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Development of Orodispersible Tablet using *Lepidium Sativum* Seed Mucilage as Natural Super disintegrant

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Abstract : Orodispersible tablets (ODTs) disintegrate or dissolve immediately on the patients' tongue or buccal mucosa. This drug delivery system is suitable for drugs undergoing low bioavailability and high first pass metabolism. It reduces dosing frequency, and thereby reduce the side effects and also makes the dosage form more cost-effective. In this study, extraction of mucilage from *Lepidium sativum* Linn seeds was investigated as a natural superdisintegrant in orodispersible tablets. The model drug chosen was Promethazine HCl, an antiemetic drug. Mucilage was isolated from *Lepidium sativum* Linn seeds and was evaluated for physicochemical characterization. Drug–excipient compatibility studies were performed by FT-IR and DSC. Promethazine HCl ODTs were prepared separately using different concentrations of (8%, 10%, 12% and 15%w/w) of isolated mucilage from *Lepidium sativum* Linn seeds (natural) and Crosscarmellose sodium (synthetic) as superdisintegrants by direct compression method. Different pre- and post compression parameters were studied. The stability studies were performed on optimized formulation F3. The dispersion time and in vitro drug release of the formulation F3 were compared with marketed orodispersible tablets of Promethazine HCl. The characterization and *in-vitro* release profile of prepared ODTs showed that the formulated Promethazine HCL tablet F3 containing 12% mucilage was effective, and suitable than marketed tablet because it has better dispersion time 29 sec and maximum % cumulative drug release i.e. 98.87%. Hence, batch F3 was considered optimized formulation. The present work revealed that isolated mucilage from *Lepidium sativum* Linn seeds has a good potential to enhance *In vitro* dispersion time and *In vitro* drug release of ODT of Promethazine HCl. Also mucilage of *Lepidium sativum* Linn seeds is better than synthetic superdisintegrants because of low cost, natural origin, less side-effect, bioacceptable, renewable source, local availability and better patient compliance.
Keywords : Promethazine hydrochloride, *Lepidium sativum*, superdisintegrant, orodispersible tablet.

1. Introduction

Drug delivery through oral route is the most common and preferred route of drug administration both for Solid and liquid dosage forms. However, solid dosage forms are popular because of the ease of administration, accurate dosage, self-medication, pain avoidance, and most importantly the patient compliance[1]. Oral administration is the most popular route due to ease of ingestion, pain avoidance, and versatility and most importantly, patient's compliance[2]. A constant focus on Novel Drug Delivery systems that offer greater patient compliance, effective dosage and minimal side effects has led to the development of oral dispersible tablets (ODTs). To improve the quality of life and treatment compliances of such patients, fast disintegrating or orally

disintegrating tablets dosage form is a better alternative for oral medication[3]. Tablets that dissolve rapidly in the oral cavity have become very popular in recent times. ODTs represent a rapidly emerging drug delivery system with better patient compliance. ODTs are used for people who have swallowing difficulties as well as for active people [4,5]. ODTs disintegrate in the patient's mouth within a few seconds and are ideal for patients having dysphasia[6,7]. Moreover, pediatric patients may have ingestion problems owing to underdeveloped muscular and nervous control[8,9]. Also utility of orally administered conventional tablets is limited in conditions of water unavailability[10]. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage form[11].

Antiemetic drugs like Domperidone, Ondensetron hydrochloride, Granisetron hydrochloride, Promethazine hydrochloride have the oral problems like less oral bioavailability, first pass metabolism in conventional tablet dosage forms. To overcome such problem the antiemetic drugs can be formulated in the form of orodispersible tablets where the drug rapidly disintegrates in mouth within fraction of seconds and improves the oral drug bioavailability.

Promethazine HCL is a first generation H1 receptor antagonist used medically as an antihistamine and entiemetic. It is chemically (RS)-dimethyl [1-methyl-2-(phenothiazone-10-yl) ethyl] amine hydrochloride is an effective and well tolerated antiemetic that has been associated with a wide range of chemotherapy and radiotherapy regimens, but in conventional dosage forms it undergoes first pass metabolism where the oral bioavailability (88%) reduced to 27%.

There are two types of superdisintegrants i.e. natural and synthetic. The natural superdisintegrants involve various natural substances like gums, mucilage and other substances of natural origin which are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength[12, 13]. Some natural substances like gum karaya, modified starch and agar have been used in the formulation of orodispersible tablets. The use of natural gums and mucilage are important part in formulation and development of different dosage forms. As general excipients for oral use example in tablets and capsules etc the option are limited. The synthetic polymers have certain disadvantages such as high cost, toxicity, environmental pollution during synthesis, non renewable sources, side-effect, less patient compliance etc. While the advantages of natural plant based material include low cost, natural origin, free from side-effect, bioacceptable, renewable source, environmentally processing, local availability, better patient tolerance as well as public acceptance, from edible source etc[14].

