 1**) is an over-the-counter non-steroidal anti-inflammatory drug (NSAID) commonly used as an analgesic and antipyretic agent but with limited anti-inflammatory effects because, in the presence of high peroxide concentrations, it has a low ability to suppress cyclooxygenase (COX), as is seen at inflammation sites. 1000 mg, the daily dose most widely ingested, [1] results in roughly 50% inhibition of both COX-1 and COX- 2 in whole body blood assays ex vivo in healthy volunteers.

COX inhibitors have been proposed to be overwhelmingly pronounced in the brain, which explains their anti-pyretic efficacy. It is used to alleviate mild to moderate headaches, body aches, menstrual cycles, sore throats and colds, toothaches, backaches, osteoarthritis, and vaccine reactions (shots) and to minimise fever [2].

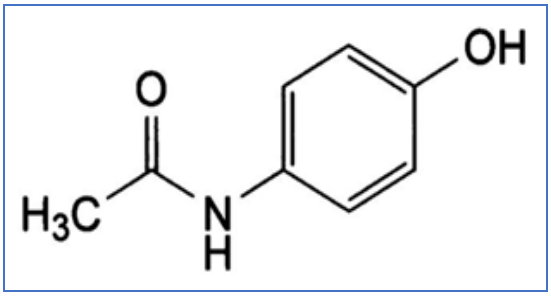

Figure 1: Structure of Paracetamol

In extreme pain, unlike opiates, it is almost inactive and has no depressant effect on breathing. It is available as a (liquid) pill, gel, suspension or solution, drops, extended-release (long-acting) pill, orally disintegrating tablet, intramuscular, intravenous and suppository type [2]. Paracetamol, at prescribed doses, is usually safe and well tolerated for human use. In comparison to NSAIDs, the frequency of gastrointestinal side effects at therapeutic doses is also minimal [3].

But acute overdosage can cause serious hepatic damage, and a normal dose can do the same in rare individuals. However, when its consistency is consistent, the protection and effectiveness of a pharmaceutical dosage type can be assured. In general, the effectiveness of pharmaceutical dosage forms depends on their formulation properties and production methods, so it is likely that the dosage form consistency can differ [3].

Dose of Paracetamol

In general, dosages for children differ according to the age of the child and the type of product, so the package instructions should always be followed (**Table 1**). In general, infant doses are based on a single dose of 10 mg of paracetamol per kilogramme of body weight that can be repeated 4-6 hours a day, with a dose not exceeding four doses every 24 hours [4].

Table 1: Dose of Paracetamol in Adult and Children

Age group	Dose
Adult	Two 500mg tablets (i.e., 1gm paracetamol) every four to six hours, not exceeding eight tablets (4gms) in any 24-hour period.
Children	**a) 2-month-old child:** single dose of 60mg (i.e. 2.5mL paracetamol liquid (oral suspension) at a strength 120mg/5 mL). Paracetamol may be given on a doctor's recommendation only following immunization **b) Under 3 months:** 10 mg paracetamol per kilogram body weight (5mg/kg if jaundiced), on a doctor's advice only. **c) 3 months to 1 year:** Between 60mg and 120mg (i.e. 2.5mL to 5mL of paracetamol liquid (oral suspension) at strength of 120mg/5mL) may be repeated every 4-6 hours to a maximum of 4 doses in 24 hours. **d) 1 to 5 years:** 120mg to 250mg (i.e. 5mL to 10mL of paracetamol liquid (oral suspension) at a strength of 120mg/5mL) may be repeated every 4-6 hours to a maximum of 4 doses in 24 hours. **e) 6 to 12 years:** 250mg to 500 mg (i.e. 5mL to 10mL paracetamol liquid (oral suspension) at a strength of 250mg/5mL) may be repeated every 4-6 hours to a maximum of 4 doses in 24 hours.

MATERIALS AND METHODS

Weight Variation Test

Materials

Electronic Analytical Balance (AY220, Shimadzu, Japan), and Tablets

Method

20 tablets were taken, and the electronic balance was used to measure each tablet separately. The total weight of all the tablets was measured and considered as the individual tablet's standard weight. All the tablets were then measured individually, and the percentage weight difference was measured to determine whether or not the individual weight was within the limit.

If no more than two tablets are beyond the percentage limit and if no tablet varies by more than twice the percentage limit, the tablets satisfy the USP test [5] (**Table 2**).

Table 2: Limit of Weight Variation Test

S. No.	Average Weight	Percentage difference
1	130 mg or less	±10
2	More than130	±7.5
3	324 mg and above	± 5

Hardness Test

Materials

Hardness tester (Veego, India), and Tablets.

Method

From each batch, 10 tablets were taken. A tablet was put individually between two anvils, strength was added to the anvils, and the crushing force was reported that only caused the tablet to break. Finally, the reading from the sliding scale was taken in kilogrammes [6].

Friability Test

Materials

Veego friability tester, Electronic Analytical Balance (AY220, Shimadzu, Japan), and Tablets.

Method

10 tablets were taken initially, and the tablets were thoroughly dusted prior to examination. The 10 tablets, which were known as the initial reading, were then weighed. All tablets were placed in the drum of the friability tester after weighing the tablets and rotated 100 times. The 10 tablets were extracted and weighed again after 100 revolutions. It was the last reading here. It measured the %. Tablets do not lose more than 1% of their total weight, according to the USP [7].

Disintegration Test

Materials

Disintegration Tester (Vanguard Pharmaceutical Machinery INC), pH meter, 0.1M HCl, and Tablets

Method

At first, the disintegration tester was assembled. Then 900ml of 0.1 M HCl (pH- 1.2) was placed in each 1000 ml beaker (N.B: The volume of the liquid was such that when the assembly is in the highest position the wire mesh was at least 15 mm below the surface of the liquid and when the assembly was in the lowest position the wire mesh was at least 25 mm above the bottom of the beaker and the upper open ends of the tubes remain above the surface of the liquid). The temperature was maintained at 37 ºC. Then one tablet was placed in each of the 6 tubes and the apparatus was operated for the prescribed period. All the tablets must disintegrate within the prescribed time. If 1 or 2 tablets fail to disintegrate completely, the test must be repeated on 12 additional tablets (**Table 3**). Disintegration is considered to be achieved when no residues remain on the screen, or if there is a residue, it consists of a soft mass having no palpably firm, unmoistened core, or only fragments of coating (tablets) may adhere to the lower surface of the disc [8].

