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Full Length Research Manuscript

Formulation and Evaluation of Taste Masked Cetrizine Dihydrochloride Orally Disintegrating Tablets: A Research

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Abstract

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. ODTs dissolve or disintegrate instantly on the patients tongue or buccal mucosa and leaves easy-to-swallow residue. It is suited for tablets undergoing high first pass metabolism and is used for reducing dosing frequency. New ODT technologies address many pharmaceutical and patient needs such as, it denotes its importance in case of pediatric, geriatric and patients suffering from nausea or repeated emesis conditions, bed-ridden patients having dysphagia. So taste masking is essential criteria following the advanced method of use of ion exchange resins. Research in developing orally disintegrating systems has been aimed to investigate different excipients as well as techniques to meet number of challenges. Orally disintegrating tablets are the safest, convenient and highly economical formulations. They show satisfactory absorption from oral mucosa; ultimately immediate pharmacological action. This research deals with formulation of orally disintegrating tablets by direct compression inorder to achieve a better dissolution rate and further improving the bioavailability of the drug. The result showed rapid dissolution of drug with the use of superdisintegrants, Ac-di-sol (Disintegration Time [DT] 5-6 sec.) as compared to sodium starch glycolate (DT 8-9 sec.) and polyplasdone (DT 8-10 sec.).

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Orally disintegrating tablets; Cetrizine Dihydrochloride; Direct compression; Sublimation.

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INTRODUCTION

Drug delivery using fast disintegrating tablets (FDTs) [1, 2] is rapidly gaining importance since tablets either disintegrate or dissolve in the mouth rapidly, without requiring water to aid in swallowing. This novel dosage form is suitable for all age groups, particularly children, elderly and patient who are ill

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and have difficulty in swallowing conventional tablets and capsules. Current approaches of making fast disintegrating tablets are maximizing the porous structure of the tablet matrix by incorporating appropriate disintegrating agents and or highly water-soluble excipients in tablet formulation. Direct compression is the easiest way of manufacturing tablets. Disintegration and solubilization of the directly compressed tablets are based on action of disintegrants, water-soluble excipients and effervescent agents. In many cases, the disintegrants play a major role in disintegration and dissolution process of FDTs made by direct compression. In today's era many people are suffering from allergic disorders which require frequent and quick treatment. Cetrizine Dihydrochloride (CTZ) is an antiallergic agent and is selective H1 recepotor antagonist. Quick onset of action is necessary in order to protect the patient from allergic conditions. The present study is aimed to design such a dosage form for CTZ, which is able to deliver drug as rapidly as possible so that onset of action is quick and patient does not require water for swallowing. Research in formulation development of pharmaceuticals is focused on design of new drug delivery system to improve patient compliance. Hence it is necessary to individualize the drug therapy to optimize the drug concentrations and manufacturing technology for patient oriented drug delivery system. Super disintegrants [3] like Croscarmellose sodium, sodium starch glycollate, crospovidone have been selected due to their fast disintegration property. Ion exchange resins [4] were used as the taste-masking agent to mask the taste of CTZ and also it is used as disintegrating agent thus improving the dissolution rate.

MATERIALS AND METHODS

Materials

CTZ was procured from college source, Tulsion 339 and Tulsion 335 from Thermax India Ltd. All the other ingredients were of A.R. grade.

Methods

Preparation of Resinates:

Studies were carried out using two weak cation exchange resins. Resinates were prepared using batch method[5]. The weighed quantity of resin was slurried with equal amount of CTZ keeping Drug: Resin ratio varying from 1:1 to 1:7. The slurry of the resin was made in 20 ml of demineralized water. The drug as a solution of 0.1N HCl was added slowly under stirred conditions. The stirring was continued for 6-7 hours. The mixture was kept aside to allow the particles to sediment and was then filtered .The residue was washed with 0.1N HCl. The concentration of free drug in the filtrate was measured spectrophotometrically with suitable dilutions. From the absorbance value the amount of uncomplexed drug and then percentage amount complexed can be determined. Also the resinates were prepared at various pH conditions to find optimum pH conducive for loading.

