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Influence of sodium starch glycolate, cros carmellose sodium and cros povidone on disintegration of directly compressed dispersible tablets of avipathi choorna

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ABSTRACT

Formulation of ayurvedic powder preparations into tablets may increase dosage uniformity. Application of direct compression method to ayurvedic preparations can be regarded as a major advance. In the present study, dispersible tablets of avipathi choorna were prepared by direct compression method. Avipathi choorna was subjected to pre formulation studies to test the suitability of direct compression method and appropriate formulations were developed. These formulations were further evaluated for hardness, friability, weight variation, disintegration tests and stability studies. Attempts were made to get minimum possible disintegration time by varying the concentrations of sodium starch glycolate, cros carmellose, cros povidone and starch. It was found that, use of mixture of disintegrating and super disintegrating agents was highly useful in the formulation of dispersible tablets of avipathi choorna. The study further revealed the usefulness of direct compression method to formulate dispersible tablets of ayurvedic preparations.

Key words: Avipathi choorna, dispersible tablets, direct compression, super disintegrants.

INTRODUCTION

A number of ayurvedic preparations are being used in the form of powders. Many of these are intended to be dispersed or mixed in liquids prior to administration. In such cases dosage is poorly regulated and has poor patient compliance. Formulation of this preparation into tablet form would be a better approach to maintain dosage uniformity and better patient compliance. Since higher temperature and moisture levels of wet granulation method may be harmful to active principles of plant product[1], direct compression method may be useful for the development of tablets for ayurvedic preparation. Avipathi choorna, an ayurvedic preparation contains various active plant materials viz, thrivruth, amalaki, vidangam, intended for many gastro intestinal disturbances like ulcer, indigestion, flatulence, constipation and belching [2-4]. Normally prescribed dose of this preparation is one teaspoonful with water or butter milk twice in a day. In the present work an attempt has been made to develop fast dispersible tablets of avipathi choorna by direct compression method to increase dosage uniformity and patient compliance.

MATERIAL AND METHODS

Avipathi choorna was obtained from native practitioner of Gulberga, di-calcium phosphate (Rolex Laboratory, Mumbai.), sodium starch glycolate, cros povidone and cros carmellose sodium (Pellet Pharma Ltd. Hyderabad.), potato starch IP, talc IP and magnesium stearate IP (Sd-fine chemicals, Mumbai.) of AR grade.

Pre-formulation studies

Each tablet contains half teaspoonful of Avipathi Choorna. The average weight of avipathi choorna equivalent to one teaspoonful quantity was determined by measuring and weighing of Avipathi choorna ten times with 3 different teaspoons, which was divided by 2 to get average weight for half teaspoon quantity of Avipathi Choorna. Prior to

compression into tablets, tabletting properties such as flow properties [5-6], compressibility index [5-6] and Bulk density [5-6] for avipathi choorna alone and blends of avipathi choorna and DCP in different proportion were determined. After a careful study, an optimum proportion was selected for compression. The results of the tabletting properties are shown in the table 1.

Preparation of tablets

By keeping composition of avipathi choorna, DCP constant and by altering composition of disintegrating agents (starch, SSG[7-14]) and super disintegrating agents (cros carmellose sodium[15-17], cros povidone[13,16,18-20]), 14 tablet formulations were compressed using a single tablet punching machine with 13mm bi flat punches. Various evaluation tests for tablets such as weight variation[21], disintegration[22], hardness[23] (Pfizer hardness tester) and friability[23] (Roche friabilator), were studied using standard methods. Stability study with respect to disintegration time for three months was carried out by storing the tablets at room and elevated temperature (45°) [24]. At the end of three months tablets were evaluated for disintegration time. Results are shown in table 2.

RESULTS AND DISCUSSION

The average weight of avipathi choorna equal to one teaspoonful quantity was found to be 1.02 ± 0.07 gm which was incorporated in two tablets. Since, tabletting properties of Avipathi choorna alone were very poor, DCP was blended in different proportions. As proportion of DCP was increased, angle of repose and compressibility index were decreased (Table 1). The 1: 0.2 proportions of avipathi choorna and DCP was selected for compression into tablets which had optimum tabletting properties. All the prepared formulations passed friability (% age friability was with in 1%), weight variation (% age deviation was with in ± 5%) and tablet hardness ranged from 2.6 to 3.0 Kg/cm2.