Table 3: Limit of Disintegration Time

S. No.	Type of tablet	Disintegration time
1	Uncoated tablet	15 minutes
2	Coated tablet	1 hour or 60 minutes

RESULTS

Weight Variation

Centanil

The % weight variation of Batch 1, 2 and 3 ranged from -1.67 to 3.51%, -1.67 to 1.72% and -1.67 to 1.75% respectively (**Table 4**). The average weight of Batch# 1, 2 and 3 was 0.584g, 0.591g and 0.583g respectively (**Table 5**).

Table 4: Individual Weight and Percentage Weight Variation of the Three Batches of Centanil Tablets

		Batch#1		Batch#2		Batch#3	
Brand	S. no.	Weight (g)	Weight % Variation	Weight (g)	Weight % Variation	Weight (g)	Weight % Variation
Centanil	1	0.58	1.72	0.58	1.72	0.58	0
	2	0.57	3.51	0.59	0	0.58	0
	3	0.57	3.51	0.59	0	0.58	0
	4	0.58	1.72	0.59	0	0.59	-1.69
	5	0.59	0	0.59	0	0.58	0
	6	0.58	1.72	0.59	0	0.58	0
	7	0.59	0	0.59	0	0.59	-1.69
	8	0.58	1.72	0.59	0	0.59	0
	9	0.60	-1.67	0.59	0	0.59	0
	10	0.59	0	0.59	0	0.58	0
	11	0.58	1.72	0.59	0	0.59	-1.69
	12	0.57	3.51	0.59	0	0.59	-1.69
	13	0.58	1.72	0.59	0	0.58	0
	14	0.58	1.72	0.59	0	0.58	0
	15	0.59	0	0.60	-1.67	0.58	0
	16	0.59	0	0.59	0	0.57	1.75
	17	0.59	0	0.59	0	0.58	0
	18	0.58	1.72	0.59	0	0.58	0
	19	0.59	0	0.60	-1.67	0.58	0
	20	0.59	0	0.59	0	0.58	0

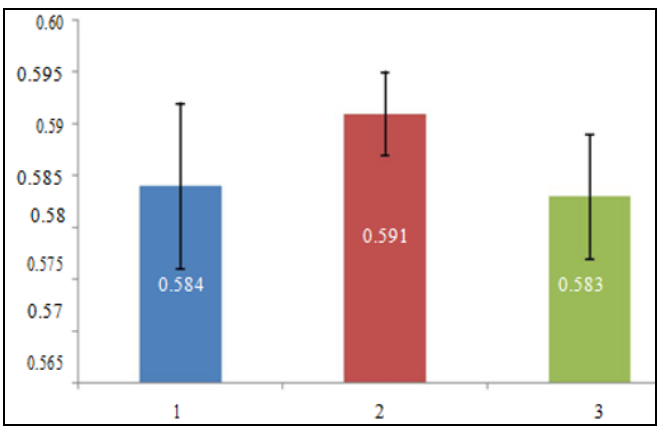

Figure 2: Mean Weight of the Three Batches of Centanil Tablets

Table 5: Mean Weight and Standard Deviation of the Three Batches of Centanil Tablets

Brand	Batch	Mean Weight (g) (n=20)	Standard Deviation
Centanil	1	0.584	0.008
	2	0.591	0.004
	3	0.583	0.006

Acimol

The % weight variation of Batch# 1, 2 & 3 ranged from -1.64 to 1.69%, -4.69 to 1.67% and -1.64 to 3.45% respectively (**Table 6**). The average weight of Batch# 1, 2 & 3 was 0.597g, 0.611g and 0.597g respectively (**Table 7**).

Table 6: Individual Weight and Percentage Weight Variation of the Three Batches of Acimol Tablets

		Batch#1		Batch#2		Batch#3	
Brand	**S. no.**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**
	1	0.59	1.69	0.60	1.67	0.59	1.69
	2	0.59	1.69	0.60	1.67	0.60	0
	3	0.59	1.69	0.60	1.67	0.59	1.69
	4	0.61	-1.64	0.60	1.67	0.58	3.45
	5	0.60	0	0.61	0	0.61	-1.64
	6	0.60	0	0.62	-1.61	0.60	0
	7	0.59	1.69	0.62	-1.61	0.60	0
	8	0.60	0	0.62	-1.61	0.60	0
	9	0.59	1.69	0.61	0	0.61	-1.64
Acimol	10	0.59	1.69	0.61	0	0.59	1.69
	11	0.61	-1.64	0.60	1.67	0.59	1.69
	12	0.60	0	0.64	-4.69	0.59	1.69
	13	0.60	0	0.62	-1.61	0.59	1.69
	14	0.60	0	0.60	1.67	0.61	-1.64
	15	0.60	0	0.61	0	0.60	0
	16	0.59	1.69	0.61	0	0.59	1.69
	17	0.59	1.69	0.62	-1.61	0.60	0
	18	0.60	0	0.62	-1.61	0.60	0
	19	0.60	0	0.61	0	0.60	0
	20	0.59	1.69	0.60	1.67	0.59	1.69

Table 7: Mean Weight and Standard Deviation of the Three Batches of Acimol Tablets

Brand	Batch	Mean weight (g) (n=20)	Standard Deviation
	1	0.597	0.007
Acimol	2	0.611	0.011
	3	0.597	0.008

Brocin

The % weight variation of Batch# 1, 2 & 3 ranged from -3.13 to 1.64%, -1.56 to 1.61% and -1.56 to 1.61% respectively (**Table 8**). The average weight of Batch# 1, 2 & 3 was 0.624g; 0.624g and 0.630g respectively (**Table 9**).