Seeds of *Lepidium Sativum* contain higher amount of mucilage and mucilage have various characteristic like binding, disintegrating, gelling etc[15,16]. The literature survey reveals that not much work has been carried out on orodispersible tablet of Promethazine HCL using *Lepidium sativum* seed mucilage. Hence the present research work was aimed at isolation and evaluation of the mucilage from *Lepidium sativum* Linn seeds and formulation and evaluation of orodispersible tablet of Promethazine HCL using mucilage of *Lepidium sativum* as natural superdisintegrant.

2. Experimental

2.1 Materials

Lepidium Sativum Linn Seeds were purchased from Wagh Brothers, Nagpur (India). Promethazine Hydrochloride was procured from Leben Laboratories, Akola (India) as gift sample. Microcrystalline cellulose, PH 102, Cross carmellose sodium and Talc were obtained from Loba chemicals, Mumbai (India). Potassium Dihydrogen O-phosphate, Di sodium hydrogen phosphate, Hydrochloric acid and Aspartame were purchased from SD Fine Chem., Mumbai (India). Acetone was purchased from Changshu Yangyuan chemicals, China. All chemicals were of analytical grade

2.2 Extraction of mucilage from *Lepidium sativum* Linn seeds

The seeds (100 g) were soaked for 12 hrs in distilled water (1litre) and then passed through blender to separate mucilage from seeds. The mass was passed through eight folds of muslin cloth. The mucilage was

precipitated from the filtrate by adding 1 litre of acetone. The powder was passed through 80 # mesh sieve and weighed to calculate the yield after drying at 55ºC for 6 hr [17,18].

2.3 Characterization of mucilage

Chemical characterization of *Lepidium sativum* mucilage was done by Molish test and Ruthenium test. Physicochemical characterization of mucilage was carried out by weight loss on drying, particle size, pH of solution, charring, swelling ratio, bulk and tapped density, compressibility index and viscosity.

2.4 Preformulation studies

Preformulation studies were performed which included melting point determination and solubility studies of drug. Also compatibility studies between drug and excepients were done by IR and DSC.

2.5 Formulation of ODTs –

ODTs of Promethazine HCl were prepared by direct compression method using natural superdisintegrant and its comparison was done with synthetic superdisintegrants. Superdisintegrant in different concentrations (8%,10%,12% and 15%) were used so as to get tablets with good disintegrating properties[15,19,20,21]. All the ingredients were passed through a 60 mesh sieve. A weighed quantity of each ingredient was taken, and the powder blend was then compressed on 10-station rotary punching machine using flat faced punches. Round punches measuring 8 mm diameter were used for compression of tablets[15]. The composition of each formulation is given in Table1.

Table 1: Composition of Orodispersible tablets

Component mg/tablet	**Formulation code**							
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**
Promethazine HCL (mg)	25	25	25	25	25	25	25	25
Microcrystalline cellulose (mg)	116	112	108	104	116	112	108	104
Mannitol (mg)	20	20	20	20	20	20	20	20
Mucilage (%)	8	10	12	14	-	-	-	-
Crosscarmellose Sodium (%) (mg)	-	-	-	-	8	10	12	14
Aspartame (mg)	10	10	10	10	10	10	10	10
Talc (mg)	10	10	10	10	10	10	10	10
Mg Stearate (mg)	3	3	3	3	3	3	3	3
Total (mg)	200	200	200	200	200	200	200	200

2.6 Evaluation of powder blend (precompression parameters)

2.6.1 Bulk Density

Loose bulk density (LBD) and tapped bulk density (TBD) of Promethazine HCl and the tablet blends were determined using bulk density apparatus.

LBD = weight of the powder / volume of the packing

TBD = weight of the powder / tapped volume of the packing

2.6.2 Compressibility Index (Carr's Index)

The compressibility index of the granules was determined by carr's compressibility index. Compressibility index (Carr's index) = [(TBD − LBD) × 100]/TBD

2.6.3 Angle of Repose (θ)

The frictional force in a loose powder or granules can be measured by angle of repose. Angle of Repose (θ) = tan-1 (h/r)

Where, θ is the angle of repose, h is height of pile and r is radius of the base of pile.

2.7 Evaluation of tablets (postcompression parameters)

2.7.1 Thickness

Thickness of tablets indicates the strength to withstand compression force applied during manufacturing process. Thickness of tablets was measured by digital caliper.

2.7.2 Hardness Test

The hardness of a tablet is an indication of its strength. The hardness was tested using Monsanto hardness tester. "Hardness factor", the average of the six determinations, was determined and reported. The force was measured in kilograms per Centimeter Square.

2.7.3 Friability Test

This in process quality control test is performed to ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and shipment. Permitted friability limit is 1.0 %. Roche friabilator (Electrolab, Mumbai) was used to measure the friability of the tablets.

