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RAPID DISPERSIBLE TABLETS OF SOME AYURVEDIC CHURNAS

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ABSTRACT

The traditional ayurvedic medicine has been a boon in the treatment of many disastrous diseases in the present day. Oral dissolving tablets are solid unit dosage forms which disintegrate rapidly in the mouth. Ashwagandha churna obtained from the herb *withania somnifera*, an ayurvedic preparation used in many complications associated with anxiety, type 2 diabetes, anti oxidant, osteoarthritis, property of tumor healing. Chemical composition of ashwagandha is withaferin-A ,Stigmasterol glucoside, withanolide-D. Arjuna churna obtained from the herb *Terminelia arjuna* helps to maintain healthy cardiovascular functions, promotes normal cholesterol levels and also used in the treatment of type 2 diabetes. Chemical composition of arjuna is arjunone, arjunolone, arjunolic acid, gallic acid, beta sitosterol. Preformulation studies of the churnas were carried out and the results showed that the churnas were not free flowing. Hence, granules were prepared using wet granulation technique. Then the granules were compressed into tablets by incorporating superdisintegrants like Sodium starch glycolate and Crosspovidone. Among the prepared formulations some showed satisfactory results.

KEY WORDS: Ashwagandha, arjuna, Sodium starch glycolate, Crosspovidone, wet granulation.

1.INTRODUCTION

The oral route of administration still continues to be the most preferred route due to its manifold advantages including the ease of administration, accurate dosing, self-medication, versatility and most important patient compliance. Topical route has limitations in its ability to allow effective drug absorption for systemic drug action. Nevertheless it is possible that at least 90% of all drugs used to produce systemic effect are administered by oral route (Lachman,1986) . Because oral dosage forms can be self-administered by the patients, they are obviously more profitable to manufacture than parenteral dosage forms that must be administered, in most cases, by trained personnel (Banker and Rhodes,2002).

A rapid dispersible tablet system can be defined as a dosage form for oral administration, which when placed in mouth, rapidly disperses and can be swallowed in form of liquid (Seager,1998). Recently this formulation is popular as Novel drug delivery system because they are easy to administer and lead to better patient compliance. Rapid dispersible tablets of Ashwaganda & Arjuna are designed for rapid & complete absorption in the gastrointestinal tract in order to achieve therapeutic success (Habib,2000). Pediatric and geriatric patient have difficulty in swallowing the conventional dosage forms these dosage forms disintegrate in the oral cavity within in a very few minutes without the need of water (Bi Y,1996). For these formulations, the small volume of saliva is usually sufficient to result in tablet disintegration in the oral cavity. The medication can then be absorbed partially or entirely into the systemic circulation, or it can be swallowed as a solution to be absorbed from the gastrointestinal tract. The basic approach for the development of rapid dispersible tablets involves the usage of superdisintegrants. As the pre formulation studies showed that the flowing properties of the churnas is poor, the granules were prepared by wet granulation method in the present study.

The objective of the present study was to develop rapid dispersible tablets of Ashwagandha & Arjuna by using Sodium starch glycolate & Crosopovidone (Superdisintegrants) which could provide hard & rapid dispersible tablets & release the drug within 3 min.

Journal of Chemical and Pharmaceutical sciences

2. EXPERIMENTAL

Materials: Ashwagandha & Arjuna churnas were obtained from Herbal drug store, Hyd. Sodium starch glycolate & Crospovidone were obtained from Premier trading ,Hyd. Lactose & Talc were obtained from Unilex exports, Hyd. Sodium lauryl sulphate were obtained from S.D. fine chemicals, Mumbai.

Pre-formulation studies (Bolton,1990):

a. Angle of repose: Angle of repose was determined by using funnel method. The accurately weighed blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap or head of blend. The drug excipient blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation: $\tan \theta = h/r$

$$\theta = \tan^{-1} \frac{h}{r}$$

Where h = height of powder heap formed, r = radius of the powder heap.

b. Loose bulk density: Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

LBD = Weight of the powder / volume of the packing

c. Tapped bulk density: It was determined by placing a graduated cylinder, containing a known mass of drug excipient blend. The cylinder was allowed to fall under its own weight on to a hard surface. The tapping was continued until no further change in volume was noted.

TBD = Weight of the powder / volume of the tapped packing.

d. Compressibility index: The Compressibility index of the blends was determined by Carr's compressibility index.

Compressibility index (%) = $(TBD - LBD) \times 100 / TBD$

Preparation of Tablets (Howard,1985): The active ingredients, Lactose & disintegrant (Sodium lauryl sulfate ,SLS) were mixed in a porcelain mortar. Disintegrants with highest water uptake are most effective in tablet systems. Hence, Sodium starch glycolate(SSG) & Crosspovidone (CP) were particularly effective in taking up of moisture. This blend was later mixed by adding a liquid binder, Tragacanth to the powder mixture for the flow of powder mixture from hopper into the dies. The wet granules were first passed through sieve no.8 & were dried in fluid bed driers. After drying, the granules were passed through sieve no.20. A dry lubricant is then added & the granules were compressed on a single station flat –faced punch of tablet compression machine. The concentration of binder & disintegrant were at 7.5% in the tablets. The concentration of Talc level was fixed at 5% for all the formulations (Table 1). Various studies such as general appearance, weight variation, hardness, friability, wetting time & disintegration tests were evaluated.