Table 8: Individual Weight and Percentage Weight Variation of the Three Batches of Brocin Tablets

		Batch#1		Batch#2		Batch#3	
Brand	**S. no.**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**
	1	0.63	-1.59	0.63	0	0.64	-1.56
	2	0.62	0	0.62	0.61	0.62	1.61
	3	0.62	0	0.62	1.61	0.63	0
	4	0.63	-1.59	0.63	0	0.63	0
	5	0.62	0	0.64	-1.56	0.64	-1.56
	6	0.62	0	0.63	0	0.63	0
	7	0.63	-1.59	0.63	0	0.63	0
	8	0.64	-3.13	0.63	0	0.63	0
	9	0.61	1.64	0.64	-1.56	0.63	0
Brocin	10	0.63	-1.59	0.63	0	0.63	0
	11	0.63	-1.59	0.63	0	0.63	0
	12	0.61	1.64	0.63	0	0.63	0
	13	0.61	1.64	0.62	0.61	0.64	-1.56
	14	0.62	0	0.62	0.61	0.64	-1.56
	15	0.62	0	0.64	-1.56	0.63	0
	16	0.63	-1.59	0.63	0	0.62	1.61
	17	0.62	0	0.63	0	0.64	-1.56
	18	0.63	-1.59	0.63	0	0.63	0
	19	0.62	0	0.63	0	0.62	1.61
	20	0.63	-1.59	0.63	0	0.63	0

Table 9: Mean Weight and Standard Deviation of the Three Batches of Brocin Tablets

Brand	Batch	Mean weight (g) (n=20)	Standard Deviation
	1	0.624	0.008
Brocin	2	0.624	0.008
	3	0.630	0.006

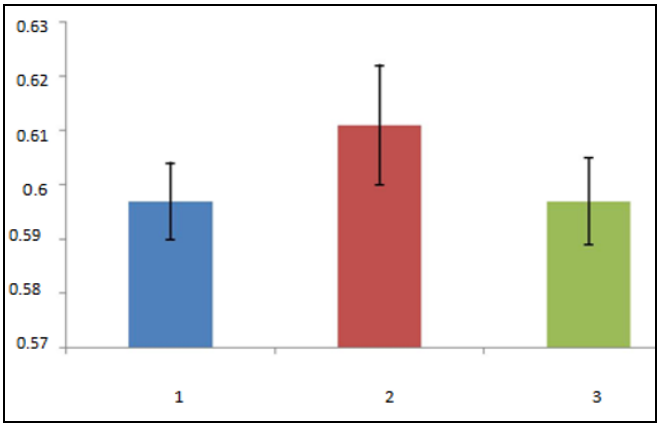

Figure 3: Mean Weight of the Three Batches of Acimol tablets

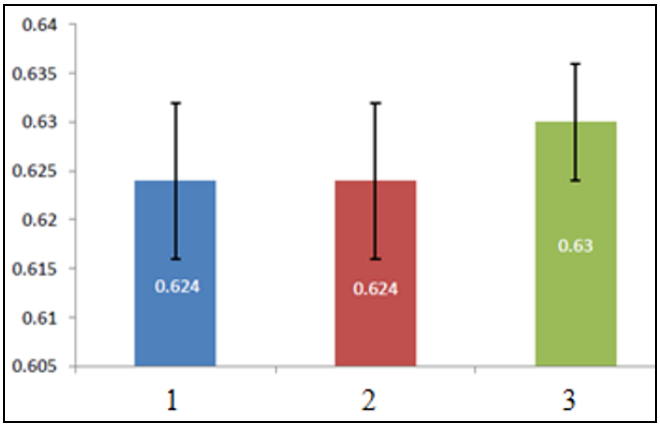

Figure 4: Mean Weight of the Three Batches of Brocin Tablets

Dolo

The % weight variation of Batch# 1, 2 & 3 ranged from -3.51 to 5.77%, -1.79 to 3.77% and -9.5 to 11.8% respectively (**Table 10**). The average weight of Batch# 1, 2 & 3 was 0.545g; 0.548g and 0.587g respectively (**Table 11**).

A-Mol

The % weight variation range of Batch# 1, 2 & 3 ranged from 1.75 to 3.57%, 0 to 1.79% & 1.75 to 3.57% respectively (**Table 12**). The average weight of Batch# 1015, 1016 and 1017 was 0.584g; 0.591g & 0.583g respectively (**Table 13**).

Table 10: Individual Weight and Percentage Weight Variation of the Three Batches of Dolo Tablets

		Batch#191		Batch#147		Batch#143	
Brand	**S. no.**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**
Dolo	1	0.55	0	0.58	0	0.63	-9.5
	2	0.55	0	0.59	3.77	0.55	3.64
	3	0.54	1.85	0.59	0	0.57	0
	4	0.54	1.85	0.59	0	0.56	1.79
	5	0.54	1.85	0.59	1.85	0.60	-5
	6	0.56	-1.79	0.59	0	0.62	-8.06
	7	0.55	0	0.59	0	0.63	-9.5
	8	0.53	3.77	0.59	0	0.62	-8.06
	9	0.54	1.85	0.59	1.85	0.62	-8.06
	10	0.52	5.77	0.59	-1.79	0.62	-8.06
	11	0.54	1.85	0.59	0	0.62	-8.06
	12	0.54	1.85	0.59	1.85	0.51	11.8
	13	0.55	0	0.59	1.85	0.53	7.55
	14	0.54	1.85	0.59	0	0.53	7.55
	15	0.56	-1.79	0.60	1.85	0.58	-1.72
	16	0.54	1.85	0.59	-1.79	0.58	-1.72
	17	0.55	0	0.59	-1.79	0.59	-3.39
	18	0.55	0	0.59	0	0.57	0
	19	0.54	1.85	0.60	0	0.61	-6.56
	20	0.57	-3.51	0.59	0	0.59	-3.39

Table 12: Individual Weight and Percentage Weight Variation of the Three Batches of A-Mol Tablets

		Batch#1		Batch#2		Batch#3	
Brand	**S. no.**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**	**Weight (g)**	**Weight % Variation**
	1	0.57	1.75	0.57	0	0.57	0
	2	0.57	1.75	0.57	0	0.56	1.79
	3	0.57	1.75	0.57	0	0.56	1.79
	4	0.56	3.57	0.57	0	0.57	0
	5	0.57	1.75	0.57	0	0.57	0
	6	0.57	1.75	0.57	0	0.57	0
	7	0.57	1.75	0.57	0	0.57	0
	8	0.57	1.75	0.57	0	0.57	0