2.7.4 Weight Uniformity Test

The percentage weight deviation of each tablet from average weight was calculated using the following formula. Deviation within the IP permissible limit of 7.5% is allowed as the tablet weighs 200 mg.

$$\% \text{ deviation} = \frac{\text{Average weight - individual weight}}{\text{Average weight}} \times 100$$

2.7.5 *In vitro* dispersion time

In vitro dispersion time was measured by dropping a tablet into a petridish containing 10 ml of phosphate buffer pH 6.8 solution (simulated saliva fluid). Three tablets from each formulation were randomly selected and tested. *In vitro* dispersion time was found and expressed in seconds.

2.7.6 Wetting time and Water absorption ratio

Two circular tissue papers of 10 cm diameter were placed in a petridish having the same inner diameter. 10 ml of phosphate buffer solution, 6.8 pH containing amaranth, a water soluble dye, was added to petridish. A tablet was carefully placed on the surface of the tissue paper so that complete tablet was not immersed in the solution. Then, the time required for buffer to reach upper surface of the tablet was noted as wetting time. The same procedure without amaranth was followed for determining water absorption ratio [14].

2.7.7 Drug content

Weighed and powdered 20 tablets. Powder containing about 25 mg of Promethazine Hydrochloride was weighed and mixed with 10 ml of 2 M hydrochloric acid and 100 ml of water was added to it. It was shaken for 15 minutes and sufficient *water* was added to produce 250.0 ml and centrifuged about 50 ml of the mixture. To 5.0 ml of the clear supernatant liquid 10 ml of 0.1 M hydrochloric acid and sufficient water was added to produce 50.0 ml. The absorbance of the resulting solution was measured at the maximum of about 249.60 nm. The content of $C_{17}H_{20}N_2S$, HCl was calculated taking 910 as the specific absorbance at 249.60 nm [22].

2.7.8 *In vitro* dissolution

In vitro drug release of the samples was carried out using USP – type II dissolution apparatus (paddle type). The dissolution medium, 900 ml of phosphate buffer (pH 6.8) solution, was placed into the dissolution flask maintaining the temperature of 37±0.5ºC and rpm of 50. One tablet was placed in each flask of dissolution apparatus. The apparatus was allowed to run for 10 min. Samples measuring 5 ml were withdrawn after every 2, 4, 6, 8 and 10 min. Samples were filtered through 10 µm filter. The fresh dissolution medium was replaced every time to maintain sink condition. The collected samples were analyzed at 249.60 nm using dissolution medium as blank. The cumulative percentage drug release was calculated.

2.7.9 Drug–Excipient Interaction/compatibility studies

FTIR study was carried out to check compatibility of drug with excipients. Compatibility of Promethazine HCL with excipient used to formulate orodispersible tablet were studied by FT-IR analysis. FTIR spectral analysis of Promethazine HCL and excipients were carried out to investigate the change in chemical composition of the drug after combining it with excipients. The compatibility study on IR was carried by Jasto 5100 type – A.

A DSC was used for thermal analysis of the drug and mixtures of drug and excipients. Tablets of Promethazine HCL selected for the study were individual samples of the drug and excipients as well as physical mixtures of the drug and selected excipients were weighed directly into the DSC aluminum crucible and scanned in the temperature range of 50–300°C under a dry nitrogen atmosphere. The heating rate was 20°C/min and the thermograms obtained were observed for any type of interactions.

2.7.10 Stability studies

The optimized formulation [F3] was subjected to accelerated stability studies at 40°C ± 2°C/75 % RH ± 5, and 25°C ± 2°C /60 % RH ±5. The sample analyzed for the hardness, weight variation, in vitro dispersion time, in vitro drug release and drug content[23]

3. Result and Discussion

3.1 Physicochemical characteristics of dried mucilage from *Lepidium sativum* Linn seeds

The dried mucilage isolated from *Lepidium sativum* Linn seeds was a light brownish white powder (yield = 22% w/w). The polysaccharide was soluble in lukewarm water forming a colloidal solution and practically insoluble in organic solvents. The pH of 1% w/v solution of polysaccharide was found to be near neutral. The polysaccharide showed good swelling and water absorption capacity. The Carr's index and angle of repose indicated that the polysaccharide has a good flow with moderate compressibility. The losses on drying and ash values were well within official limits. The results of physicochemical characterization of dried mucilage from *Lepidium sativum* Linn seeds are reported in Table 2.

