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EVALUATION OF ACETAMINOPHEN TABLETS BY CONTROL TEST

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ABSTRACT

Various pharmacopoeial and non-pharmacopoeial control test applied to Acetaminophen tablets were used to evaluate for the uniformity of weight, diameter, thickness, medicaments, hardness and friability. The tests were intended to check the compliance of the prepared tablets with the accepted specifications.

INTRODUCTION

For our study Acetaminophen tablets have been prepared using different disintegrants (sodium carboxy methyl cellulose, corn starch, veegum, Avicel 101) at four different hardness for each formulation and have been tested for uniformity of weight, diameter, thickness, friability and active ingredient. The results have been interpreted statistically and the tablets have been found to be within the limits of B.P. and USP.

MATERIAL AND METHOD

Details of the various pharmacopoeial and non-pharmacopoeial tests applied have been described elsewhere (Ahmed, 1992).

RESULTS AND DISCUSSION

Uniformity of weight of Acetaminophen tablets:

The Acetaminophen tablets prepared in the laboratory under different hardness were examined for their uniformity of weight and for tablet to tablet variations. It was found that the tablets are of an average weight of 600 mg ± 5% which is within the limits of the percentage deviation allowed by USP (1980) for tablets weighing 325 mg or more. The observed variations have been summarized in table 1 with respect to the standard deviation and coefficient of variation.

Uniformity of thickness of Acetaminophen tablets:

The values of thickness (mm) for the tablets of different formulation are given in table 2. From the results it may be inferred that the deviation in thickness is within ± *5%.* This is tolerable for the normal manufacturing practices. The value of standard deviation and coefficient of variation are also reported in the tables. The thickness may vary with no change in weight due to difference in the granulation and pressure applied to the tablets, wear and tear on length of punches as well as on the speed of tablet compression. Tablet thickness is generally controlled to

minimize appearance problems, to assure that tablets will fit into the container and to assure that they can be accurately counted by the filling equipment. Some filling equipments depends on the uniform thickness of the tablets as a counting mechanism.

Uniformity of diameter for Acetaminophen tablets of different formulation:

A single punch tablet press, model TDP (China) was used for the compression of the tablets. An examination of these tablets showed a slight variations in diameter (12.38 to 12.47 mm) (Table 4) which is within the B.P. limits i.e. ± 5% and hence negligible. The slight variations in diameter of the tablets may either be due to an uneven surfaces of punch and die or due to the less precise measurement with the micrometer screw gauge.

Hardness of tablets:

The tablet requires a certain amount of strength, or hardness, to with standmechanical shocks of handling during its manufacture, packaging and transport. In addition tablets should be able to withstand reasonable abuse when in the hands of the consumer. Adequate tablet hardness and resistance to powdering and friability are necessary requisites for consumer acceptance. More recently, the relationship to and importance of hardness as it may influence tablet disintegration and, perhaps more significantly, drug dissolution release rate have become apparent (Herbert *et al.,* 1981). It may be especially important to carefully monitor tablet hardness for drug products that possess real or potential bioavailability problems or are sensitive to altered dissolution-release profiles as a function of the compressive force employed.

In the present study, tablets of four different hardness were prepared from each formulation. A Monsanto hardness tester was used to determine the hardness. The observed variations have been summarized in (table *5)* with respect to the standard deviation, and coefficient of variation.

Friability of Acetaminophen tablets of different formulation:

The percentage friability of the Acetaminophen tablets of different formulation (table 6) shows that the greater the hardness of the tablets the lesser is the percentage friability. As the hardness of the tablets are increased gradually there is a markable decrease in the percentage friability in all formulations. The possible reason for this result may be that at high compressional force the granules are packed strongly togather and there is low degree of crumbling during friability. So more harder the tablets less will be the percentage friability and vise versa.

Variation of Acetaminophen contents from tablet to tablet and uniformity of medicament:

The B.P. (1988) specifications for acetaminophen tablets requires analysis for content uniformity in which 10 individual tablets must be analysed. In order to test the Acetaminophen tablets formulations used in the present work 10 tablets of each batch from all formulations were assayed individually and the results evaluated statistically. The values of mean and coefficient of variation are given in table 7. In all cases the values are less than 2.5% indicating the uniformity of distribution of the active ingredient in tablets. These values are under the limit of B.P. (1988) as described by Acetaminophen tablets i.e. ±5%. The uniformity of Acetaminophen content was calculated by average assay method and were found under the B.P. (1988) limit i.e. ± 5% shown in table 7.