	9	0.57	1.75	0.57	0	0.57	0
A-Mol	10	0.58	0	0.57	0	0.56	1.79
	11	0.56	3.57	0.57	0	0.57	0
	12	0.57	1.75	0.57	0	0.57	0
	13	0.57	1.75	0.57	0	0.57	0
	14	0.57	1.75	0.56	1.79	0.57	0
	15	0.57	1.75	0.56	1.79	0.56	1.79
	16	0.57	1.75	0.57	0	0.57	0
	17	0.57	1.75	0.56	1.79	0.57	0
	18	0.57	1.75	0.56	1.79	0.57	0
	19	0.57	1.75	0.57	0	0.58	-1.72
	20	0.57	1.75	0.57	0	0.57	0

Table 11: Mean Weight and Standard Deviation of the Three Batches of Dolo Tablets

Brand	Batch	Mean weight (g) (n=20)	Standard Deviation
	1	0.545	0.011
Dolo	2	0.548	0.008
	3	0.587	0.036

Table 13: Mean Weight & Standard Deviation of the Three Batches of A-Mol Tablets

Brand	Batch	Mean weight (g) (n=20)	Standard Deviation
	1	0.584	0.008
A-Mol	2	0.591	0.004
	3	0.583	0.006

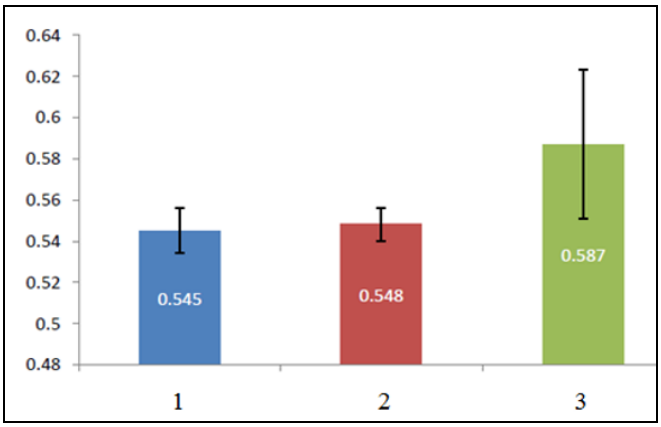

Figure 5: Mean Weight of the three batches of Dolo Tablets

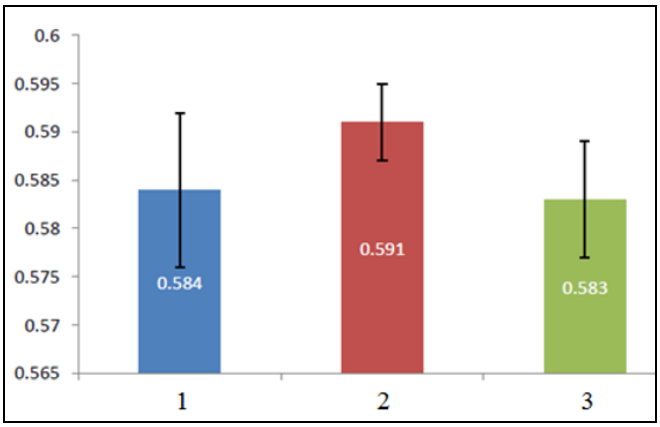

Figure 6: Mean Weight of the three batches of A-Mol Tablets

Hardness

Centanil

The hardness of Batch# 1, 2 & 3 ranged from 7.2 to 9.1kg, 6.0 to 10.1kg and 13.0 to 17.7kg respectively (**Table 14**). The average hardness of Batch# 1, 2 & 3 was 8.41kg, 7,84kg and 15.54kg respectively (**Table 15**).

Acimol

The hardness of Batch# 711, 591 and 650 ranged from 8.8 to 11.6kg, 10.0 to 13.1kg and 8.4 to 12.4kg respectively (**Table 16**). The average hardness of Batch# 1, 2 & 3 was 10.03kg, 11.74kg and 10.77kg respectively (**Table 17**).

Table 14: Hardness of the Three Batches of Centanil Tablets

Brand	Tab No.	Batch#1 Hardness (kg)	Batch#2 Hardness (kg)	Batch#3 Hardness (kg)
	1	9.1	6.0	13.0
	2	7.8	10.1	16.8
	3	7.2	6.6	15.2
	4	8.3	8.0	15.0
Centanil	5	9.0	6.8	13.4
	6	8.8	10.1	17.7
	7	8.6	6.4	15.8
	8	8.6	7.2	15.5
	9	8.5	8.2	16.2
	10	8.2	9.0	16.8

Table 16: Hardness of the Three Batches of Acimol Tablets

Brand	Tab No.	Batch#1 Hardness (kg)	Batch#2 Hardness (kg)	Batch#3 Hardness (kg)
Acimol	1	9.1	11.0	10.8
	2	11.4	12.0	10.8
	3	9.8	12.2	11.6
	4	9.8	14.0	10.2
	5	11.2	10.8	12.4
	6	8.8	13.1	11.8
	7	8.8	11.2	10.5
	8	10.8	10.7	9.8
	9	11.6	10.0	8.4
	10	9.0	12.4	11.4

Table 15: Mean Hardness and Standard Deviation of the Three Batches of Centanil Tablets

Brand	Batch	Mean hardness (kg)	Standard Deviation
Centanil	1	8.41	0.572
	2	7.84	1.498
	3	15.54	1.482

Table 17: Mean Hardness and Standard Deviation of the Three Batches of Acimol Tablets

Brand	Batch	Mean hardness (kg)	Standard Deviation
Acimol	1	10.03	1.124
	2	11.74	1.225
	3	10.77	1.143

