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Research Paper

EFFECT OF NOVEL PROCESSED SUPERDISINTEGRANTS ON ORAL DISPERSIBLE TABLET OF DICLOFENAC SODIUM

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Co-processing is an alternate way that new excipients are coming to market without experiencing the thorough wellbeing testing of a totally new chemical. It could be characterized as consolidating two or more settled excipients by a fitting procedure. Co-processing of excipients could prompt the development of excipients with better properties thought about than the basic physical mixtures of their components. In the present study the novel co-processed Superdisintegrants were prepared by solvent evaporation method. A blend of Croscarmellose sodium and sodium starch glycolate in the ratio of 1:1, 1:2 & 2:1 prepared and evaluated for Bulk density, Tapped density, Carr's Index and Angle of repose. In the present study Diclofenac sodium used as a model drug. Tablets were prepared by direct compression technique using novel co-processed Superdisintegrants and evaluated for thickness, weight variation test, drug content, hardness, and friability and *in-vitro* drug release studies. Among the various formulations of fast dissolving tablet of Diclofenac sodium, the formulation containing 4% w/w of co-processed Superdisintegrants sodium starch glycolate and Croscarmellose sodium in 1:1 Proportion is the best formulation having least time for tablet disintegration.

Key words: Excipients, Co-processing, dispersible tablet, Diclofenac sodium, superdisintegrants.

INTRODUCTION

1. The IPEC- piece aide draft characterizes co-processed excipients are co-processing of two or more than two compendial or non-compendial excipients. They are intended for alteration of physical properties which was not achievable by basic physical blending. Co-processing is an alternate way that new excipients are coming to market without experiencing the thorough wellbeing testing of a totally new chemical. It could be characterized as consolidating two or more settled excipients by a fitting procedure[1]. Advantages to using co-processed excipients include a reduction in the number of raw materials and processing time required for a given formulation and a potential for improved batch to batch consistency[2].

2. The essential explanation behind the absence of new chemical excipients is the generally high cost included in excipients revelation and improvement. On the other hand, with the expanding number of new medication moieties with changing physicochemical and stability properties, there is developing pressure on formulators to search down new excipients to accomplish the desired set of functionalities[3]. Co-processing of excipients could prompt the development of excipients with better properties thought about than the basic physical mixtures of their components[4].

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3. Materials and methods

Diclofenac sodium purchased from Karnataka fine chem, Lactose and Mannitol purchased from Vasa chemical, Bangalore, Croscarmellose sodium and sodium starch glycolate, Magnesium state and Talc are purchased from SD fine chem. All the chemicals used are analytical grade only.

4. Preparation of co-processed superdisintegrants

The co-processed superdisintegrants were prepared by solvent evaporation method. A blend of SSG and crospovidone (In the ratio of 1:1, 1:2 and 2:1) was added to 10 ml of isopropyl alcohol. The contents of the beaker (250 ml capacity) were stirred on a magnetic stirrer. The temperature was maintained between 65° to 70°, and stirring was continued till most of isopropyl alcohol evaporated. The wet coherent mass was granulated through #60-sieve. The wet granules were dried in a hot air oven at 60° for 20 min. The dried granules were sifted on #60-sieve and stored in air tight container till further use. The prepared mixture was evaluated for flow properties and polymer-polymer compatibility studies such as FTIR study[5].

5. Evaluation of co-processed mixture of CCS and SSG

Angle of repose: For the measurement of angle of repose, a glass funnel was secured with its tip at a given height (h) above a piece of graph paper placed on a horizontal surface. Powder was poured through the funnel until the apex of the conical pile touched the tip of the funnel. The angle of repose was calculated with the formula $\theta = \tan^{-1} h / r$, where θ is the angle of repose and r is the radius of the conical pile[6].

Bulk density: The bulk density was determined as the ratio of weight to the volume of sample.

Tapped density; The tapped density was determined as the ratio of weight to the volume of sample after tapping a measuring cylinder for 100 times on an Electrolab Tap density tester.

