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"Study of post compression parameters of various marketed paracetamol tablets in india"

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Abstract:-

The aim of the present experiment was to evaluate post compression parameters of various brands of paracetamol tablets containing 650 mg of drug and to determine whether all the formulations used were equivalent or significantly different. Evaluation of paracetamol tablet pharmaceutical and chemical equivalence in order to determine their interchangeability. The purpose of the study is to ensure the quality and safety of various brands of Paracetamol tablets available in market.

Keywords:- Paracetamol 650, Potassium dihydrogen , 0.2 N Sodium Hydroxide Solution ,0.2 M Potassium dihydrogen phosphate ,Phosphate Buffer Solution , Distilled Water.

Introduction:-

Paracetamol is a non-steroidal anti- inflammatory drug .It is prominately used as antipyretic and analgesic . Paracetamol is also name as Acetominophen(4-hydroxy acetanilide).

Paracetamol is one of the most popular and widely used drugs for the treatment of pain and fever.

It has a very similar structure of aspirin and because of this they are recognised by the same enzyme.

The enzyme is responsible for biosynthesis of prostaglandins which are involve in the dilation of blood vessels that cause the pain experienced in headache.

Reduction of the amount of prostaglandins therefore helps prevent headache and other pain like migraine headache,muscularaches,neurolgia, backache,joint pain ,rheumatic pain,general pain, toothache,period pain and also used for the reduction of fever of bacterial or viral origin.

Paracetamol is predominantly safe in normal doses, higher doses causes hepatic disorder.

Evaluation of different parameters like hardness, weight variation, friability, disintegration time and dissolution profiles were performed.

Therapeutic effectiveness and bioavailability of tablet depends on these parameters.

PROCEDURE:-

The dissolution method is a kinetic method .i.e., periodical samples are withdrawn for the determination

1) Phosphate buffer solution pH 7.8(900ml) is measured and transferred into the dissolution flask.
2) The temperature is maintained at 37±0.50 C.
3) Various marketed paracetamol tablet containing 650 mg drug is placed at the bottom of the jar.
4) The paddle is rotated at 50 rpm .
5) Five ml of sample is withdrawn at 0 min and transferred into the test tube appropriately labeled. Immediately 5ml of phosphate buffer solution pH 7.8 is replaced into the dissolution flask .
6) Similarly samples are collected at 1,2,3,4,5,6,7,8,9,10 min intervals. A 5 ml of fresh dissolution medium is replaced in the flask whenever the sample is withdrawn .
7) All samples are filtered using wattman filterpaper .
8) The absorbance at 249 nm is measured in uv spectrophotometer using the phosphate buffer solution as a blank.
9) The absorbance are recorded in the table and further calculations are done
10) A graph is plotted by taking cumulative percent of drug dissolved on y-axis and time on x-axis .

Fig No: 1 – Dissolution Apparatus

RESULTS AND DISCUSSIONS:-

WEIGHT VARIATION : The weight variation of various brands of paracetamol are shown below in table no :1

Table No1- Weight variation studies of marketed paracetamol products.

SL. NO	BRAND	LABEL CLAIM	AVG OF 20 TABLES	% DIFFERENCE	CONCLUSION
1	Medamol 650 mg	650	0.774	1.0	Passes
2	Paracip 650 mg	650	0.748	0.6	Passes
3	P- 650 mg	650	0.843	0.7	Passes
4	Crocin- 650 mg	650	0.860	0.7	Passes
5	Paracetamol(janaushad) 650 mg	650	0.842	0.7	Passes
6	Dolo – 650 mg	650	0.822	0.4	passes

FRIABILITY :

The friability of various brands of paracetamol are shown below in the table no 2

Table No 2- Friability data of marketed paracetamol products

SL.NO	BRANDS	FRIABILITY(%)
1	Medamol 650 mg	0.25
2	Paracip 650 mg	0.40
3	P- 650 mg	0.11
4	Crocin- 650 mg	0.23
5	Paracetamol(janaushad) – 650 mg	0.00
6	Dolo – 650 mg	0.36

DISINTEGRATION:

The disintegration of various brands of paracetamol is shown below in table no :3

Table No 3- Disintegration data of studies of marketed paracetamol products

SL.NO	BRANDS	DISINTEGRATION TIME (mins)
1	Medamol 650 mg	1.31
2	Paracip 650 mg	1.13
3	P- 650 mg	0.15
4	Crocin- 650 mg	2.10
5	Paracetamol(janaushad) – 650 mg	1.00
6	Dolo – 650 mg	0.45

HARDNESS :

Hardness of various marketed brands of paracetamol are shown below in table no :4

Table No 4-Hardness studies of marketed paracetamol products

SL.NO	BRANDS	HARDNESS(kg/cm^2)
1	Medamol 650 mg	4.6
2	Paracip 650 mg	4.0
3	P- 650 mg	4.3
4	Crocin- 650 mg	4.3
5	Paracetamol(janaushad) – 650 mg	4.5
6	Dolo – 650 mg	4.2

DISSOLUTION :-

The dissolution profile of marketed tablets like Medomol 650, Paracip 650, P-650, Crocin 650 and Paracetamol 650 mg (Janaushad) are listed in the following table.