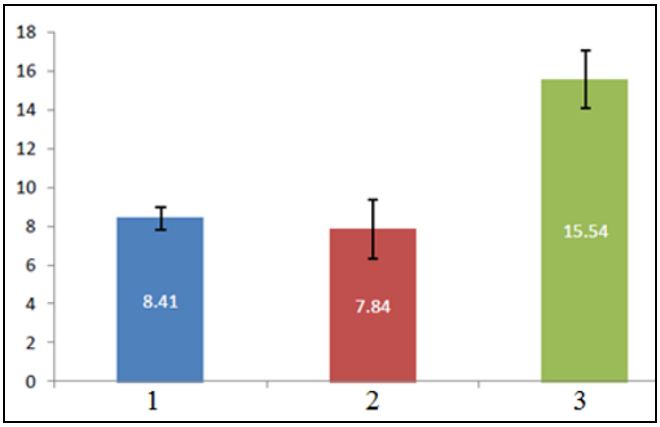

Figure 7: Mean Hardness of the Three Batches of Centanil Tablets

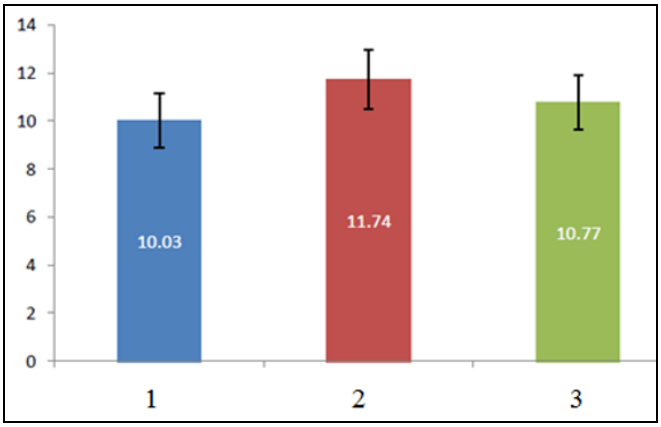

Figure 8: Mean Hardness of the Three Batches of Acimol Tablets

Brocin

The hardness of Batch# 1, 2 & 3 ranged from 13.5 to 18.7kg, 12.0 to 17.1kg and 12.5 to 19.0kg respectively (**Table 18**). The average hardness of Batch# 1, 2 & 3 was 15.46kg, 14.58kg and 15.18kg respectively (**Table 19**).

Dolo

The hardness of Batch# 1, 2 & 3 ranged from 11.4 to 17.6kg, 12.1 to 16.5kg and 5.4 to 18.4kg respectively (**Table 20**). The average hardness of Batch# 1, 2 & 3 was 13.33kg, 14.87kg and 10.15kg respectively (**Table 21**).

Table 18: Hardness of the Three Batches of Brocin Tablets

Brand	Tab No.	Batch#1 Hardness (kg)	Batch#2 Hardness (kg)	Batch#3 Hardness (kg)
Brocin	1	13.7	13.7	14.9
	2	13.5	12.0	16.3
	3	16.8	14.7	17.9
	4	14.7	14.6	12.5
	5	16.2	14.0	14.7
	6	16.0	13.9	16.9
	7	14.4	14.5	19.0
	8	18.7	16.0	12.7
	9	16.6	17.1	13.3
	10	14.0	15.3	13.6

Table 20: Hardness of the Three Batches of Dolo Tablets

Brand	Tab No.	Batch#1 Hardness (kg)	Batch#2 Hardness (kg)	Batch#3 Hardness (kg)
Dolo	1	12.4	12.1	5.4
	2	13.9	15.7	5.6
	3	12.2	15.9	18.4
	4	11.4	12.9	17.2
	5	12.9	15.5	8.2
	6	17.6	16.5	16.2
	7	12.5	15.2	7.6
	8	13.0	14.9	5.0
	9	15.3	16.0	10.4
	10	12.1	14.0	7.5

Table 19: Mean Hardness and Std. Deviation of the Three Batches of Brocin Tablets

Brand	Batch	Mean hardness (kg)	Standard Deviation
Brocin	11031	15.46	1.673
	11171	14.58	1.380
	F118	15.18	2.258

Table 21: Mean Hardness and Standard Deviation of the Three Batches of Dolo Tablets

Brand	Batch	Mean hardness (kg)	Standard Deviation
Dolo	191	13.330	1.850
	147	14.870	1.434
	143	10.150	5.181

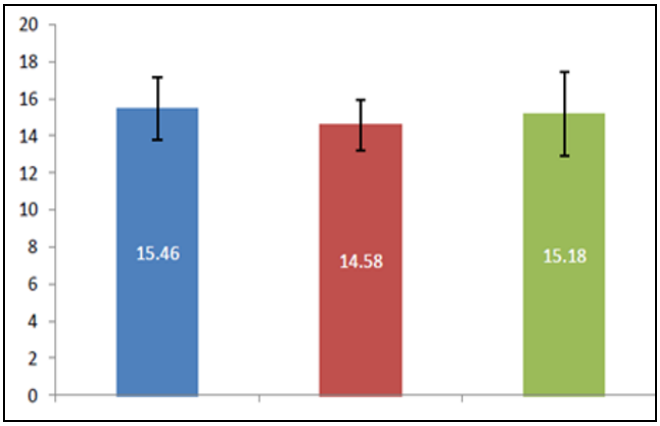

Figure 9: Mean Hardness of the three batches of Brocin Tablets

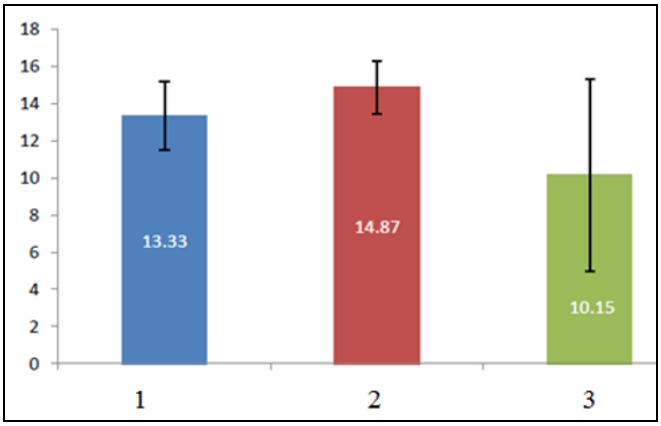

Figure 10: Mean Hardness of the three batches of Dolo Tablets.