Table 2: Physicochemical characteristics of dried mucilage from *Lepidium sativum* Linn seeds

Sr. No	Parameters	Results
1.	Colour	Brownish white powder
2.	Solubility	Forms colloidal solution, soluble in luke warm water, practically insoluble in ethanol and chloroform
3.	Odour	Characteristic
4.	Appearance	Lustrous
5.	Identification: a) Mounted in ruthenium red b) Molish test	 Particles stained red Particle stained blue
6.	Percentage yield	22%
7.	pH(1%w/v)	Neutral
8	Loss on drying	10.4%.
9	Melting point	130.83°C
10	Swelling ratio	17
11	Viscosity	6.15cps at 50 r.p.m for 0.7 % solution.
12	Bulk density (gm/ml)	0.058±0.05 (gm/ml)
13	Tapped density	0.69±0.03 (gm/ml)
14	Carr's index (%)	15.94±1.003
15	Hausners ratio	1.18±0.02
16	Angle of repose (θ)	30±1.5

3.2 Drug-Excipient compatibility by FTIR

IR graphs shown in Fig 1 to Fig 4 revealed that there was no physicochemical interaction between Promethazine HCl and natural superdisintegrant i.e. mucilage of *Lepidium sativum* and synthetic superdisintegrants i.e. Crosscarmellose sodium used in the formulation as the peaks observed in IR spectra of drug are retained in IR spectra of mixture of drug and polymer.

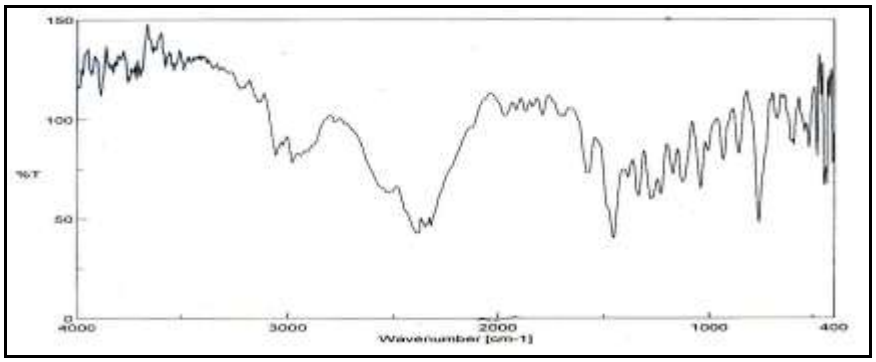

Fig. 1: IR spectra of Promethazine HCL

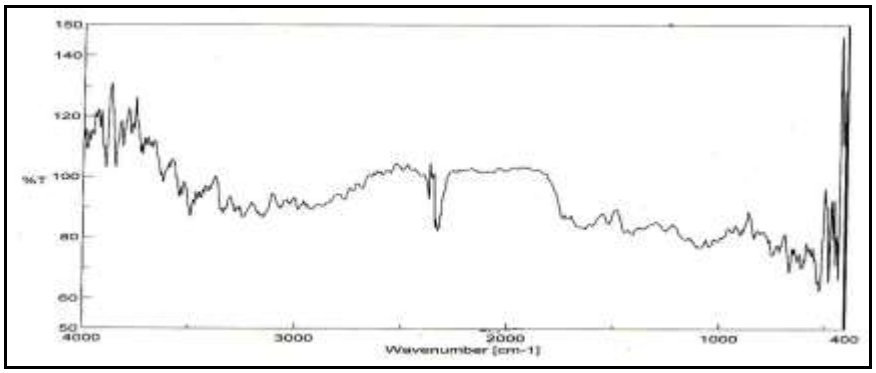

Fig. 2: IR spectra of mucilage of *Lepidium sativum*

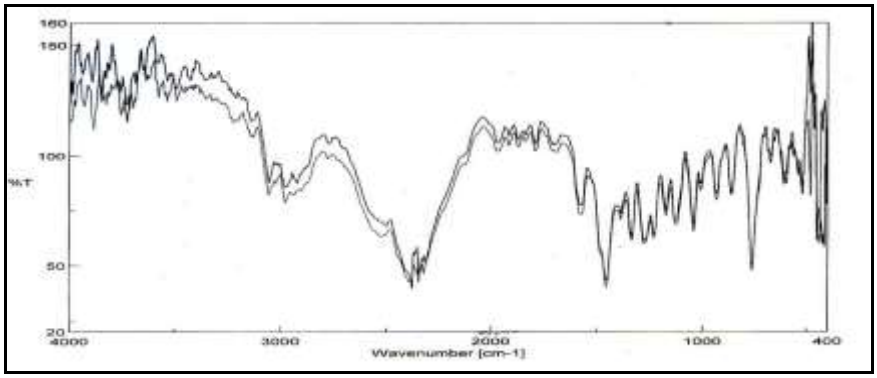

Fig. 3: IR spectra of physical mixture of Promethazine HCL + Mucilage + Excipients