Taste Evaluation:

The healthy human volunteers were used for taste masking; informed consent was obtained from all of them. Taste evaluation was done by a panel of 10 members using time intensity [6] method. Sample equivalent to normal dose was held in mouth for 10 sec., bitterness levels were recorded instantly and then after 10sec, 1, 2, 5, and 15 minutes. Volunteer's opinion for bitterness values were rated by giving different score values. That is 0: no bitterness, 1: acceptable bitterness, 2: slight bitterness, 3: moderately bitterness, 4: strong bitterness.

Descriptive statistics mean and standard deviation were calculated for all variables. Paired t test was applied using INSTAT software. Value $P < 0.05$ has been considered as statistical significant level.

Characterization of Drug: Resin (1:6) Complex:

IR spectroscopy:

The drug, resin and resinate were subjected to Fourier Transform Infra Red (FTIR) studies to check drug resin interaction using FTIR (SHIMADZU 8400 S). The KBr disk method was used for preparation of sample.

X-ray diffraction analysis:

The drug, resin and resinate was subjected to x-ray diffraction study using P.W. 1729, X-Ray Generator, Philips, Netherland. To study X-ray diffraction pattern, the sample was placed into aluminum holder and the instrument was operated between initial and final 2θ angle of 5-50º respectively in an increment of 0.4º2θ.

Differential Scanning Calorimetery (DSC) Study:

The drug, resin and resinate were subjected to study using (Mettler TA 4000) DSC apparatus. First 10-30 mg of sample was weighed into aluminum crucible. The drug, resin and resinate were analyzed by heating at scanning rate of 20ºC / minute over a temperature range of 40 to 250º C.

Evaluation of Taste Masked Drug: Polymer (1:6):

The drug and the prepared taste masked complex were evaluated for Bulk density, Carr's index, and angle of repose.

In vitro Release of Drug from the Resinate:

Weighed quantity of resinate equivalent to normal dose was suspended in distilled water using USP type II dissolution apparatus and quantity of drug release was determined periodically. The testing was carried out in triplicate.

Preparation of FDT's using CTZ : FDT's of CTZ were prepared by using Ac-Di-sol (Croscarmellose Sodium), Polyplasdone XL (Crospovidone) and Primojel (Sodium Starch Glycollate) as the superdisintegrants in the concentration of 2%, 3%, 4% and 5% of the weight of the tablets. Tablets were prepared by direct compression method using Sixteen-station tablet machine (Cadmach, India). Table 1 indicates the formulation design of FDT's.

Table 1: Formulation design of FDT's

Name of the ingredients	Formulations(mg)		
CTZ	5	5	5
Tulsion 339	30	30	30
Microcrystalline cellulose	66.75	66.75	66.75
Aspartame	1	1	1
Superdisintegrants	*	**	***
Mannitol	41	41	41
Flavour	1	1	1
Magnesium stearate	0.875	0.875	0.875
Aerosil	0.875	0.875	0.875
Total	**150**	**150**	**150**

*A1,A2,A3,A4 represents 3.5,5.25,7,8.75 AC-Di-Sol respectively

**B1,B2,B3,B4 represents 3.5,5,7,8.75 polyplasdone XL respectively

***C1,C2,C3,C4 represents 3.5,5,7,8.75 primojel respectively

Evaluation of FDT's: The formulated FDT's were evaluated for different parameters like thickness, uniformity of weight, hardness, water absorption ratio, in vitro and in vivo disintegration time.

Thickness Thickness of the tablets was determined using a thickness gauge (Mitutoyo, New Delhi, India). Five tablets from each batch were used, and average values were calculated.

Weight variation test [7] To study weight variation 20 tablets of each formulation were weighed using an electronic balance (Schimadzu), and the test was performed according to the official method.