A-Mol

The hardness of Batch# 1, 2 & 3 ranged from 10.0 to 19.0 kg, 13.3 to 18.6kg and 117.9 to 18.0kg respectively (**Table 22**). The average hardness of Batch# 1, 2 & was 14.86kg, 16.24kg and 16.18kg respectively (**Table 23**).

Table 22: Hardness of the Three Batches of A-Mol Tablets

Brand	Tab No.	Batch#1 Hardness (kg)	Batch#2 Hardness (kg)	Batch#3 Hardness (kg)
A-Mol	1	18.0	14.0	16.0
	2	16.2	18.6	14.3
	3	9.8	17.4	17.5
	4	15.3	16.2	18.1
	5	16.0	17.9	17.9
	6	17.5	16.5	17.6
	7	17.0	13.6	15.9
	8	7.9	17.1	19.0
	9	13.7	17.8	10.0
	10	17.2	13.3	15.5

Table 23: Mean Hardness and Standard Deviation of the Three Batches of A-Mol Tablets

Brand	Batch	Mean Hardness (kg)	Standard Deviation
A-Mol	1015	14.86	1.673
	1016	16.24	1.380
	1017	16.18	2.258

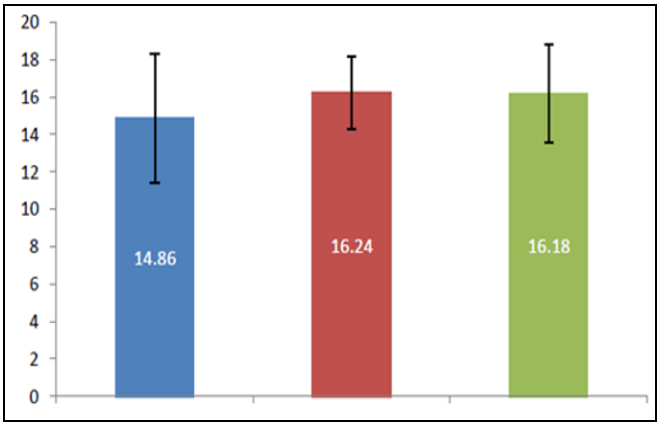

Figure 11: Mean Hardness of the Three Batches of A-Mol Tablets

Friability

Napa

The percentage friability of Batch# SVA120 was 0.51%, Batch# SUL330 was 0.84% and Batch# 04450 was 0.34% (**Table 24**).

Table 24: Study of Friability of Napa Tablets

Batch	Initial weight of 10 tablets	Final weight of 10 tablets	% friability
SVA120	5.85	5.82	0.51
SUL330	5.92	5.87	0.84
04450	5.82	5.80	0.34

Parapyrol

The percentage friability of Batch# 711 was 0.51%, Batch# 591 was 0.66% and Batch# 650 was 0.33% (**Table 25**).

Table 25: Study of Friability of Parapyrol Tablets

Batch	Initial weight of 10 tablets	Final weight of 10 tablets	% friability
711	5.93	5.90	0.51
591	6.09	6.05	0.66
650	5.98	5.96	0.33

Reset

The percentage friability of Batch# 1103 was 0.48%, Batch# 11171 was 0.48% and Batch# F118 was 0.63% (**Table 26**).

Table 26: Study of Friability of Reset Tablets

Batch	Initial weight of 10 tablets	Final weight of 10 tablets	% friability
11031	6.23	6.20	0.48
11171	6.26	6.23	0.48
F118	6.34	6.30	0.63

Zerin

The percentage friability of Batch# 191 was 0.91%, Batch# 147 was 0.55 and Batch# 143 was 0.85% (**Table 27**).

Table 27: Study of Friability of Zerin Tablets

Batch	Initial weight of 10 tablets	Final weight of 10 tablets	% friability
191	5.48	5.43	0.91
147	5.49	5.46	0.55
143	5.86	5.81	0.85

Tamen

The percentage friability of Batch# 1017 was 0.35%, Batch# 1016 was 0.35% and Batch# 1015 was 0.18% (**Table 28**).

Table 28: Study of Friability of Tamen Tablets

Batch	Initial weight of 10 tablets	Final weight of 10 tablets	% friability
1015	5.68	5.67	0.18
1016	5.67	5.65	0.35
1017	5.70	5.68	0.35

Disintegration Time

Napa

The disintegration time for Batch# SVA120, SUL330 and 04450 ranged from 80-111sec, 56-196 sec and 99-106 sec respectively (**Table 29**). The mean disintegration time of Batch# SVA120, SUL330 and 04450 was 95.167sec, 92.333sec and 102.5sec (**Table 30**).

Parapyrol

The disintegration time for Batch# 591, 650 and 711 ranged from 3870-3959sec, 3709-4148sec and 230-1222sec respectively (**Table 31**). The mean disintegration time of Batch# 591, 650 and 711 was 3910.333 sec, 3913.167 sec and 834.833 sec respectively (**Table 32**).

Reset

The disintegration time for Batch# 11031, 11171 and F118 ranged from 50-148 sec, 74-139 sec and 45-86 sec respectively (**Table 33**). The mean disintegration time of Batch# 11031, 11171 and F118 was 88.333 sec, 107.167 sec and 56 sec respectively (**Table 34**).

Zerin

The disintegration time for Batch# 143, 191 and 147 ranged from 126-608 sec, 370-416 sec and 198-238sec respectively (**Table 35**). The mean disintegration time of Batch# 143, 191 and 147 was 88366.167sec, 390.667sec and 219sec respectively (**Table 36**).

Tamen

The disintegration time for Batch# 1015, 1016 and 1017 ranged from 116-138sec, 196-249sec and 155-192sec respectively (**Table 37**).