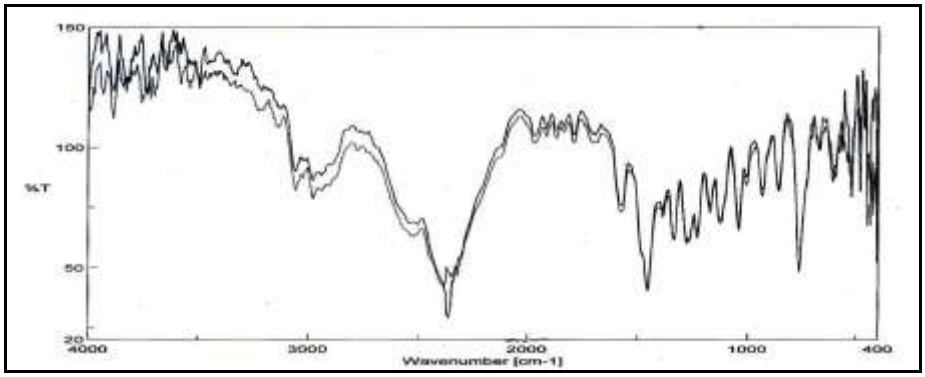

Fig. 4: IR spectra of physical mixture of Promethazine HCL + Crosscarmellose sodium + Excipients

3.3 Drug-Excipient compatibility by DSC

DSC curves obtained for Promethazine HCL showed a melting endotherm at 232.760 ^{o}C, for Mucilage a melting endotherm was observed at 130.830 ^{o}C, for physical mixture of Promethazine HCL+ Mucilage + Excipients the melting endotherm was at 235.150 ^{o}C and for physical mixture of Promethazine HCL+ Crosscarmellose sodium + Excipients the melting endotherm was at 235.980 ^{o}C as shown in Fig 5. Presence of all peaks indicates that all ingredients are compatible with each other.

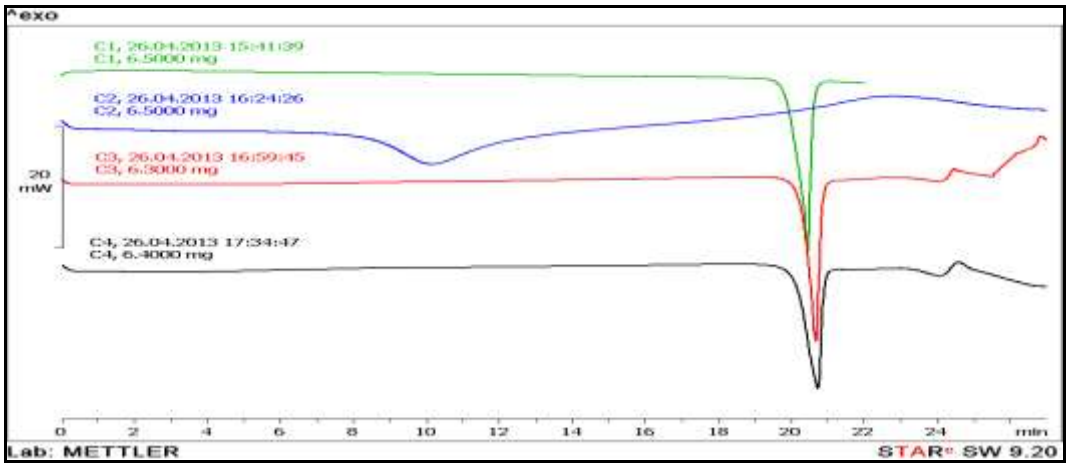

Fig. 5: a) DSC spectra of Promethazine HCL(-----) , b) Mucilage(-----), c) Promethazine HCL+ Mucilage + Excipients, (-----)d) Promethazine HCL + Crosscarmellose sodium + Excipients(-----)

3.4 Evaluation of Tablets

The results of precompression parameter evaluation indicated good free flowing properties of the powder blend as shown in (Table 3). The weights of the prepared tablets were within the acceptable limits for uncoated tablets as per the United States Pharmacopoeia. The hardness of tablets was found to be in the range of 3.1-3.5 kg/cm^2. Friability was observed to be between 0.45% and 0.55%, which was less than 1%, indicating that the tablets had a good mechanical resistance. The percentage drug content of all the formulations was between 97.32% w/w and 99.21% w/w. The results of postcompression parameters are summarized in Tables 4. The *in vitro* dispersion time for all the formulated tablets from batch F1 to F8 was within a range of 29 sec to 68 sec. The tablets prepared from natural superdisintegrant (F1-F4) showed better dispersion time and F3 formulation showed least dispersion time within 29sec than other tablets prepared from synthetic superdisintegrants as shown in Fig-6. The wetting time and water absorption ratio are important criteria for understanding the capacity of a disintegrant to swell in the presence of a small amount of water. The wetting time for all the formulations from F1 to F8 were found to be in the range of 22sec to 59sec (Fig-7), which complies with the official specifications.The water absorption ratio for all the formulations from F1 to F8 were found to be in the range of 85.64 to 96.56 (Fig-8) which was satisfactory in giving effective and better formulations of rapid dissolving tablets. The *in vitro* drug release rate of formulations F1-F4 formulated with

the help of mucilage of *Lepidium sativum* Linn seed as a natural superdisintegrant are shown in Fig 9 whereas the *in vitro* drug release rate from formulations F5-F8 containing synthetic superdisintegrant are shown in Fig 10. The *in vitro* drug release rate from the formulations containing mucilage of *Lepidium sativum* Linn seed was found to be rapid as compared to the formulations containing crosscarmellose sodium. Formulation F3 was the optimised formulation with maximum *in vitro* drug release 98.87% and is better than the tablet prepared from synthetic superdisintegrant, this is due to the excellent swelling property of mucilage**.**

