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A NOVEL APPROACH TOWARDS THE TREATMENT OF BARIATRICS

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ABSTRACT

Over weight and obesity are rising medical conditions. There are many detrimental health effects of obesity such as CV diseases, diabetes, high cholesterol etc. The traditional methods to overcome obesity by using antihyperlipedemic drugs which have side effects such as stomach pain, diarrhoea, leakage of oily stools etc. To overcome these side effects, there is a need to develop a nobel method for treatment of obesity. One novel approach to treat obesity is "inhibition of fat absorption in GIT". This can be achieved by formulating a tablet using absorbent such as kaolin and talc. Five batches of floating tablets with variable concentration of absorbents are formulated and named as F1-F5 formulations. F5 formulation is optimized due its high swelling index of 144.85 and high floating duration of 18 hours. The tablet will float in GIT remains non disintegrated and absorbs all the fats present in the GIT, thus inhibiting fat absorption by the body. The tablet with absorbed fat will be eliminated from the body as such. This novel approach towards bariatrics will not have side effects and hence preferable over traditional drugs for the treatment of obesity.

KEYWORDS: Anti hyperlipidemic, fat absorbing tablets, bariatrics, obesity.

INTRODUCTION

Over weight and obesity are rising medical conditions. There are many detrimental health effects of obesity such as CV diseases, diabetes, high cholesterol etc. The traditional methods to overcome obesity by using antihyperlipedemic drugs which have side effects such as stomach pain, diarrhoea, leakage of oily stools etc. To overcome this side effects, there is a need to develop a nobel method for treatment of obesity. One novel approach to treat obesity is “inhibition of fat absorption in GIT”. This can be achieved by formulating a tablet using absorbent such as kaolin and talc.The tablet remains floating in the GIT due to the presence of sodium bicarbonate.During its residence time in GIT the tablet absorbs tha fat present in the GIT and prevents the fat absorption by body.The tablet with absorbed fat get excreted unchanged.

FORMULATION OF FLOATING TABLETS BY DIRECT COMPRESSION METHOD

1. Weigh the accurate amount of Hydroxy Propyl Methyl Cellulose; Sodium Carboxy Methyl Cellulose, Eudragit and Potato starch mix them thoroughly.
2. In another beaker take 700mg of povidone and add boiled water with continuous stirring for 5minutes until it forms a solution.
3. Then add the povidone solution to above mixture of powders and make dough.
4. Pass it through sieve no. # 22, so that uniform granules are formed.
5. Dry the granules for temperature not exceeding 40^{o}c and moisture content should be around 0.5%.
6. If the granules are still wet wait for 20mins for drying and preserve it in air tight container. The care must be taken so that it gets protected from moisture.
7. To these dried granules, add all the lubricants and blend the granules and shake it for uniform mixing.
8. Punch the granules to form a tablet in a 16mm of diameter.

Table 1: Formulation Table.

S.No	Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)	F5(mg)
1	Povidone K-30	70	70	70	70	70
2	HPMC	72	81	90	99	108
3	Sodium CMC	24	27	30	33	36
4	Eudragit	60	60	60	60	60
5	Sodium bicarbonate	20	20	20	20	20
6	Citric acid	20	20	20	20	20
7	Kaolin	50	55	60	65	70
8	Aerosol	40	40	40	40	40
9	Talc	40	45	50	55	60
10	Magnesium stearate	40	40	40	40	40
11	Calcium carbonate	10	10	10	10	10
12	Potato starch	qs	qs	qs	qs	qs
	Total Weight	690	690	690	690	690

RESULTS AND DISCUSSION

PRE FORMULATION STUDIES

Organoleptic Properties

Table 2: Organoleptic properties.

Polymers	Parameters			
	Colour	**odour**	**Taste**	**Appearance**
Eudragit	Colourless	Faint amine like	Tasteless	cloudy granules
HPMC	White	odourless	Tasteless	powder
Kaolin	White to yellowish	Odourless	Tasteless	Powder
Talc	White	Odourless	Impalpable	Crystalline powder

DISCUSSION

The colour, odour, taste and appearance are the organoleptic properties of tablet that were observed. From table 2 it is shown that the tablet was found to be white to off white coloured, odourless, tasteless and crystalline powder.

Fig. 1: Tablets Observed for Organoleptic Properties.

DETERMINATION OF SOLUBILITY

The solubility of tablet was determined in various solvents. The observed solubility is reported below:

1) Soluble in methanol water and DMSO and N, N- di methyl formamide
2) Sparingly soluble in ethanol, propylene glycol.
3) Very slightly soluble in hexane, dichloromethane, and methylbenzene

PRE COMPRESSION STUDIES

Table 3: Pre Compression Studies.

Polymer code	Weight variation(%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)
F1	0.79±0.08	5.0	0.72±0.01	2.6±0.09
F2	0.49±0.07	4.5	0.68±0.0.9	2.6±0.09
F3	068±0.07	5.5	0.69±0.07	2.7±0.07
F4	0.99±0.064	5.0	0.66±0.08	2.75±0.08
F5	0.1	5.5	0.25	2.54
Acceptance criteria	Up to 7.5	4-8	<1	-

DISCUSSION

Bulk density, Tapped density, Hausner's ratio, Carr's index and Angle of repose are the various pre-compression parameters that were performed for a tablet. All the values in table 3 are the mean ± SD of three determinations (n=3). The studies showed fair to good flow properties for all formulations (F1-F5) as observed in table 3.

POST COMPRESSION STUDIES

Table 4: Post Compression Studies.