Carr's index; The percentage compressibility (Carr's index) was calculated as the ratio of the difference between the tapped density and bulk density to the tapped density.

Hausner ratio: Hausner ratio is equal to the ratio of the tapped density to bulk density

6. Preparation of Oral Dispersible tablet of Diclofenac Sodium by direct compression method

All the ingredients were passed through #60-sieve separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets using 6 mm round flat punches.

Evaluation of tablet

Weight variation test: 20 tablets were selected randomly from the lot and weighed individually to check for weight variation.

Thickness: Thickness of tablet is measured by using vernier calipers. Three tablets are selected at random from each batch. It is expressed in mm.

Hardness: Hardness of the tablet, which is the force applied across the diameter of the tablet to break a tablet into halves, was measured using a Pfizer tablet hardness tester.

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Table 1: Formulation of Oral Dispersible tablet

S.No	Ingredients	T1	T2	T3	T4	T5
1	Diclofenac sodium	50	50	50	50	50
2	Lactose	30	30	30	30	30
3	Mannitol	101	101	101	101	101
4	SSG	8	-	-		-
5	CCS	-	8	-	-	-
6	SSG:CCS (1:1)	-	-	8	-	-
7	SSG:CCS (1:2)	-	-	-	8	-
8	SSG:CCS (2:1)	-	-	-	-	8
9	Magnesium sterate	3	3	3	3	3
10	Talc	8	8	8	8	8
	Total wt	200mg	200mg	200mg	200mg	200mg

Evaluation of tablet

Weight variation test: 20 tablets were selected randomly from the lot and weighed individually to check for weight variation.

Thickness: Thickness of tablet is measured by using vernier calipers. Three tablets are selected at random from each batch. It is expressed in mm.

Hardness: Hardness of the tablet, which is the force applied across the diameter of the tablet to break a tablet into halves, was measured using a Pfizer tablet hardness tester.

Friability (F): Friability of the tablet determined using Roche friabiltor. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25rpm and dropping a tablet at l height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were de-dusted using a soft muslin cloth and reweighed[7].

Disintegration time: The in-vitro disintegration time was determined using disintegration test apparatus. A tablet was placed in each of the six tubes of the apparatus and one disc was added to each tube. The time in seconds taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds. The in vitro disintegration time is measured using an IP 2007 disintegration test apparatus, with distilled water at 37±2° temperature[8].

Wetting time: 5 round shaped 10cm diameter tissue paper tissue paper is placed in a petri dish of same size. 10 ml of deionized water at 37°C ±0.5°C having eosin, a water soluble dye is poured to the petridish. A single tablet was gently placed on the surface of the tissue paper. The time needed for the water to succeed on the surface of the tablet was noted as the wetting time[9].

Result and Discussion

Evaluation of superdisintegrants

The superdisintegrants are evaluated for flow properties before novel co-processing. The values given in the table no 2, implying SSG shows excellent flow character and CCS shows fair flow character.

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Table 2: Evaluation of flow properties of SSG and CCS

superdisintegrants	Hausner's ratio	Carr's index	Angle of repose
SSG	1.27	21.42	29.35
CCS	1.52	34.21	35.53

Evaluation of flow properties novel co processed superdisintegrant (SSG and CCS)

The co-processed superdisintegrants were evaluated for their flow properties. The angle of repose of co-processed superdisintegrants was found to be in the range of 25-30°, Carr's index in the range of 10-15% and Hausner's ratio in the range of 1.10-1.14 which indicates excellent flow of powder.