Table 3: Result of Precompression parameters of Promethazine HCL tablets

Formulation code	Bulk density (gm/ml) mean (±SD) n=3	Tapped density (gm/ml) mean (±SD) n=3	Carr's index(%) mean (±SD) n=3	Hausner's ratio mean (±SD) n=3	Angle of repose (θ) mean (±SD) n=3
F1	0.418±0.001	0.454 ±0.003	7.92 ±0.14	1. 08± 0.01	21.21±0 .85
F2	0.414 ±0.002	0. 445 ±0.001	8.01±0.12	1.08± 0.01	22.59±0.80
F3	0.530±0.001	0.588 ±0.001	9.86 ±0.15	1.10± 0.02	24.45±1.00
F4	0. 570±0.003	0.663 ±0.002	10.00±0.12	1.11± 0.03	25.52±1.18
F5	0.530±0.002	0.588 ±0.001	10.01±0.12	1.10± 0.02	23.78±1.00
F6	0.418±0.004	0.475 ±0.003	12.0 ±0.16	1.13± 0.02	24.55±0.99
F7	0.410±0.001	0.460 ±0.002	10.09±0.12	1.11± 0.02	22.95±1.05
F8	0.448±0.004	0. 505 ±0.003	11.28±0.14	1.12 ± 0.03	23.85±0.98

SD= Standard deviation

n= 3 all parameter shown above are based on 3 replicate and expressed as mean

Table 4: Result of Post-compression parameters of Promethazine HCL tablets

Formulation	Thickness (mm)mean (±SD) n=3	Hardness (kg/cm2)mean (±SD)n=3	Weight variation (mg)mean (±SD) n=3	Friability (%)	Drug content (%)mean (±SD) n=3
F1	3.4 ± 0.01	3.1 ± 0.1	197 ± 1.05	0.51	98.15±1.2
F2	3.5 ± 0.04	3.2 ± 0.15	198± 1.04	0.46	98.79±1.7
F3	3.4 ± 0.03	3.4 ± 0.15	199 ± 1.00	0.53	99.21±1.4
F4	3.5 ± 0.02	3.3± 0.15	197 ± 1.25	0.53	97.32±1.5
F5	3.4 ± 0.03	3.4 ± 0.11	198 ± 1.10	0.45	98.71±1.32
F6	3.3 ± 0.02	3.3 ± 0.11	199 ± 1.3	0.53	97.43±1.25
F7	3.3± 0.03	3.5± 0.3	197 ± 1.11	0.55	97.64±1.45
F8	3.5 ± 0.01	3.4 ± 0.12	198± 1.10	0.40	98.57±1.5