Polymer code	Bulk density (gm /ml)	Tapped density (gm/ml)	Hausner's ratio	Carr's index (%)	Angle of repose (θ)	Type of Flow
F1	0.710	0.873	1.251	19.714	39^0	**Fair**
F2	0.712	0.870	1.206	17.126	37^0	**Fair**
F3	0.718	0.871	1.223	18.513	37^0	**Fair**
F4	0.410	0.483	1.178	15.113	34^0	**Good**
F5	0.63	0.78	1.23	19.230	35^0	**Good**

All the values in table 4 are the mean ± SD of three determinations (n=3).

DISCUSSION

Weight variation, Hardness, Friability, Thickness, Content uniformity of the tablets were evaluated and the results are tabulated in table 4.

Weight variation

Weight variation of all the formulations was found to be in acceptable range.

Hardness

The tablet hardness of all the formulations prepared by direct compression method was found to be within acceptable range of 4-8 kg/cm^2.

Friability

Friability of all the formulations were within the acceptable limit of<1%.

Thickness

The tablet thickness of all the formulations were in the range of 2.54 mm to 2.75 mm.

Table 5: Post Compression Studies.

Formulation Code	Floating lag time	Swelling index (%)	Floating duration(hrs)
F1	25sec	100.85	12
F2	24sec	139.5	14
F3	30sec	101.5	16
F4	1 min 24 secs	142.5	17
F5	2 mins	144.85	18

All the values in table 4.4 are the mean ± SD of three determinations (n=3).

Fig. 2: Tablet Kept in an HCl Solution for Floating.

DISCUSSION

Floating lag time, Swelling index, Floating duration of all the formulations were evaluated and tabulated in table 5. From the table 5, it was observed that with increase in the

concentration of polymer, floating lag time, swelling index, floating duration also increases. For optimized (F5) formulation the values are as follows: Floating Lag Time; 2 mins is the time taken by the tablet to emerge on the surface of the medium. Swelling Index; 144.85% is the swelling index of the tablet. Floating Duration; 18-h is the duration of time for which the tablet constantly remained on the surface of the medium.

CONCLUSION

The fat absorbing floating tablets were prepared and evaluated. The optimized formulation (F5) showed Weight variation (%) – 0.1, Hardness (kg/cm^2) – 5.5, Friability (%) – 0.25, Thickness (mm) – 2.54 to 2.75, Floating lag time (mins) – 2, Swelling index (%) – 144.85, Floating duration (hours) – 18. The optimised formulation can float in the GIT, adsorb, absorb the fat, lipids and oils present in the GIT. After 18hrs the unabsorbed fat will be removed from body along with tablet. In this way the absorption of fat by the body can be prevented and hence it will be useful in management of Bariatrics.

REFERENCES

1. Leon Lachman, Herbert A, Lieberman "The Theory And Practice of Industrial Pharmacy", Special Indian Edition, Published By CBS Publishers &Distributors Pvt. Ltd.New Delhi-110002, INDIA., 296-303.
2. Patrick J. Sinko, "Martin's Physical Pharmacy and Pharmaceutical Sciences", Fifth Edition, Published by Wolters Kluwer (India) Pvt. Ltd. New Delhi., 552-559.
3. KD Tripathi "Essentials Of Medical Pharmacology" Fifth Edition, Published by Jaypee Brothers Medical Publishers. Pvt.Ltd. New Delhi, India., 451-453.
4. Suresh P. Vyas & Roop K. Khar, "Controlled Drug Delivery,Concepts & Advances.", Second Edition Published by M K Jain for Vallabh Prakashan,C-5,SMA Cooperative Industrial Estate, GT Karnal Road, DELHI-110022, 2012; 196-216.
5. Shobha Rani R. Hiremath, "Textbook of Industrial Pharmacy Drug Delivery Systems, and Cosmetics and Herbal Drug Technology", Published by Universities Press (India) Private Limited, Hyderabad, India. 5-18.
6. Yanovski SZ, Yanovski JA. JAMA. Long-term drug treatment for obesity: A systematic and clinical review. July 2016, 2014; 311(1): 74–86.
7. Suresh P. Vyas & Roop K. Khar, "Controlled Drug Delivery,Concepts & Advances." Second Edition Published by M K Jain for Vallabh Prakashan,C-5,SMA Cooperative Industrial Estate, GT Karnal Road, DELHI-110022, 2012; 196-216.

8. Shobha Rani R. Hiremath, “Textbook of Industrial Pharmacy Drug Delivery Systems, and Cosmetics and Herbal Drug Technology”, Published by Universities Press (India) Private Limited, Hyderabad, India. 5- 18.
9. Vishal Bhardwaj, Nirmala, S.L. Harikumar, "Floating Drug Delivery System: A Review", ISSN2229 5402Pharmacophore, 2013; 4(1): 26-38.
10. Judith Lorraine Page, Daniel H. Haigh, “Polymers for controlling body weight of animals and pharmaceutical compositions thereof” US patent EP0050347B1.
11. Bryn Hird, Ronald Jandacek, “Use of non-digestible polymeric foams to sequester ingested materials thereby inhibiting their absorption by the body” US Patent US20030072804A1.
12. W. Harry Mandeville, III, George M. Whitesides, Stephen Randall Holmes-Farley, “Fat-binding polymers” US Patent US6264937B1.
13. Judith L. Page, Daniel H. Haigh, James Peters. “Weight control with fat imbibing polymers” US Patent JPH05186357A.
14. Osamu Kanauchi, KeijiDeuchi, “Weight control with fat imbibing polymers” US Patent US5453282A.
15. Gordon L. Amidon, Lizbeth B. Sherman, John R. Crison, “Polymers for controlling body weight of animals and pharmaceutical compositions thereof” US Patent US5569452A.
16. Allan S. Hoffman, N. S. Choi “Method for reducing absorption of undesired lipids in the gastrointestinal tract” US Patent US5597810A.