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FORMULATION AND IN-VITRO EVALUATION OF PRAVAL BHASMA TABLET

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ABSTRACT

Praval bhasma is mostly available in powder dosage form. One of the major problems with this dosage form is inaccuracy of dosage. Higher dose of Praval bhasma contain major amount of calcium carbonate produce adverse effects. Therefore uncoated tablets of Praval bhasma were prepared by conventional wet granulation method using starch (as paste), methyl cellulose and gelatin at 2 % concentration and evaluated for in-vitro parameters both official and non-official, viz. weight variation, friability, hardness, assay of calcium carbonate, disintegration time, dissolution study and drug interaction study. Results of study revealed that all prepared tablets fulfilled the official (IP) standards for weight uniformity, hardness, friability test, assay of calcium carbonate and disintegration tests was done. Based on dissolution efficiency (DE_{60}) value order of performance of binders was starch (as paste)> methylcellulose > gelatin. Analysis of variance (ANOVA) of DE_{60} values followed by Dunnett's 't' Test indicates ($p < 0.001$) that the tablets formulated with different binders produces significant difference in dissolution profile. Dissolution of Praval bhasma tablets obeys first order kinetics. The IR spectra of Praval bhasma in pure form and prepared tablets were found to be identical, indicating no interaction of binders in prepared tablets.

Keywords: Praval Bhasma, Tablet Formulations, Evaluation parameters, Starch (as paste), methylcellulose and gelatin.

INTRODUCTION

Praval bhasma is prepared as an Ayurvedic medicine, available in powder dosage form that contain large amount of calcium carbonate[1] is used in treatment of acidity and it related disorders. Higher dose of calcium carbonate containing antacid products may produce acid rebound effects, systemic alkalosis and hypercalcemia.[2] Praval bhasma powder contains inorganic substances and possesses poor compressibility and poor flow properties.[3] Therefore it is worth to formulate and evaluate the Praval bhasma tablets using different binders. Excipients are the additives used to prepare the convenient dosage form suitable for administration to the patients.[4, 5] The objective of present study was to formulate and in-vitro evaluate Praval bhasma tablet for improving the accuracy of dosage, increased shelf life, ease of administration and increased efficacy.

EXPERIMENTAL

Materials

Pure and authenticated Praval bhasma powder procured from Shree Baidyanath Ayurved Bhavan Pvt. Ltd., Nagpur. Praval bhasma 50 mg tablet Mfg. by Ayurveda Rasashatra Pvt.Ltd., Pune, was procured from the local market. Starch, methylcellulose, gelatin, talc, magnesium stearate and lactose were procured from Global Marketing Pvt. Ltd, Nagpur. All other reagents used were of analytical grade.

Preparation of Praval bhasma tablets

Praval bhasma tablets each containing 50 mg was prepared by conventional wet granulation method employing three commonly used binders starch (as paste), methylcellulose and gelatin. Coded formula A, B and C showen in Table:1, all binders were used at 2 % concentration of formula. A 2 - 5 % is the usual concentration range for all the binders' used6. Granules were compressed into tablets of hardness 5 to 6 kg/sq.cm using Cadmach single punch tablet machine.

Methods

Interaction study

IR spectra of pure Praval bhasma and prepared tablets

Assay

Assay of calcium carbonate performed by using complexometric titration method prescribed in the USP.[7]

Dissolution Study

The dissolution rate of Praval bhasma from the tablets, both formulated and commercial was studied. Experimental conditions were, medium was 0.1N HCl, apparatus model: DA3 (paddle type-1)8 and temperature was 37^{0}C ± 0.5^{0}C. Dissolution test was carried out using 900 ml of 0.1 N HCl as a dissolution medium at paddle speed of 50 rpm for 60 min, the sample of 1 ml was withdrawn at each 10 min. intervals, filtered and diluted suitably, it was replaced by same amount of the fresh medium each time, absorbance of resulting solution was measured at about 263 nm against 0.1 N HCl as a blank. The amount of dissolved drugs was calculated using standard calibration curve. From dissolution data, dissolution efficiency (DE_{60}) was calculated.[9, 10]

Weight variation,

Weight variation test of the tablets was performed as per IP11. Twenty tablets of each formulation were weighed and the average weights and Maximum Deviation of average weights were calculated.