SD= Standard deviation

n= 3 all parameter shown above are based on 3 replicate and expressed as mean

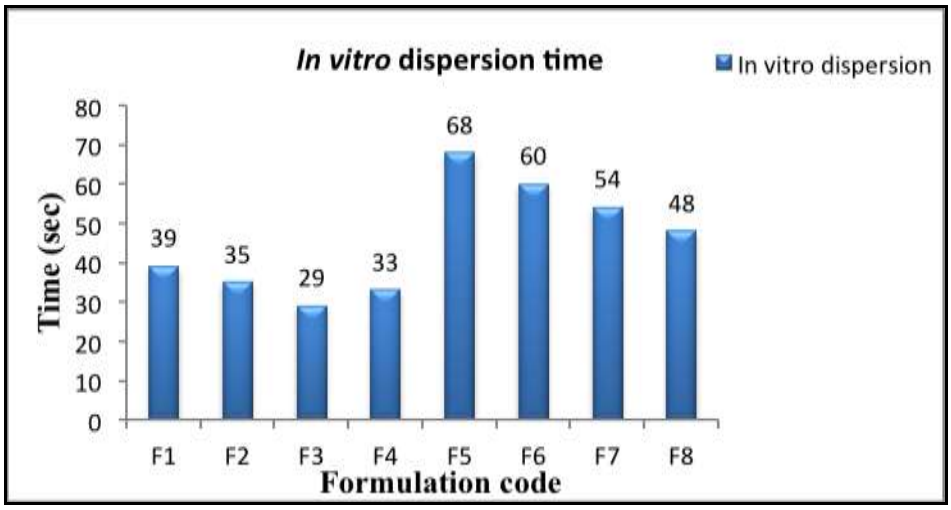

Fig. 6: *In vitro* dispersion time of Promethazine HCL tablets

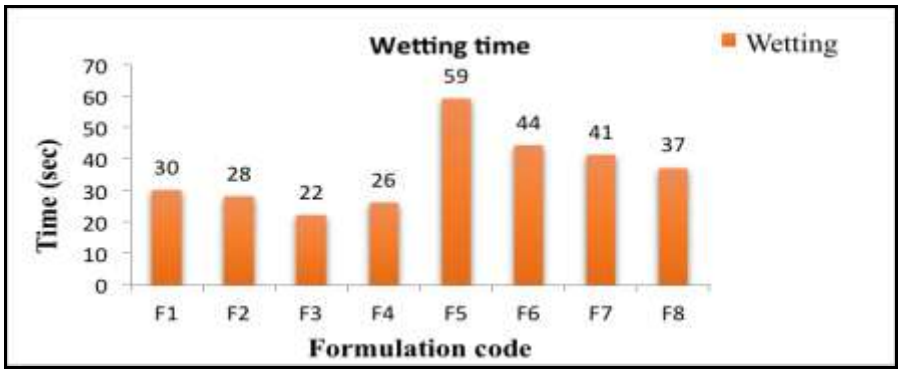

Fig. 7: Wetting time of Promethazine HCL tablets

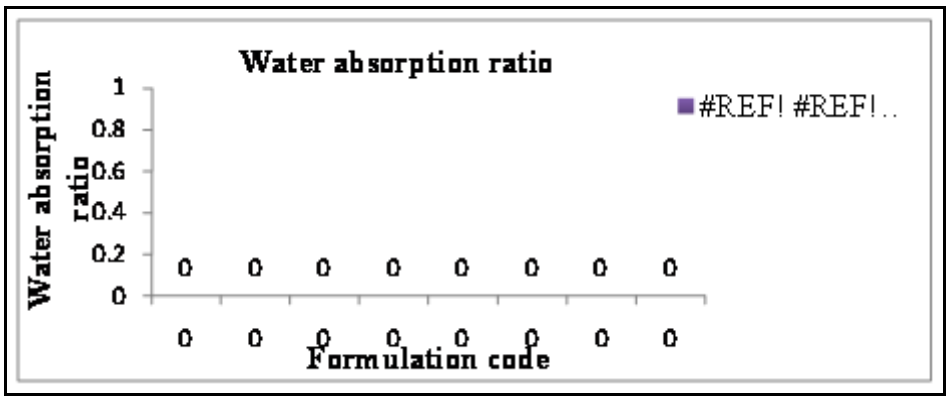

Fig. 8: Water absorption ratio of Promethazine HCL tablets

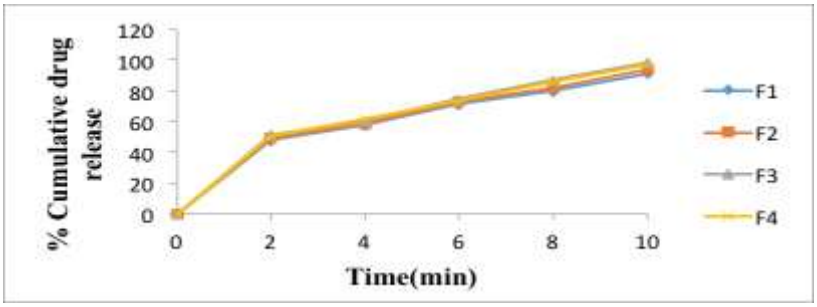

Fig. 9: *In vitro* drug release profile of Promethazine HCL tablets containing mucilage

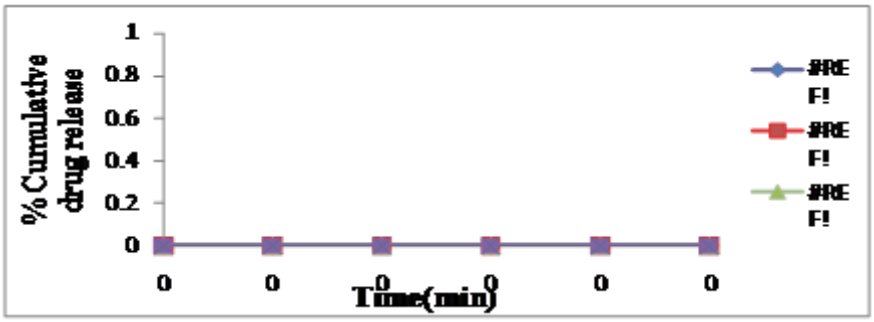

Fig. 10: *In vitro* drug release profile of Promethazine HCL tablets containing crosscarmellose sodium

3.5 Stability studies:

The stability of the optimized formulation F3 was studied as shown in **Table 5** for two months at accelerated conditions of 40±2^{0}C/75±2% RH. The formulations were found to be stable, with insignificant change in the hardness, weight variation, in vitro dispersion time, in vitro drug release and drug content.