Table 1
Weight Variation of Acetamlnophen Tablets

Formulation	Batch No.	E X (mg)	*X	Variance	S.D.	% Average deviation	Permissible limit USP
	1	11746	487.30	145.31	12.05	2.05	616.7-558
A	2	12126	606.30	326.91	18.08	2.98	636.6-580
	3	11654	582.70	207.40	14.40	2.47	612-553.5
	4	11555	577.75	290.60	17.04	2.95	606.6-549
	1	11808	590.40	211.04	14.53	2.46	619.9-560.8
B	2	11887	594.35	128.12	11.32	1.90	624-564.6
	3	11775	588.75	298.94	17.29	2.90	618-559
	4	12092	604.60	366.72	19.15	3.16	634.8-574
	1	11666	583.30	192.21	13.86	2.37	612.5-554
C	2	11819	590.90	252.55	15.89	2.68	620.5-561
	3	11791	589.50	264.25	16.25	2.75	619-560
	4	11640	582.00	117.60	10.84	1.86	611-553
	1	11685	584.30	330.00	18.16	3.10	614-555
D	2	11869	593.40	178.24	13.35	2.23	623-564
	3	11769	588.50	266.34	16.32	2.77	619-559
	4	11692	584.60	301.04	17.35	2.96	614-555
	1	11404	570.20	294.66	17.16	3.00	599-542
E	2	11807	590.40	154.22	12.42	2.10	620-561
	3	11745	587.30	530.58	23.03	3.90	616-566
	4	11544	577.20	270.76	16.45	2.85	606-548

*Each value is the mean of 20 tablets.
A = Control formulation.
B = Fromulation containing 6% Na-CMC.
C = Fromulation containing 6% Corn starch.
D = Fromulatjon containing 6% Veegum.
E = Fromulation containing 6% Avicel 101.

Table 2
Variation in Thickness of Acetamunophen Tablets

Formulation	Batch No.	E X No.	*X (mg)	Variance	S.D.	% Average deviation
A	1	44.3	4.43	0.00134	0.037	0.84
	2	44.6	4.46	0.00027	0.016	0.34
	3	44.6	4.46	0.00384	0.062	1.39
	4	44.3	4.43	0.00096	0.03 1	0.70
B	1	43.3	4.33	0.00090	0.030	0.69
	2	43.8	4.38	0.00250	0.049	1.12
	3	41.9	4.19	0.00096	0.031	0.74
	4	41.8	4.18	0.00048	0.022	0.53
C	1	43.2	4.33	0.00078	0.028	0.65
	2	41.5	4.15	0.00980	0.099	2.38
	3	44.1	4.41	0.07400	0.273	6.19
	4	44.6	4.46	0.07400	0.272	6.10
D	1	45.6	4.56	0.0010	0.032	0.70
	2	45.3	4.53	0.0012	0.034	0.76
	3	44.9	4.49	0.0010	0.031	0.70
	4	44.8	4.48	0.0007	0.026	0.58
E	1	45.6	4.56	0.0019	0.044	0.97
	2	44.9	4.49	0.0036	0.059	1.33
	3	44.8	4.48	0.0031	0.055	0.34
	4	44.2	4.42	0.0002	0.015	0.55

*Each value is the mean of 10 tablets.
A = Control formulation.
B = Fromulation containing 6% Na-CMC.
C = Fromulation containing 6% Corn starch.
D = Fromulation containing 6% Veegum.
E = Fromulation containing 6% Avicel 101.

Table 3
Variation in Diameter of Acetamlnophen Tablets

Formulation	Batch No.	E X (mg)	*X (mm)	Variance	S.D.	% Average deviation
A	1	124.3	12.43	0.0068	0.082	0.66
	2	124.3	12.43	0.0090	0.095	0.76
	3	124.1	12.41	0.0099	0.099	0.08
	4	124.2	12.42	0.0110	0.103	0.83
B	1	124.7	12.47	0.0068	0.082	0.66
	2	124.1	12.41	0.0140	0.119	0.96
	3	124.5	12.45	0.0120	0.110	0.87
	4	124.6	12.46	0.0070	0.084	0.68
C	1	124.5	12.45	0.070	0.085	0.68
	2	123.8	12.38	0.022	0.148	1.19
	3	124.3	12.43	0.022	0.149	1.20
	4	124.4	12.44	0.011	0.110	0.86
D	1	124.5	12.45	0.012	0.110	0.87
	2	124.5	12.45	0.012	0.110	0.87
	3	124.4	12.44	0.009	0.097	0.78
	4	123.8	12.38	0.017	0.132	1.06
E	1	124.1	12.41	0.014	0.119	0.96
	2	124.1	12.41	0.009	0.099	0.80
	3	123.9	12.39	0.09	0.099	0.80
	4	124.5	12.45	0.012	0.108	0.86