Table 3: Evaluation of novel co processed superdisintegrant

Ratio	Hausner's ratio	Carr's index	Angle of repose
1:1	1.17	14.6	30.50
1:2	1.14	12.49	30.43
2:1	1.10	10.0	25.13

Pre- compression evaluation

Fast dissolving tablets of diclofenac sodium were prepared using co-processed superdisintegrants and superdisintegrants of Sodium starch glycolate and croscarmellose sodium alone. A total of five formulations and were made. Tablets are prepared by direct compression method and pre compression parameters are performed for determining flow properties. The result shows that the formulated blend were good in flow properties. **Evaluation of tablet** As the blends were good flowing, tablets obtained were of uniform weight with acceptable variation as per IP specification. Drug content was found to be in the range of 95 to 104%, which was within acceptable limits. Hardness of the tablets was found to be in the range of 2.0-3.0 kg/cm^2. Friability below 1% was an indication of good mechanical resistance of the tablets. Wetting time was found to be in the range of 25- 110 sec. *In vitro* disintegration study were

Table 4: Pre- compression evaluation

Code	Ratio	Hausner's ratio	Carr's index%	Angle of repose(θ)
T1	SSG	1.27	21.42	29.35
T2	CCS	1.52	34.21	35.53
T3	SSG+CCS (1:1)	1.46	31.57	32.50
T4	SSG+CCS (1:2)	1.50	33.33	32.43
T5	SSG+CCS (2:1)	1.33	25.00	30.13

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Table 5: Evaluation of tablet

Code	Thickness	Avg weight (mg)	Hardness (kg/cm^2)	Friability (%)	DT (Sec)	Wetting time (Sec)	Assay (%)
T1	1.5mm	209	3.1	0.65	183.13	110	98.23
T2	1.5mm	202	3.0	0.71	120.45	85	95.12
T3	1.5mm	204	2.9	0.80	43.32	25	101.48
T4	1.5mm	202	3.0	0.62	52.00	43	104.48
T5	1.5mm	204	3.2	0.68	68.00	39	100.23

performed for all formulation and comparatively co-processed formulation contain 1:1 ration of SSG and CCS take least time for disintegration with respect to their physical mixture formulations. Such a difference in disintegration time between both of these formulations indicates that in co-processed formulation there might be increase in capillary action of Superdisintegrants which might have led to improved water uptake.

CONCLUSION

Among the various formulations of fast dissolving tablet of Diclofenac sodium, the formulation containing 4% w/w of co-processed Superdisintegrants sodium starch glycolate and Croscarmellose sodium in 1:1 Proportion is the best formulation having least time for tablet disintegration . Thus from the present work it reveals that the co-processed Superdisintegrants gives the better results than the physical mixture. From the present studies it can be concluded that novel co processed superdisintegrants are suitable for Oral Dispersible tablet formulation

REFERENCE

1. Bhagyashree A, Pakhale, D, Shinkar M, Saudagar R. co-processed excipient: an overview. *WJPR*. 2015; 4(1)

2. Gilbert S. Banker. *Modern Pharmaceutics Revised and Expanded*. 4th ed. CRC Press; 2002

3. Vijay M, Prashant K. *Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes*. Elsevier, academic press; 2014

4. Ashok T, Madhavi C, Nandini K, Sirisha S. Co-Processed Excipients: New Era in Pharmaceuticals, *Asian J. Res. Pharm. Sci. 2019; 9(1):01-05.*

5. Ladola M, A. Development and Evaluation of Melt-in-Mouth Tablets of Metoclopramide Hydrochloride Using Novel Co-processed Superdisintegrants, *Indian J Pharm Sci*. 2014 76(5): 423–429.

6. Pattanayak P, Mohapatra P, Jena R, Panda S. Standardization of Sulaharan Yoga: An ayurvedic tablet formulation, *Indian J Pharm Sci*. 2011;73(1): 65–70.

7. Mamatha K, Subharna M, Pranusha P, Pallavi

K. fast disintegrating tablets of nevirapine. *Asian J. Pharm. Res*. 2014; 4(3): 129-134

8. Piyush J, Gupta N, Sandeep S. formulation and evaluation of mouth dissolving tablets of omeprazole, *Int J Curr Pharm Res*. 8(2), 48-51

9. Kapil C, Bharat P, Abhishek C, Varun T. formulation and evaluation of fast dissolving tablets of telmisartan, *IJPSR, 2013;* 4(4): 1514-1520