Drug content Five tablets were weighed individually and powdered. The powder equivalent to average weight of tablets were weighed and extracted in water and concentration of drug was determined by measuring absorbance at 239 nm by Ultra Violet (UV) spectrophotometer (Schimadzu 1601)

Hardness and Friability [7] For each formulation the hardness and friability of 6 tablets were determined using the Monsanto hardness tester (Cadmach, Ahmedabad, India) and the Roche Friabilator (LabHosp Mumbai, India) respectively.

Disintegration time [8] In vitro disintegration time of 6 tablets from each formulation was determined by using Digital Tablet Disintegration Apparatus (Veego Scientific, Mumbai, India). In vitro disintegration test was carried at 37 ± 2ºC in 900 ml distilled water. In vivo disintegration time of tablet was checked in healthy human volunteers by putting a tablet on tongue and time required for complete disintegration was checked.

Water absorption ratio [9] A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was kept on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R, was determined using following equation: R = 100 x Wb –Wa / Wa.

Where, Wa = Weight of tablet before water absorption. Wb = Weight of tablet after water absorption.

Dissolution studies [10] The in vitro dissolution studies were carried out using United States Pharmacopoeia (USP) apparatus type II (VGA Scientific 6DA Apparatus) at 100 rpm. The dissolution medium used was distilled water (900 ml) maintained at 37± 0.5 º C. Aliquots of dissolution media were withdrawn at different intervals, concentration for CTZ was determined by measuring absorbance at 239 nm by UV spectrophotometer. The dissolution experiments were conducted in triplicate.

Stability Studies Stability study was conducted by storing the tablets at 40 ± 2ºC/75 ± 5% Relative Humidity (RH) for three months. The content and dissolution behavior from dissolving tablets were tested monthly for three months.

RESULT AND DISCUSSION

For preparation of resinate batch method was preferred because of its convenience. The results revealed that ion exchange resin Tulsion 339 in drug to resin ratio of 1:1 was found to complex with the drug to maximum extent. Table 1 show the maximum adsorption of Tulsion339, which may be attributed to the difference of crosslinking, exchange capacity and form of resin.

Attempts were made to optimize the drug loading process by carrying out the loading at different drug: resin concentrations, which show that 1:6 as the best ratio (Table 2).

The pH also has an important role on ionisation of resins having weak acid (carboxylic functionality) is vulnerable to changes in pH. Results reveal that best loading occurs at pH 7 (Table 3). Thus the resinate prepared by batch method using Tulsion 339 in drug: resin ratio of 1:6 at pH 7 gives optimum drug loading.

The taste masked resinate was given to panel of healthy human volunteers for taste masking evaluation using time intensity method which shows satisfactory masking of taste (Table 4).

The interaction between the drug and the carrier often lead to identifiable changes in IR profile of the complex. The drug and the complex were subjected to IR analysis in order to evaluate possible solid-solid interaction between the drug and the resin.

The data was compared with the standard spectrum for CTZ and the characteristics peaks associated with specific structural characteristics of the molecule and their presence/absence in the resin as well as complex were noted.

The IR spectra of the complex (Fig. 1) showed that there was no significant evidence for interaction between drug and resin. Peaks of both drug as well as resin were observed and interpreted.

The X-ray diffraction pattern of complex of drug: Tulsion 339 (1:6) showed no defined peak attributed to CTZ; this implies the absence of apparent crystallinity in the complex. However in the pure CTZ powder typical peak of CTZ is present, so conforming the satisfactory sensitivity of the method (Fig. 2). DSC studies showed characteristic crystallinity of pure drug while the drug resin complex indicates complete absence of the peak indicating conversion of crystalline form of drug to amorphous form. (Fig. 3).

The optimised CTZ: Tulsion 339 (1:6) complex was evaluated for micromeritic properties like Bulk density, Carr's index and Angle of repose (Table 5) .It was found that all the properties of resin such as angle of repose were retained in the complex, which is important from formulation point of view.