Table 29: Disintegration Time of the Three Batches of Napa Tablets

Brand	Tab no.	Batch# 1015 Time (sec)	Batch# 1016 Time (sec)	Batch# 1017 Time (sec)
Tamen	1	116	196	155
	2	119	220	157
	3	121	222	162
	4	133	226	171
	5	135	230	177
	6	138	249	192

Table 31: Disintegration time of the Three Batches of Parapyrol Tablets

Brand	Tab no.	Batch# 591 Time (sec)	Batch# 650 Time (sec)	Batch#711 Time (sec)
Parapyrol	1	3870	3709	230
	2	3889	3712	611
	3	3892	3913	726
	4	3895	3971	1081
	5	3957	4026	1139
	6	3959	4148	1222

Table 30: Mean Disintegration Time and Standard Deviation of the Three Batches of Napa Tablets

Brand	Batch	Mean time (sec) (n=6)	Standard deviation
Napa	SVA120	95.167	11.957
	SUL330	92.333	54.485
	04450	102.5	3.209

Table 32: Mean Disintegration Time and Standard Deviation of the Three Batches of Parapyrol Tablets

Brand	Batch	Mean time (sec) (n=6)	Standard deviation
Parapyrol	591	3910.333	37.946
	650	3913.167	175.143
	711	834.833	382.304

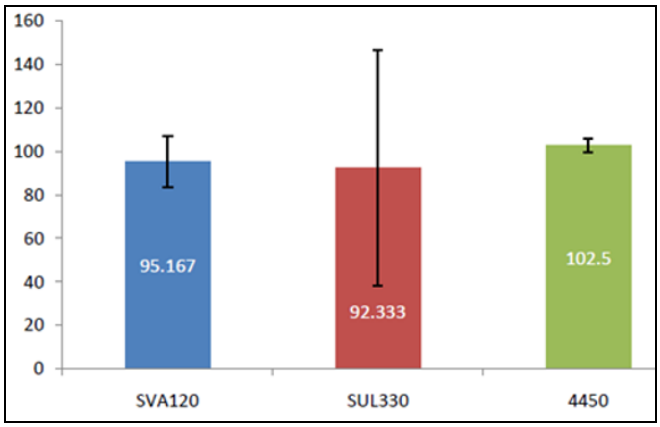

Figure 12: The Mean Disintegration Time of Three Batches of Napa Tablet

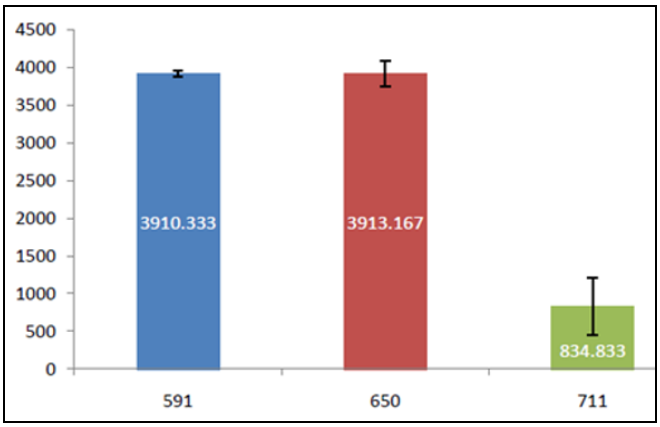

Figure 13: The Mean Disintegration Time of Three Batches of Parapyrol Tablet

Table 33: Disintegration Time of the Three Batches of Reset Tablets

Brand	Tab no.	Batch# 11031 Time (sec)	Batch# 11171 Time (sec)	Batch# F118 Time (sec)
Reset	1	50	74	45
	2	60	81	46
	3	70	99	48
	4	76	119	52
	5	126	131	59
	6	148	139	86

Table 35: Disintegration Time of the Three Batches of Zerin Tablets

Brand	Tab no.	Batch# 143 Time (sec)	Batch# 191 Time (sec)	Batch# 147 Time (sec)
	1	126	370	198
	2	217	375	210

Zerin	3	313	378	218
	4	383	400	222
	5	550	405	228
	6	608	416	238

Table 34: Mean Disintegration Time and Standard Deviation of the Three Batches of Reset Tablets

Brand	Batch	Mean time (sec) (n=6)	Standard deviation
Reset	11031	88.333	39.343
	11171	107.167	26.731
	F118	56	15.556

Table 36: Mean Disintegration Time and Standard Deviation of the Three Batches of Zerin Tablets

Brand	Batch	Mean time (sec) (n=6)	Standard deviation
Zerin	143	366.167	187.253
	191	390.667	18.801
	147	219.000	13.957

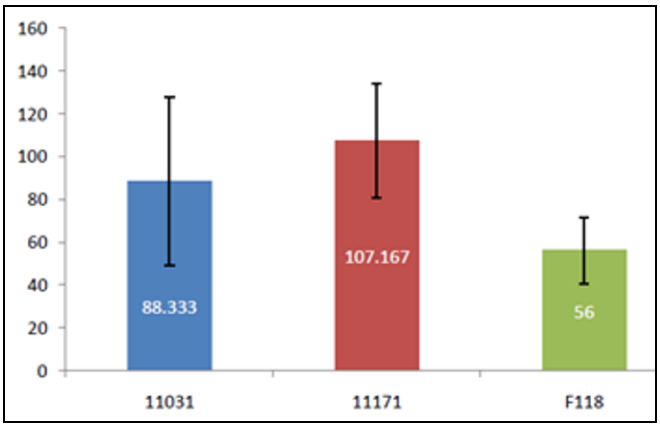

Figure 14: The Mean Disintegration Time of Three Batches of Reset Tablet

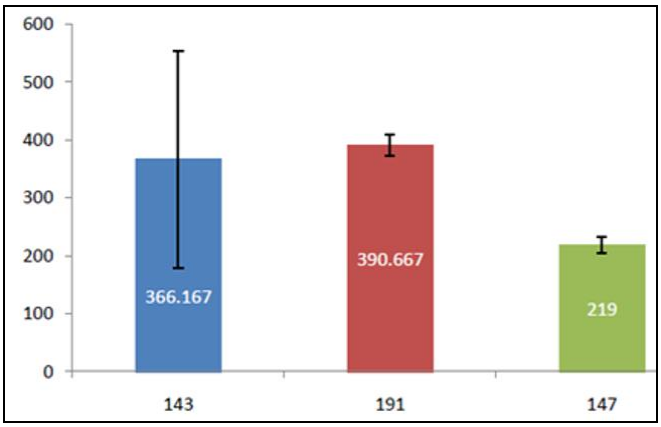

Figure 15: The Mean Disintegration Time of Three Batches of Zerin Tablet

Table 37: Disintegration Time of the Three Batches of Tamen Tablets

Brand	Tab no.	Batch# 1015 Time (sec)	Batch# 1016 Time (sec)	Batch# 1017 Time (sec)
Tamen	1	116	196	155
	2	119	220	157
	3	121	222	162
	4	133	226	171
	5	135	230	177
	6	138	249	192

