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Original Research Article

EFFECT OF DIFFERENT TABLET DISNTEGRANTS ON PROCHLORPERAZINE MALEATE TABLETS

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Abstract: The study is performed to determine the effect of selected superdisintegrants, Primellose and Primojel, on the Disintegration time (DT) of tablets of Prochlorperazine maleate. The molecule is an antiemetic and a high rate of disintegration would give faster pharmacological effect. 1%, 2% and 4% concentrations of the selected disintegrants were added and all other composites were kept constant. 4% Primellose gave the best result with a DT of 1 min 45 s.

Key Words: Prochlorperazine maleate, disintegrant, magnesium stearate

Introduction

Prochlorperazine maleate is an antiemetic, dopamine (D-2 receptor) antagonist.[1] It is also used to alleviate the symptoms of vertigo.[2] The oral tablets available give an onset of action in half to one year. The use of conventional tablets is still not obsolete and thus the use of disintegrants is equally important to give better and fast pharmacological effects. Disintegration test is of importance for the immediate release oral formulations. Faster disintegration refers to faster availability of drug, thus it is important to make the selection of appropriate disintegrant in correct quantity to make the API available to the body. Out of many disintegrants Primojel (sodium starch glycolate) and Primellose (cross linked carboxymethyl cellulose sodium) are selected to make a comparative study of the efficacy of the two disintegrants. The disintegrants can soak many times their weight of water.

With the new advents in pharmacy faster disintegrating agents 'super disintegrants' are in use whih are effective in low concentration, but being hygroscopic in nature these are avoided in moisture sensitive drugs.[4]

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Materials and Methods

Materials :Prochlorperazine maleate, primojel, primellose, ammonium acetate, glacial acetic acid, lactose, magnesium stearate

Method of preparation of acetate buffer solution pH 4.5: 77.1 g of ammonium acetate R was dissolved in water R. 70 ml of glacial

acetic acid R was added and diluted to 1000.0 ml with water R.[5]

Method of tablet preparation by wet granulation method: All the composites were passed through mesh no. 40. Calculated amount of Prochlorperazine maleate was mixed with that of Lactose thoroughly in a mortar. Primojel & Primellose were added separately in calculated amount to make the formulations A & B respectively. Water as the granulating fluid was added and mixed to form a dough mass. This dough was turned into granules by passing through mesh No. 12. These granules were dried at 60°C for 2h. These dried granules were broken by passing through mesh no.16. Magnesium stearate as lubricant was added in the calculated amount to each formulation. The granules were then compressed into tablets on a tablet punch machine.

Disintegration time determination using Basket rack assembly: One tablet was placed in each of the six tubes of the basket. The apparatus using acetate buffer as the immersion fluid was maintained at temperature between 35-39 °C. The time of disintegration of the tablets was noted.

The prepared tablets were evaluated to determine the various tablet parameters.

Table 1: Composition of the Prochlorperazinemaleate Tablets being formulated

Composites	Primojel as disintegrant			Primellose as disintegrant		
	1% (Form.A1)	2%(Form. A2)	4% (Form. A3)	1% (Form. B1)	2% (Form. B2)	4% (Form. B3)
Prochlorperazine maleate	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg
Diluent (Lactose)	40 mg	40 mg	40 mg	40 mg	40 mg	40 mg
Disintegrant	0.45mg	0.9mg	1.8 mg	0.45mg	0.9mg	1.8 mg
Magnesium stearate	1.8 mg	1.8 mg	1.8 mg	1.8 mg	1.8 mg	1.8 mg
Purified water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Result AND DISCUSSION

Standard procedures were adopted to determine the evaluation parameters of the tablets of Prochlorperazine maleate. The results are as shown in table 2 & 3

Table 2: Evaluation Parameters of the various tablets of Prochloperazine maleate

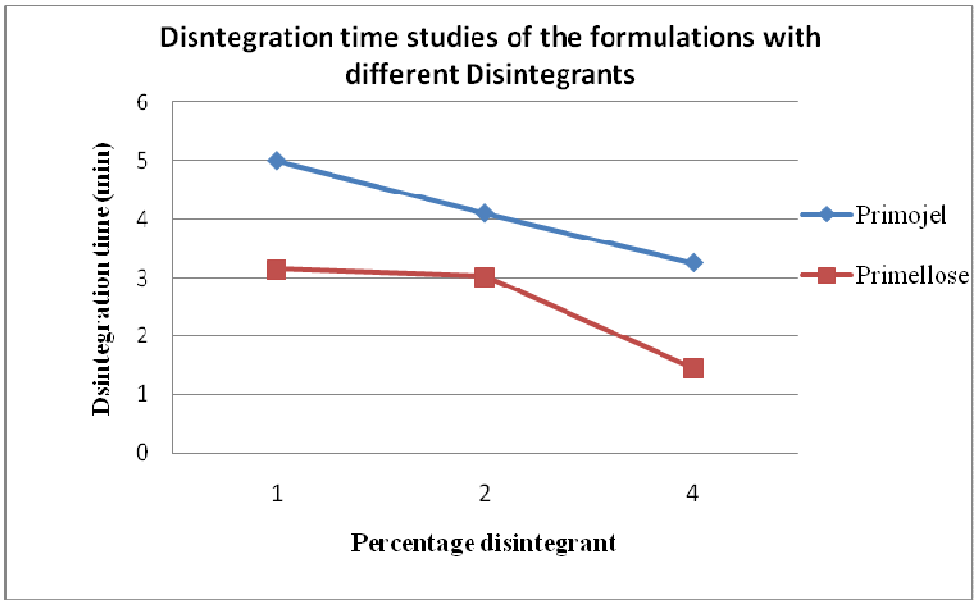
Formulation	**Thickness(mm)**	**Hardness (kg/cm^2)**	**% Friability**	**Weight of tablets (mg)**
A 1	3.1±0.1	4.6±0.21	0.38	49±0.15
A 2	2.8±0.16	4.8±0.18	0.36	49.5±0.22
A 3	3.1±0.08	4.7±0.24	0.25	50±0.23
B 1	2.9±0.09	4.6±0.25	0.37	49±0.20
B 2	3.0±0.1	4.5±0.20	0.35	49.5±0.19
B3	2.9±0.09	4.7±0.24	0.19	50±0.18

Values are expressed as Mean±SD

Table 3: Disintegration time of theProchlorperazine maleate Tablets being formulated

Form. A1	Form. A2	Form. A3	Form. B1	Form. B2	Form. B3
5 min	4 min 10 s	3 min 25 s	3 min 15 s	3 min 2 s	1 min 45 s

Graph 1



Conclusion: Different disintegrants were used to study their effect on the rate of disintegration of the prochlorperazine maleate tablets. The concentrations of the API and other excipients were kept constant. Out of all the varying concentrations of the selected disintegrants, Primojeland Primellose, 4% Primellose (B 3) gave the least disintegration time of 1 min & 45 s (Formulation B 3) though there was not much variation of DT between 1% and 2% Primellose. The increasing concentration of Primojel in the formulations gave approximate a linear change (decrease) in DT.

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