TABLE 1: FORMULAE OF PRAVAL BHASMA TABLETS

Parameters	Formulations*(± S.D.)			
	A	B	C	S**
Uniformity of weight (mg)	220	220	222	221
(Maximum Deviation in %)	0.3 %	0.4 %	0.6 %	0.4 %
Hardness Test (Kg/cm2)	5.9	4.1	5.2	5.6
Friability Test (%)	0.001	0.061	0.002	0.052
Disintegration Time (min:second)	4:00	3:20	2:40	2:00
Assay of Calcium carbonate	83.00± 0.6690	82.29± 0.7223	81.93± 0.3605	82.32± 0.5342
Dissolution Time (% of drug dissolved in 60 min.)	98.34± 0.0824	96.72± 0.0139	84.68± 0.0729	98.84± 0.0654
DE_{60} (%)	79.30	78.50	52.26	9.82
K_1 (min^{-1})	0.068	0.064	0.029	0.069

TABLE: 2 EVALUATION CHARACTERISTIC OF PRAVAL BHASMA TABLET

Ingredients (mg/Tablet)	Formulations		
	A	B	C
Praval bhasma	50	50	50
Starch (as paste)	5	--	--
Methyl cellulose	--	5	--
Gelatin	--	--	5
Potato starch (Dry)	34	34	34
Lactose	125	125	125
Talc	3	3	3
Magnesium stearate	3	3	3
Total weight (mg)	**220**	**220**	**220**