Table No :5 -Drug release profile of Medamol 650 mg tablet

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*5	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.096	1.884	100	188	940	169.2	169.2	26.03
2	2	0.097	1.905	100	190	950	171	171.94	26.45
3	3	0.127	2.535	100	253	1265	227.7	230	35.38
4	4	0.172	3.48	100	348	1740	313.2	318.09	48.93
5	5	0.216	4.405	100	440	2200	396	403.09	62.01
6	**6**	**0.292**	**6.002**	**100**	**600**	**3000**	**540**	**550.09**	**84.62**
7	7	0.451	9.461	100	946.1	4730	851.4	866.34	133.24
8	8	0.349	7.291	100	729.1	3645	656.1	675.77	103.93
9	9	0.331	6.906	100	690.8	3454	621.7	644.13	99.0

Table No : 6-Drug release profile of Paracip 650 mg tablet

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*(5)	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.242	4.95	100	495	2475	445.5	445.5	68.53
2	2	0.300	5.75	100	575	2875	517.5	519.47	86.25
3	3	0.280	6.17	100	617	3085	555.3	560.65	79.91
4	**4**	**0.329**	**6.77**	**100**	**677**	**3385**	**609.3**	**617.73**	**95.03**
5	5	0.386	7.97	100	797	3985	717.3	729.12	112.17
6	6	0.336	6.92	100	692	3460	674.5	695.30	106.96

Table No :7- Drug release profile of P-650 mg tablet

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug Release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*(5)	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.064	1.212	100	121.2	606	109.08	109.08	16.78
2	2	0.165	3.334	100	333.4	1667	300.06	300.06	46.25
3	3	0.251	5.140	100	514	2570	462.6	464.87	71.51
4	4	0.281	5.771	100	577	2885	519.3	524.14	80.65
5	5	0.317	6.527	100	652.7	3263.5	587.43	599.15	92.17
6	**6**	**0.387**	**7.997**	**100**	**799**	**3995**	**719.1**	**726.82**	**111.81**

Table No : 8 - Drug release profile of Crocin 650 mg

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug Release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*(5)	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.039	0.686	100	68.6	34.3	61.74	61.74	9.49
2	2	0.146	2.934	100	293.4	1469.5	264.06	264.40	40.6
3	3	0.176	3.565	100	356.5	1782.5	320.8	325.49	50.07
4	4	0.204	4.153	100	415.3	2078	373.77	375.5	57.78
5	5	0.243	4.97	100	497	2485	447.3	453.7	69.50
6	**6**	**0.301**	**6.191**	**100**	**619.1**	**3095.5**	**557.1**	**566.1**	**87.09**
7	7	0.365	7.535	100	753.5	3767.5	678.15	696.41	102.14

Table No : 9 - Drug release profile of Paracetamol 650 mg (janaushad)

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug Release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*5	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.032	0.5468	100	54.68	273.4	49.14	49.14	7.6
2	2	0.240	4.972	100	497.2	2486	447.48	447.67	68.85
3	3	0.255	5.291	100	529.1	2645.7	476.19	496.45	73.58
4	4	0.286	5.951	100	595.1	2975.5	535.59	540.9	83.19
5	5	0.294	612.12	100	612.1	3060.6	550.8	559.17	86.00
6	**6**	**0.336**	**701.48**	**100**	**701.4**	**3507.4**	**631.2**	**642.33**	**98.79**

Table No : 10 – Drug release profile of Dolo 650 mg

Sl.no	Time (min)	Abs at 249nm	Conc (mg/ml)	Dilution factor	Conc (mg/ml)	Amount In 5 ml (mg)	Amount In 900ml(mg)	Cumulative amount	% Drug Release
(1)	(2)	(3)	(4)	(5)	(6)=(4)*(5)	(7)=(6)*(5)	(8)=(6)* 900/1000	(9)#	(10)= (9)*100 /650
1	1	0.227	4.636	100	463.6	2318	417.24	417.24	64.1
2	2	0.286	5.876	100	587.6	2938	528.84	531.15	81.71
3	**3**	**0.374**	**7.724**	**100**	**772.4**	**3862**	**695.16**	**698.09**	**106.9**
4	4	0.381	7.871	100	787.1	3935	708.39	712.25	109.57
5	5	0.417	8.628	100	862.8	4314	776.52	780.45	120.06

Table No : 11 - Comparative drug release profiles of Paracetamol tablet

Sl.no	Time	Medamol 650	Paracip 650	P-650	Crocin 650	Paracetamol 650(janaushad)	Dolo – 650
1	1	26.03	68.53	16.78	9.49	7.6	64.1
2	2	26.45	86.25	46.25	40.6	68.85	81.71
3	3	35.38	79.91	71.51	50.07	73.58	**106.94**
4	4	48.93	**95.03**	80.65	57.78	83.19	109.57
5	5	62.01	112.17	**92.17**	69.50	86.60	120.06
6	6	**84.62**	106.96	111.81	87.09	**98.79**	
7	7	133.24			**102.14**		
8	8	103.93					
9	9	99.0					