a. General Appearance: The general appearance of a tablet, its visual identity and overall "elegance" is essential for consumer acceptance. Includes in are tablet's size, shape, color, Presence or absence of an odor, taste, surface texture, Physical flaws and consistency and legibility of any Identifying marking.

b. Weight Variation: Randomly, twenty tablets were selected after compression and the mean weight was determined. None of the tablets deviated from the average weight by more than $\pm 7.5\%$ (USP XX).

c. Friability: Friability is a crucial parameter for evaluation of tablets. Friability is a measure of mechanical strength of the tablet. Roche friabilator is used to determine the friability. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as:
 $\% \text{ Friability} = 1 - (\text{loss in weight} / \text{Initial weight}) \times 100$

d. Hardness (Crushing strength) : Tablet hardness is measured with hardness testers like Monsanto. A tablet is placed in the hardness tester and load required to crush the tablet is measured. The hardness of tablet made from churnas is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablet.

Journal of Chemical and Pharmaceutical sciences

e. Wetting time: A piece of tissue paper folded twice was placed in a Petri dish & wetted with distilled water. A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted.

f. Disintegration time: Six tablets selected from each batch were placed in the disintegration tubes and time was noted. The conventional test employs a volume of 900 ml of distilled water. A modified USP disintegration test apparatus is used.

3.RESULTS

The churnas were subjected to Pre-formulation studies like angle of repose and compressibility index. From the results it was found that the churnas were not free flowing. So, wet granulation method was used for compression into tablets. The tablets were evaluated for hardness, weight variation, friability, disintegration time & wetting time. Formulation studies showed appreciable hardness characteristics which facilitated in rapid disintegration. The friability of formulations indicated that the tablets were mechanically stable. The acceptable weight variation range was found to be $\pm 7\%$. Hence the entire formulated tablets passed the weight variation test. The disintegration time of formulation was around 1min30sec. AG8, AG7, AG4 and AR2 formulations shows rapid disintegration which contains 20%, 15% Crospovidone and Sodium starch glycolate 20% respectively. It was found that Crospovidone performed better than other disintegrant used. The disintegration time for all the formulations are shown in table-3. Wetting time for all batches is shown in table-3. Higher uptake of water leads to faster disintegration of tablets.

In conclusion, the results indicated that formulation AG8 containing 40% Crospovidone can be effectively used in the clinical formulation of fast dissolving tablets. Crospovidone was most suitable super disintegrant for formulation of Ashwagandha and Arjuna & it is evident that wet granulation method can be applied successfully to formulate rapid disintegrating tablets of ayurvedic churna preparations.

Table 1:Composition of Rapidly Dispersible Tablets:

INGREDIENTS	AG1	AG2	AG3	AG4	AG5	AG6	AG7	AG8	AR1	AR2
Drug	175	175	175	175	175	175	175	175	175	175
Sodium Starch Glycolate	10	20	30	40	-	-	-	-	30	-
CrossPovidone	-	-	-	-	10	20	30	40	-	30
Lactose	45	35	25	15	45	35	25	15	25	25
Tragacanth	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Talc	5	5	5	5	5	5	5	5	5	5
Sodium Lauryl Sulphate	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5

Table 2: Characteristics of Granules:

Formulation	ANGLE OF REPOSE[°]	COMRESIBILITY INDEX[%]
AG1	33.66	20.09
AG2	30.45	23.07
AG3	31.59	20.83
AG4	30.30	23.17
AG5	32.13	21.28
AG6	30.41	22.08
AG7	31.59	23.17
AG8	31.29	23.83
AR1	29.07	19.02
AR2	29.08	20.04

Journal of Chemical and Pharmaceutical sciences

Table 3: Evaluation of Churnas:

Code	Wt. variation (%)	Hardness (Kg/cm ²)	Friability	Disintegration time (min)	Wetting time(min)
AG1	7.5	3.0	0.62	2.09	2.34
AG2	7.5	4.1	0.44	2.15	2.16
AG3	7.5	3.5	0.19	2.30	1.59
AG4	7.5	3.1	0.17	2.10	1.30
AG5	7.5	4.1	0.23	2.16	2.10
AG6	7.5	3.6	0.43	2.56	1.58
AG7	7.5	2.8	0.15	1.20	1.06
AG8	7.5	2.5	0.12	1.15	0.54
AR1	7.5	3.2	0.16	2.44	1.53
AR2	7.5	2.8	0.13	1.16	0.59

REFERENCES

- Banker GS, Rhodes CT, Modern pharmaceutics, 4th ed., New York, Marcel Dekker, 2002, 167-184.
- Bi Y, Sunada H, Yonezawa Y, Dayo K, Otsuka A, Iida K, Preparation and evaluation of a compressed tablet rapidly disintegrating in oral cavity, Chem.Pharm.Bull., 44, 1996, 2121-2127.
- Bolton S, Pharmaceutical Statistics, New York, Marcel Decker Inc., 1990.
- Habib W, Khankari R, Hontz J, Fast-dissolving drug delivery systems, critical review in therapeutics, Drug Carrier Systems, 17, 2000, 61-72.
- Howard C.Ansel, Introduction to pharmaceutical dosage forms, 4th ed., Lea & febiger, Philadelphia, 1985.
- Lachman L, Liberman HA, Kanig JL, The theory and practice of industrial pharmacy, 3rd ed., Bombay, Varghese publishing house, 1986.
- Seager H, Drug delivery products and the zydis fast dissolving dosage forms, J.Pharm. Pharmacol., 50, 1998, 375-382.