The complex was subjected to dissolution studies in 900ml distilled water by using USP type II apparatus at 100 rpm and temperature condition at 37± 0.5°C, which shows that drug release was 100% within 0.5 minutes as compared to the conventional marketed tablet. (Table 6)

Thus use of cation exchange resin offers good method for preparing taste-masked substrate of CTZ. Further the rate of dissolution was also improved as compared to the conventional tablets. This can be formulated in suitable dosage form such as dispersible tablets or mouth dissolving tablets.

Table No. 1: Selection of Resin

Resin	Concentration (mg)		Percentage of drug bound to resin
	Drug	Resin	
Tulsion 335	100	100	64.10 ± 0.12
Tulsion 339	100	100	78.26 ± 1.05

Each reading is a mean of three determinations ± SD

Table No. 2: Effect of Drug: Resin Ratio on Loading

Resin	Concentration (mg)		Percentage of drug bound to resin
	Drug	Resin	
Tulsion 339	100	100	66.10 ± 0.19
Tulsion 339	100	200	77.35 ± 1.48
Tulsion 339	100	300	89.91 ± 0.22
Tulsion 339	100	400	92.10 ± 0.61
Tulsion 339	100	500	96.10 ± 0.52
Tulsion 339	100	600	97.10 ± 0.76
Tulsion 339	100	700	97.08 ± 0.99

Each reading is a mean of three determinations ± SD

Table No. 3: Effect of PH on Loading

Resin	Ratio	pH	Percentage of drug bound to resin
Tulsion 339	1:6	2	47.32 ± 1.59
		3	54.32 ± 1.49
		4	60.26 ± 0.25
		5	71.44 ± 0.67
		6	86.11 ± 0.80
		7	97.13 ± 0.34
		8	85.14 ± 1.24
		9	74.68 ± 0.67

Each reading is a mean of three determinations ± SD

Table No. 4: Volunteers opinion test for CTZ before and after taste masking

Sr. No	Time (seconds)	Before taste masking Mean ± SD	After taste masking Mean ± SD
1	10	2.1 *** ± 0.34	0.3 ***± 0.63
2	60	3.2 *** ± 0.21	0.5*** ± 0.84
3	120	3.5 ***± 0.11	0.4 ***± 0.69
4	300	3.7 *** ± 0.65	0.1 *** ± 0.31
5	600	3.7 *** ± 0.78	0
6	900	4 *** ± 0.0	0

P< 0.001***

Each reading is a mean of ten determinations ± SD

Table No. 5: Micromeritic properties of drug and Resinate

Property	Drug	Resinate
Carr Index (%)	13.12 ± 0.68	15.20 ± 0.78
Bulk Density (g/ml)	0.354 ± 0.43	0.435 ± 0.53
Angle of Repose	11.52 ± 1.82	13.08 ± 0.43

Each reading is a mean of three determinations ± SD

Table No. 6: Invitro release of CTZ

Time (min)	% Release of Conventional marketed tablet	% Release from resinate of CTZ
0.5	85.13 ± 0.80	100.01 ± 0.54
1.0	94.87 ± 0.98	-
1.5	95.99 ± 0.10	-
2.0	96.13 ± 0.64	-
2.5	98.45 ± 0.56	-
3.0	99.15 ± 0.31	-
3.5	99.21 ± 0.91	-
4.0	99.85 ± 0.54	-
5.0	100.11± 1.54	