Table 38: Mean Disintegration Time and Standard Deviation of the Three Batches of Tamen Tablets

Brand	Batch	Mean time (sec) (n=6)	Standard deviation
Tamen	1015	127	9.402
	1016	223.833	17.140
	1017	169	14.043

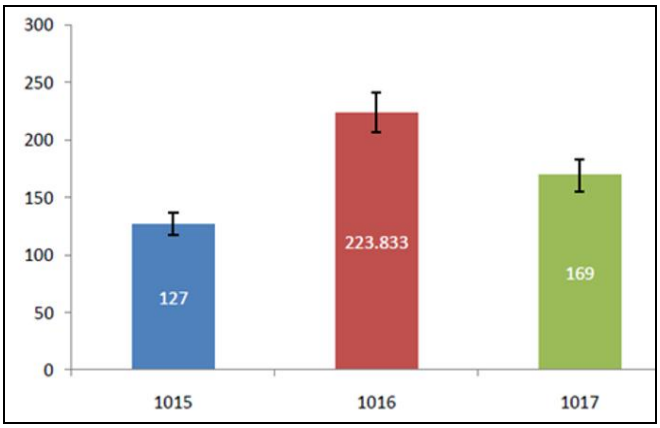

Figure 16: The Mean Disintegration Time of Three Batches of Tamen Tablets

The mean disintegration time of Batch# 1015, 1016 and 1017 was 127sec, 223.833 and 169sec respectively (**Table 38**).

DISCUSSION

Weight Variation

The combined impact of the weight variation test is to ensure that the same batch is within the reasonable limits for all tablets in a batch. Tablets are expected to conduct a test of weight variation where the active ingredient occupies a major portion of the tablet and where weight regulation can be assumed to be sufficient

control of the uniformity of the drug content. It is necessary that the tablets meet the specification indicating the uniform distribution of the active ingredient within the tablets. All the three batches of Napa (SVA120, SUL330 and 04450), Parapyrol (711, 591 and 650), Reset (11031, 11171 and F118), Zerin (191 and 147) and Tamen (1015, 1016 and 1017) showed a percentage weight variation within the range of ±5 and, therefore, comply with the specification of USP that is mentioned in **Table 2**. Batch # 143 of the Zerin brand did not, however, reach the range and was found to have a percentage weight difference of -9.5 to 11.8 percent, which is below the appropriate range of ±5 percent , resulting in the active ingredient being non-uniformly distributed. All the other 14 batches of the five separate brands have passed the criteria of quality control.

Hardness

In order to withstand the mechanical shocks of handling and transportation, tablets require a certain amount of strength or stiffness, but are soft enough to be able to disintegrate properly after swallowing. As there is also a relationship between the tablets 'hardness and disintegration rate, it is critical that the tablets' hardness is within the appropriate range. Tablets with higher values of hardness tend to have an increased duration of disintegration. However, a minimum hardness of 4kg is essential. All the three batches of Napa (SVA120, SUL330 and 04450), Parapyrol (711, 591 and 650), Reset (11031, 11171 and F118), Zerin (191, 147 and 143) and Tamen (1015, 1016 and 1017) have a hardness within the acceptable range and, therefore, comply with the specification of USP.

Friability

When they are exposed to pressures from collision and tablets falling towards each other and other solid substances, tablets should be able to avoid abrasion, which can result in the removal from the tablet surface of small fragments and particles. A overall weight loss of not more than 1% of the weight of the tablets being tested is usually considered appropriate during the friability test and no damaged or crushed tablets are collected. All the three batches of Napa (SVA120, SUL330 and 04450), Parapyrol (711, 591 and 650), Reset (11031, 11171 and F118), Zerin (191, 147 and 143) and Tamen (1015, 1016 and 1017) have passed the friability test and have met the specification of USP which specifies that if friability study is performed with ten tablets of any batch they must not lose 1% of their initial weight.

Disintegration

The disintegration test is an important physical parameter in the form of a solid dose and is essential for improved bioavailability. If the tablet is properly disintegrated, then the tablet's dissolution profile will be good, leading to better absorption and thus better therapeutic action. Therefore, a drug's efficacy is related to its time of disintegration. Disintegration time may vary considering to its disintegrator used. All the three batches of Napa (SVA120, SUL330 and 04450), Parapyrol (711, 591 and 650), Reset (11031, 11171 and F118), Zerin (191, 147 and Tamen (1015, 1016 and 1017) have a disintegration time that is within the acceptable range and have met the specification of USP where a majority of the tablets have a maximum disintegration time of 30 minutes.

CONCLUSION

Paracetamol is a drug without a prescription. It is also important that it is made according to Good Manufacturing Practice (GMP). In this review, all batches were found to comply with the specification, with the exception of one batch of Zerin (batch # 143), which did not comply with the percentage weight variance test, potentially resulting in non-uniform ingredient distribution. The results comply with the BP and USP specifications that are required for therapeutic efficacy. It is also important that all parameters are met by the tablets, because they are all essential. If the hardness is increased, then the rate of disintegration will increase, affecting the dissolution profile.

As this will affect the dissolution profile, it is therefore important for the drugs to disintegrate properly. From these tests, pharmaceutical equivalence can also be determined. To my knowledge, not much work has been undertaken to establish the parameters of paracetamol quality control in India. Therefore, further research on

quality control parameters needs to be carried out because paracetamol, an OTC drug, is widely used by individuals and the product needs to be of good and acceptable quality.

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CONFLICT OF INTEREST

None

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