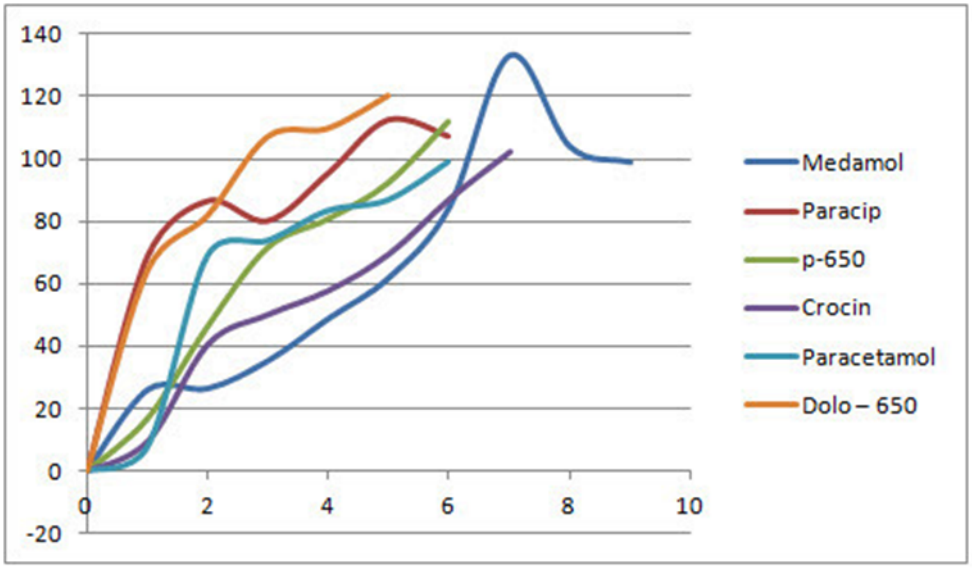

Fig No 2: - Dissolution profile of six different brands of paracetamol tab

CONCLUSION:-

As a result of this study we have concluded that all the six brands of Paracetamol tablets meet the criteria laid in the official monographs and though they differ slightly in terms of various parameters like weight variation, hardness, friability, shows its complete release at in the range of 4 to 7 mins .All marketed paracetamol tablets of 650 mg were all under specified IP limits.

Reference :-

1.Nayak AK. Comparative in vitro dissolution assessment of some commercially available paracetamol tablets. Int J Pharm Sci Rev Res. 2010;2:29-30.

2.. Paracetamol Information Centre. Paracetamol Chemistry,2000.

3. British Pharmacopoeia Commission. British Pharmacopoeia, 13th Edition, Stationery Office, Great Britain, 2013.

4.Binega G and Wondimsigegn D et al.,(2013); "Analysis and comparison of paracetamol tablets dispensed in legal dispensaries and non pharmaceutical shops in Gondar town ,north west ,Ethiopia"; Int J of Phar and Ind Res ;3(2); 144-151

5. D.R Jadge and A.N Despande et al., (2014); "Comparative invitro evaluation of different brands of paracetamol tablets marketed in Maharashtra state"; Int J of Pharma Sci and Health Care; 4(4) ; 40-7

6. https://www.drugbank.ca/drugs/DB00316 (Cited on 17/12/18 at 2.45 PM)

7. Kar A and Amin MN et al., (2015) ; "Quality analysis of different marketed brands of paracetamol available in Bangladesh" ; Int Cur pharm J; 4(9); 432-5

8. Mathur N and Kumar R et al., (2015); " Evaluation of quality control parameters on various brands of paracetamol tablet formulation" ;World J of Pharm and Pharma Sci ;4 (7); 976-984

9. Nayak AK (2010); "Comparative in vitro dissolution assessment of some commercially available paracetamol tablets"; Int J of Pharma Sci Review and Res ; 2(1); 29-30.

10. Rahman ZU and Khan I et al.,2013; "Post-Market In-Vitro Comparative Evaluation of Quality Control Parameters of Paracetamol Compressed Tablets Manufactured in Local Industrial Zones of Kpk Pakistan"; The Pharma innovation J ; 2(3); 11-5

11.Siew A (2016) ; “dissolution testing” ;Pharma Tech;40(11); 56-64

12.Bertolini A, Ferrari A, Ottani A, Guerzoni S, Tacchi R, Leone S. Paracetamol: new vistas of an old drug, CNS Drug Rev,12(3-4),2006, 250-75.

13.Knochen M, Giglio J, Boaventure FR. Flow-injectionspectrophotometric determination of paracetamol intablets and oral solutions, J Pharmaceut Biomed. Jpba, 33,2003, 191-197