Each reading is a mean of three determinations ± SD

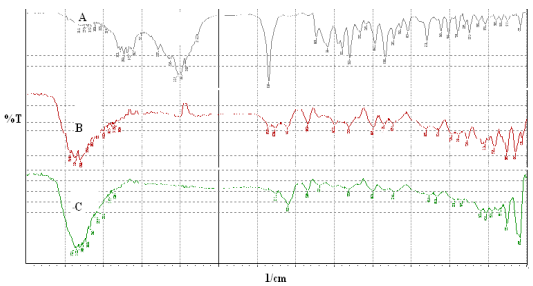

Fig. 1: IR of A) Pure Drug, B) Resin C) Complex

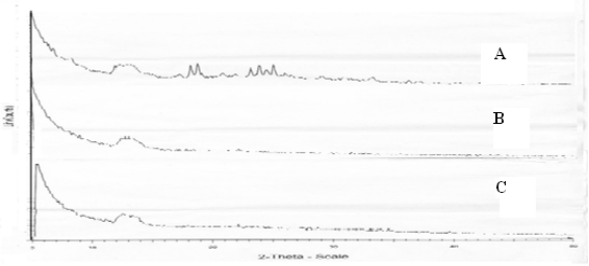

Fig. 2: XRD of A) Pure Drug, B) Resin C) Complex

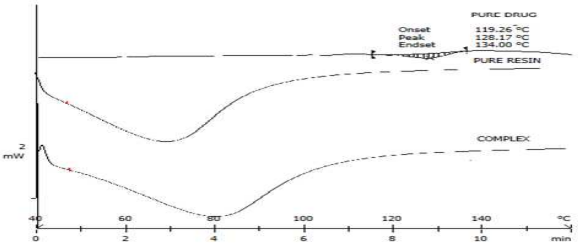

Fig 3: DSC Of A) Pure Drug, B) Resin C) Complex

Powder Properties of Control Formulation by Direct Compression

It was found that powdered blend of controlled formulation for direct compression was low in angle of repose, compressibility and found excellent in flowability. It has also showed less porosity than powders containing superdisintegrants. The porosity gets altered by the number of contact points and by the shape and diameter of constituent particles. As tablet porosity and average pore size decreases with increase in compression forces due to high compressibility of Microcrystalline Cellulose (MCC), it was observed that there is decrease in porosity with increase in MCC contents [11].

Powder Properties of Formulation Containing Ac-Di-Sol

Powder properties of formulation containing 2, 3, 4 and 5% of Ac-Di-Sol as superdisintegrant, for direct compression had angle of repose in range of 4.5 – 9.79 while percentage compressibility values were ranged in 12.0-15.0 %. Porosity, which was ranged between 13.3 -15.7 %, was found to increase with increase in concentration of superdisintegrant. Also all formulation had shown good flowability [12].

Powder Properties of Formulation Containing Polyplasdone-XL

It was observed that formulations containing Polyplasdone-XL as superdisintegrant have angle of repose between ranges of 7.54- 12.91, which was higher than control formulation. Also it was observed that there was increase in percentage compressibility with increase in concentration of superdisintegrants while porosity was more than powder blend of control formulation and it was increased with increase in concentration of Polyplasdone-XL, which is because of highly spongy and porous nature of Polyplasdone-XL. Powdered blend of all formulation had shown good flowability.

Powder Properties of Formulation Containing Primojel

It was observed that powder blend containing Primojel as superdisintegrant had shown angle of repose between 13.3- 19.10 and percentage compressibility between 12.2-15.5 %, which indicated that all powders had good flowability. Porosity of the powder blend is directly proportional to concentration of Primojel.

Tabletting properties of Control Formulation

By comparing tablet properties of control tablet with other tablet prepared by using various concentration of superdisintegrant, it was found that control tablet had greater hardness while showing less water absorption ratio. MCC has more free hydroxyl group and thus the interaction forces in a contact point may be stronger because of stronger hydrogen bond of hydroxyl groups, which can cause increase in hardness. During manufacture of MCC accessible amorphous region of cellulose molecules are hydrolyzed so that MCC shows relatively high crystallinity. So it can absorb only small amount of water and reaches equilibrium rapidly. Also, MCC particles are concave convex shape and their pores are fairly collapsed by compression due to which tortuosity of a pore in MCC tablet is increased which

ultimately hampers the water absorption ratio. Control tablet had also shown least friability and it had passed for both weight variation and uniformity of content test. It was found that, in vitro disintegration time of control tablet was 29 seconds while that of in vivo was 34 seconds.