*Each value is the mean of 10 tablets.
A = Control formulation.
B = Fromulation containing 6% Na-CMC.
C = Fromulation containing 6% Corn starch.
D = Fromulation containing 6% Veegum.
E = Fromulation containing 6% Avicel 101.

Table 4
Variation in Hardness of Acetaminophen Tablets

Formulation	Batch No.	EX (mg)	*X (mm)	S.D.	Variance
A	1	37.2	3.7	0.600	0.360
	2	61.8	6.2	1.072	1.148
	3	69.4	6.9	0.696	0.484
	4	74.7	7.5	0.719	0.516
B	1	28.3	2.8	0.315	0.099
	2	37.5	3.7	0.365	0.133
	3	54.7	5.5	0.156	0.025
	4	58.1	5.8	0.153	0.023
C	1	33.7	3.4	0.271	0.074
	2	43.6	4.4	0.281	0.790
	3	54.7	5.5	0.156	0.025
	4	58.1	5.8	0.153	0.023
D	1	29.3	2.9	0.562	0.315
	2	34.3	3.4	0.344	0.118
	3	41.4	4.1	0.377	1.420
	4	53.1	5.3	0.938	0.879
E	1	33.7	3.4	0.438	0.191
	2	41.5	4.2	0.314	0.331
	3	48.1	4.8	0.73 1	0.453
	4	57.5	5.7	0.658	0.453

*Each value is the mean of 10 tablets.
A = Control formulation.
B = Fromulation containing 6% Na-CMC.
C = Fromulation containing 6% Corn starch.
D = Fromulation containing 6% Veegum.
E = Fromulation containing 6% Avicel 101.

Table 5
Percentage Friability of Acetaminoplien Tablets with Different Hardness

Formulation	Batch No.	Disintegrant used	*Hardness (kg/cm^2)	Percentage friability
A	1	Control	3.7	3.19
	2		6.2	2.33
	3		6.9	2.25
	4		7.5	2.06
B	1	Na-CMC 6%	2.8	3.98
	2		3.7	3.46
	3		4.8	2.11
	4		6.4	1.85
C	1	Corn starch 6%	3.4	3.56
	2		4.4	2.16
	3		5.5	1.78
	4		5.8	1.24
D	1	Veegum 6%	2.9	3.17
	2		3.4	3.16
	3		4.1	2.77
	4		5.3	2.36
E	1	Avicel pH 101 6%	3.4	2.92
	2		4.2	2.53
	3		4.8	2.35
	4		5.7	1.75

*Average hardness of 10 tablets.

Table 6
Uniformity of Acetaminophen Content and Uniformity of Distribution of Acetaminophen Content

Formulation	Bach No.	Acetaminophen % Average method	Acetaminophen content % Individual assay method	
			Mean	% Average deviation
A	1	1.63	0.841	1.19
	2	2.25	0.831	1.57
	3	1.64	0.836	1.77
	4	1.55	0.846	1.18
B	1	1.55	0.833	1.73
	2	2.60	0.828	2.23
	3	2.22	0.825	2.42
	4	2.40	0.829	1.52
C	1	1.07	0.851	1.62
	2	2.56	0.831	2.24
	3	3.30	0.849	2.15
	4	1.63	0.842	1.71
D	1	2.00	0.834	1.39
	2	1.25	0.827	0.07
	3	2.94	0.847	1.97
	4	1.76	0.828	1.76
E	1	2.19	0.827	1.60
	2	3.30	0.833	2.05
	3	1.63	0.818	1.43
	4	3.87	0.835	2.18

A = Control formulation.
B = Fromulation containing 6% Na-CMC.
C = Fromulation containing 6% Corn starch.
D = Fromulation containing 6% Veegum.
E = Fromulation containing 6% Avicel 101.

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