Initially, disintegration time of formula F-1 was evaluated to know weather 5% starch alone could provide the desired rate. However, these tablets failed the disintegration test. With an intention for reducing the disintegration time, the amount of starch was increased to 10% in the formulation F-2. These tablets, even though passed the disintegration test, took more than 2 min (140 sec) to disintegrate. In order to further improve the disintegration property, disintegrating agent. SSG (4% and 8%) was used along with 5% and 10% starch in formulations F-3, F-4 and F5 and F6 respectively. Disintegration time was lowered to 85.45 sec, 65.10 sec, 64.25 sec and 55.33 sec. In order to further improve the disintegration property, super disintegrating agents such as cros carmellose sodium (2% and 4%) and cros povidone(2% and 4%) was used along with 5% and 10% starch, The results of disintegration test of F-7,F-8,f-9 F-11, F-12 and F-13, have indicated that, the disintegration time was not lowered significantly with the rise in the concentration of any one of the disintegrants used. But the disintegration test of F-10 and F-14 (disintegration time is 45.34 ± 0.66 sec and 44.24 ± 0.38) revealed that, an increase in the concentration of both the disintegrants has lowered the disintegration time significantly. This

Table 1: Tabletting properties of avipathi choorna

Properties of AVC and DCP	Angle of Repose	Compressibility Index (%)	Bulk Density
AVC alone (1: 0)	36.27 ± 0.38	38.44 ± 0.28	0.68 ± 0.11
1 : 0.1	30.73 ± 0.32	32.97 ± 0.19	0.70 ± 0.01
1 : 0.2	25.25 ± 0.21	28.87 ± 0.42	0.76 ± 0.01
1 : 0.3	22.56 ± 0.22	27.27 ± 0.52	0.81 ± 0.00
1 : 0.4	20.19 ± 0.25	26.30 ± 0.11	0.87 ± 0.01
1 : 0.5	19.75 ± 0.14	26.02 ± 0.24	0.92 ± 0.01
1 : 0.2 + 1% Talc + 1% Magnesium stearate	22.68 ± 0.45	27.45 ± 0.22	0.75 ± 0.01

Tabletting properties of avipathi choorna alone and along with other excipients (DCP) = di calcium phosphate, talc and magnesium stearate) were determined in triplicates. Mean values ± standard error mean (SEM).

Table 2: Results of Evaluation Tests for Tablets

Formula	Composition of Disintegrants (%)				Hardness (Kg/ Cm2)	Friability (%)	Disintegration time (sec)	Disintegration time after 3 months (sec)	
	Starch	SSG	Cros carmellose sodium	Cros Povidone				Room temperature	45°
F1	5	-	-	-	2.65 ± 0.04	0.96 ± 0.10	292.15 ± 0.34	294.14 ± 1.20	301.00± 1.52
F2	10	-	-	-	2.88 ± 0.08	0.94 ± 0.01	140.05 ± 0.12	142.02 ± 0.57	146.33 ± 0.33
F3	5	4	-	-	2.83 ± 0.06	0.93 ± 0.60	85.44 ± 0.58	84.38 ± 0.33	86.50 ± 0.28
F4	5	8	-	-	2.98 ± 0.07	0.84 ± 0.04	65.10 ± 1.10	66.18 ± 0.58	68.66 ± 0.33
F5	10	4	-	-	2.96 ± 0.05	0.99 ± 0.08	64.25 ± 0.60	63.34 ± 0.67	65.33 ± 0.33
F6	10	8	-	-	3.00 ± 0.08	0.91± 0.09	55.33 ± 0.48	56.40 ± 0.88	57.00 ± 0.57
F7	5	-	2	-	3.00 ± 0.03	0.82 ± 0.10	50.12 ± 0.70	51.36 ± 0.41	53.33 ± 0.33
F8	5	-	4	-	3.00 ± 0.04	0.94 ± 0.08	48.30 ± 0.90	49.42 ± 0.33	52.00 ± 0.00
F9	10	-	2	-	2.95 ± 0.08	0.86 ± 0.06	49.15 ± 1.50	49.84 ± 0.57	51.33 ± 0.33
F10	10	-	4	-	2.90 ± 0.06	0.90 ± 0.05	45.34 ± 1.24	46.70 ± 0.67	49.00 ± 0.00
F11	5	-	-	2	2.80 ± 0.07	0.90 ± 0.04	49.26 ± 0.94	48.20 ± 0.44	50.33 ± 0.33
F12	5	-	-	4	2.85 ± 0.05	0.94 ± 0.06	45.20 ± 1.02	46.86 ± 0.68	47.66 ± 0.33
F13	10	-	-	2	2.95 ± 0.05	0.96 ± 0.08	46.14 ± 1.14	47.24 ± 0.89	49.00 ± 0.00
F14	10	-	-	4	2.95 ± 0.06	0.99 ± 0.07	44.24 ± 0.68	44.74 ± 0.94	45.66 ± 0.33

Prepared Tablet formulations were evaluated for various quality control tests such as hardness test, friability test, disintegration time and disintegration time after storage for 3 months reported in triplicates. Mean values ± standard error mean (SEM).

may be due to combined effect of both disintegrants at higher proportion.

After storing the tablets for three months at room temperature the disintegration time was remained almost similar, where as, at elevated temperature (45°) the disintegration time was slightly increased.

CONCLUSION

The super disintegrants like sodium starch glycolate, cros carmellose sodium and cros povidone alone were able to decrease the disintegration time. However, combinations of such agents with other disintegrating agents were found to be highly beneficial in reducing the disintegration time to the required level.

From the results it may be concluded that the super disintegrating agents (sodium starch glycolate, cros carmellose sodium and cros povidone) in combination with disintegrating agents may be useful and can be adopted in formulation of directly compressible, dispersible tablets of polyherbal ayurvedic preparations.

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