Tabletting Properties of Formulation containing Ac-Di-Sol

Hardness of all tablets found between 3.2- 3.4 kg while friability and weight variation test result were found within acceptable limits. Also all tablets were passed for uniformity of content test. Ac-Di-Sol is made by cross -linking (etherification) reaction of Sodium Carboxy Methyl Cellulose (Sodium CMC). This cross linking greatly reduced water solubility of Sodium CMC while permitting material to swell and absorbs water many times it's weight without loosing fiber integrity. Due to this it was found that as concentration of Ac-Di-Sol increased water absorption ratio was also increased and it was ranged between 69.0-95, which was highest than formulation prepared with other disintegrant. As shown in table 4. Tablet prepared by using Ac-Di-Sol as superdisintegrant were found to have more water absorption ratio and hence both invitro and in vivo disintegration time for all formulations was very less when compared with other superdisintegrants.

Evaluation of mouth dissolving tablets (n=3)

Parameters	A1	A2	A3	A4	M1
Uniformity of weight	Passes	Passes	Passes	Passes	Passes
Uniformity of content(%)	99.01±1.2550	100.08±1.211	99.18±0.9986	99.23±1.219	99.3±0.9872
In vitro disintegration time (sec)	23±0.121	15±0.2134	17±0.1652	16±0.3558	24±0.6651
In vivo disintegration time (sec)	27±0.2115	21±0.8760	22±0.9231	23±0.3623	28±0.6180
Hardness(kg/cm2)	3.2±0.210	3.3±0.4139	3.3±0.5266	3.2±0.5128	3.5±0.1935
Friabiltiy (%)	0.73±0.167	0.64±0.3764	0.71±0.6524	0.69±0.8834	0.76±0.565
% water absorption ratio	69.11±0.121	76.2±0.551	89±0.4144	95.4±0.4508	64±0.1120

Parameters	B1	B2	B3	B4	M1
Uniformity of weight	Passes	Passes	Passes	Passes	Passes
Uniformity of content (%)	99.61±1.2651	99.0±1.5110	99.41±0.9877	99.06±1.210	99.3±0.9872
In vitro disintegration time (sec)	24±0.111	17±0.1422	16±0.1733	18±0.3558	24±0.6651
In vivo disintegration time (sec)	29±0.2115	23±0.8760	24±0.9231	22±0.3623	28±0.6180
Hardness(kg/cm2)	3.2±0.10	3.2±0.4199	3.3±0.6678	3.2±0.8342	3.5±0.1935
Friabiltiy (%)	0.71±0.1711	0.77±0.3764	0.67±0.653	0.69±0.8230	0.76±0.565
% water absorption ratio	69.11±0.121	76.2±0.551	89±0.4144	95.4±0.4508	64±0.1120

Parameters	C1	C2	C3	C4	M1
Uniformity of weight	Passes	Passes	Passes	Passes	Passes
Uniformity of content(%)	99.01±1.255	99.01±1.255	99.01±1.255	99.01±1.255	99.3±0.9872
In vitro disintegration time (sec)	25±0.121	15±0.2134	17±0.1652	16±0.3558	24±0.6651
In vivo disintegration time (sec)	27±0.1588	22±0.7860	23±0.1931	23±0.2623	28±0.6180
Hardness(kg/cm2)	3.2±0.3343	3.3±0.9237	3.3±0.4587	3.2±0.1480	3.5±0.1935
Friabiltiy (%)	0.71±0.163	0.65±0.1764	0.71±0.654	0.7±0.8344	0.76±0.565
% water absorption ratio	70.15±0.11	76.0±0.547	90.4±0.444	97.2±0.408	64±0.1120