***Result of six determinations**
****Commercial brand.**

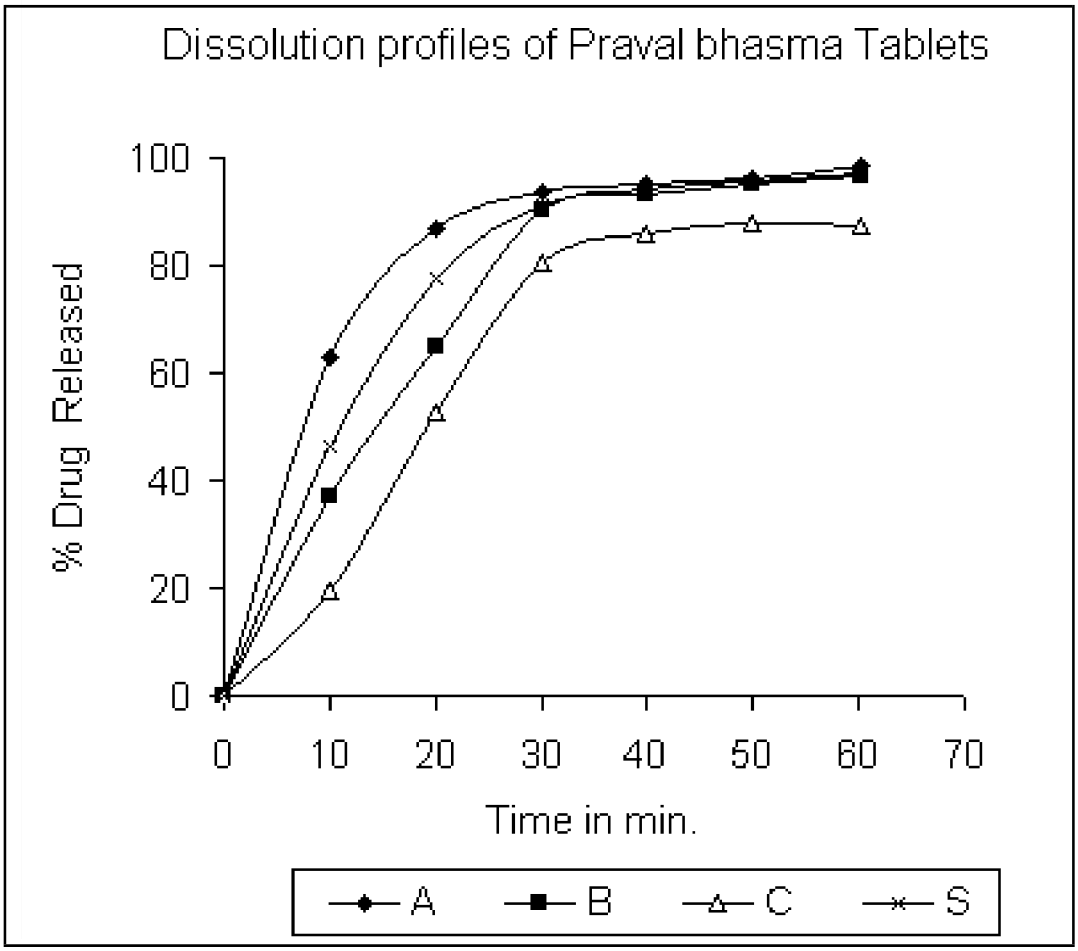

Figure 1 : *In-Vitro* Dissolution profiles of formulated and commercial Praval bhasma Tablets

Hardness and Friability

Hardness was determined using Pfizer hardness tester11, and friability of tablets was determined in Roche Friabilator. [11]

Disintegration study

Disintegration time in distilled water was determined by Electrolab disintegration apparatus[11] model ED-2L, speed 30 cycles/min. and temperature was 370 ± 0.5^0 C. Observation and results are showen in Table: 2

Statistical analysis

Statistical analysis of dissolution data was done by using analysis of variance (anova) method followed by dunnett's "t" test[12] which reflect on significant differences in dissolution profile of praval bhasma tablets prepared by using different binders.

RESULTS AND DISCUSSIONS

Prepared tablets were found to be contain of calcium carbonate 83.00 %, 82.29 %, 81.93 % and 82.32 % for formula a, b, c and s respectively. All prepared tablets fulfilled the official (ip) tests for uniformity of weight. Hardness of tablets was found to be in range of 4 to 5.9 kg/sq.cm. The percentage weight loss in the friability test was less than 0.1 %. Disintegratation time was 2 to 4 min. Tablet formulation with different binders fulfilled all the official standards (ip) of uncoated tablets. Dissolution profiles of various tablets are showed in table: 2. Dissolution of praval bhasma from tablets followed first order kinetics (fig: 1). Dissolution of praval bhasma from commercial product was much higher than that of other prepared formulations. Tablets formulated with starch (as paste) exhibited higher de 60 value and dissolution rates (98.34 %) comparable to methyl cellulose (96.72 %) and gelatin (84.68 %). Analysis of variance (anova) of de60 values indicated highly significant ($p<0.001$) difference in the dissolution characteristic of the formulated tablets due to various binders. Dunnett's

't' test indicated that the tablet formulated with various binders produced significant difference in dissolution profile. Based on de60 value the order of performance of binders was starch (as paste) > methylcellulose > gelatin. The ir spectrum of praval bhasma in pure form and prepared tablets was found to be identical, indicating no interaction of binders in prepared tablets. The tablet formulated with starch (as paste) and methylcellulose as binders showed moderate dissolution rates and DE_{60} value comparable to the commercial brand, but the tablets formulated with gelatin as binders showed low dissolution rate and de60 value. Hence the observed difference in the dissolution characteristics of the tablets prepared with various binders is due to the difference in their disintegration and deaggregation properties. From the present study it was concluded that, it is possible to formulate of praval bhasma tablet by using starch (as paste), methylcellulose as binders, which gave optimum results.

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