Tabletting Properties of formulation containing Polyplasdone-XL

Tabletting properties of tablet containing 2%, 3%, 4% and 5% of Polyplasdone-XL as superdisintegrant have shown in table 4. Hardness of all tablets was found in the range of 3.2- 3.4 kg while friability was observed below 1% which is an indication of good mechanical resistance of tablet. Also rise in water

absorption ratio was found with increase in concentration of crospovidone. Due to highly porous structure of crospovidone, it draw large amount of water by water wicking mechanism into porous network of tablet and thus crospovidone swells very little, yet rapidly absorbs water into its network. Due to this with increase in concentration of Polyplasdone-XL improved water uptake and reduction in disintegration time was observed with all four formulation containing Polyplasdone-XL as compared to control tablet. It was found that invitro disintegration time was ranged between 16-24 seconds while in vivo disintegration time was ranged between 22-29 seconds, which was quite less than control tablet.

Tabletting Properties of formulation containing Primojel

As per table 5, it was found that hardness of all formulations containing Primojel was found in the range of 3.2- 3.4 kg while both friability and weight variation was observed in acceptable limit. Tablet also passes for uniformity of content test. It was also observed that water absorption ratio of tablet was directly proportional to concentration of Primojel. But both in vivo and in vitro disintegration time was increased with increase in concentration of Primojel. Superdisintegrant action of Primojel, which is governed by it's extensive swelling which increase with increase in concentration of Primojel. Also formations of viscous plugs were observed with increasing concentration of superdisintegrant. Due to these viscous plugs, though tablets breaks, their plugs were not passed through mesh of disintegration test apparatus and ultimately disintegration time was found to be increased with increasing concentration of Primojel.

Stability Studies During storing the tablets at 40 ± 20C/75 ± 5% RH for three months, the tablets were tested for their contents and dissolution behavior monthly. It was observed that the content from the tablets remained same. While the dissolution release rate of tablets is decreased with time. This is due to slight increase in hardness of tablets followed by decrease in disintegration time.

CONCLUSION

Batch process of complexation of CTZ with tulsion 339 produced efficient drug loading. The process of complexation completely inhibited the crystallinity of CTZ and revealed the amorphous nature of complex. The improvement in release rate of the drug from the drug resin complex was observed. The volunteers rated the complexes as tasteless and agreeable. Tablets prepared showed fast disintegration and dissolution, which is the major aim.

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REFERENCES

1) Yang S, Fu Y. J Pharm Pharmacol 2004; 56(4): 429.
2) Tripathi K D. 5 Hydroxy Tryptamine its antagonist and Drug Therapy of Migraine, Essential of Medical pharmacology, 6th Edn., Jaypee Brothers Medical Publisher (P) Ltd., New Delhi, 2008,pp. 192.
3) Swarbrick J. Superdisintegrants: Characterization and Function, Augsbeiger, L., et al. Encyclopedia of Pharmaceutical Technology.Pharmaceu Tech, Inc., North California, 2007; 20(3): pp. 3553.
4) Swarbrick J. Complexation: Cyclodextrin, Masher, G., Thompson, D.O.Encyclopedia of Pharmaceutical Technology.Pharmaceu Tech, Inc., North California, 2007, 20(2): pp. 681.
5) Lalla J K, Mamania H M. Indian J Pharm Sci 2004; 66(3): 350-353.
6) Borodkin S, Sundberg D. J Pharm Sci 1971; 60(10): 1523-1527.
7) Lachman, L., et al. Tablets, Banker, G.S., Anderson ,N.R. Theory and Practice of Industrial Pharmacy,

3rd Edn., Varghese Publishing House, Mumbai, 1990, pp. 293.

8) Bi Y X, et al. Drug Dev Ind Pharm 1999; 25(5): 571.

9) Dr. Avani F. Pharminfo net 2006; 4(1).

10) Rockville M.D., 2000. The United States Pharmacopoeia-32/ National Formulary-27, Asia Ed, 34(5): 1243.

11) Sugao H, et al. J Pharm Sci 1998; 87(1): 96-100.

12) Avari J G, Bhalekar M. Indian Drugs 2004; 41(1): 19-23.

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