Table 5: Results of stability testing of Promethazine HCL tablets

Test parameter	Initial value	Stability result 40°c /75 RH(±SD) n=3				
		0 days	15 days	30 days	45 days	60 days
Weight variation (mg)	198.21 ±1.31	198.21 ±1.31	198.11 ±1.24	198.00 ±1.17	197.84 ±1.03	197.75 ±1.01
Hardness (kg/cm2)	3.4±0.32	3.4±0.32	3.48±0.13	3.44±0.15	3.47±0.24	3.44±0.18
In vitro dispersion time (sec)	29±1.5	29±1.55	29± 1.23	28± 1.81	28± 1.65	28± 1.60
In vitro drug release (%)	98.81±1.6	98.81±1.6	98.71±0.83	98.75±1.9	98.86±0.95	98.77±0.93
Drug content(%)	99.7±1.33	99.7±1.33	99.5±1.27	98.43±1.54	99.21±1.08	98.15±1.24

SD= Standard deviation
n= 3 all parameter shown above are based on 3 replicate and expressed as mea

Table 6: Characterization of the marketed tablets of Promethazine HCL and compared with F3 formulation

Sr. No	Evaluation Parameter	Marketed tablets	F3 Formulation
1.	Thickness(±SD) n=3	3.2±0.01mm	3.4±0.03mm
2.	Hardness(±SD)n=3	3.5±0.3 kg/cm^2	3.4±0.15 kg/cm^2
3.	Friability	0.50%	0.53%
4.	In vitro Dispersion time (±SD) n=3	61±1.51sec	29±1.55sec
5.	% cumulative Drug rleased after 10 min	94.18±0.9%	98.87±1.2%

SD= Standard deviation
n= 3 all parameter shown above are based on 3 replicate and expressed as mean

3.6 Comparison of drug release with marketed formulation:

The characterization and *In vitro* release profile of marketed tablet of Promethazine HCl showed that the formulated Promethazine HCL Tablet F3 were effective and suitable than marketed tablet because it has better dispersion time 29 sec and maximum % cumulative drug release i.e. 98.87% . The results are shown in Table 6.

4. Conclusion

In conclusion, it can be stated that the objective of the study has been achieved. From the above study, F3 formulation containing 12% mucilage of *Lepidium sativum* was concluded as an optimized formulation due to its less dispersion time. Formulation (F3) was compared with marketed conventional tablets of Promethazine HCl. The characterization and *in vitro* release profile of marketed tablet of Promethazine HCl showed that the formulated Promethazine HCL tablet F3 were effective and suitable than marketed tablet because it has better dispersion time 29 sec and maximum % cumulative drug release i.e. 98.87%. Hence on the basis of formulation development, *in vitro* dispersion time and *in vitro* drug release results, formulated orodispersible tablets of Promethazine HCl using mucilage of *Lepidium sativum* were superior and effective in achieving patient compliance, better in terms of palatability, physical and chemical properties with reference product. Results revealed that mucilage of *Lepidium sativum* acts as better superdisintegrating agent and also enhances or promotes the dissolution of the drug.

References

1. Chein Y.W. Oral drug delivery and delivery systems. 2nd ed. New York: Marcel Dekker, 1992.
2. Konapure A.S., Chaudhari PS, Oswal RJ, Kshirsagar SS, Antre RV and Chorage TV, Mouth dissolving tablets-an innovative technology, Int J Applied Bio and Pharm Tech, 2011, 2(1), 496-503.
3. Yutaka M, Yuki T, Masanobu Y, Ryoji T, Junko A, Kozo T, Evalution of the disintegration time of rapidly disintegrating tablets via a novel method utilizing a CCD camera, Chem Pharm Bull, 2002, 50(9), 1181-1186.
4. Raghaendra R, Ketan T, Sumanji B, Formulation and evaluation of fast dissolving tablet of metoprolol tartrate, Int J Pharm Clin Res, 2010, 2,40–5.
5. Setty CM, Prasad DV, Gupta VRM, Development of fastdispersible acelofenac tablets: effect of functionality of superdisintegrants, Indian J Pharm Sci, 2008,70,180–5.
6. Karthikeyan M, Mukhthar UAK, Megha M, Shadeer HP, Formulation of diclofenac tablets for rapid pain relief, Asia Pacific J Trop Dis 2012, 2 Suppl 3,08–11.
7. Shweta SG, Tapar KK, Borse MD, Ghuge RA, Taste masking and characterization of diphenhydramine hydrochloride byspray-drying technique, Int J Pharm Res Dev 2010, 1, 17.
8. Hirani JJ, Dhaval RJ, Vadalia RK, Orally Disintegrating Tablets: A Review. Trop J Pharm Res, 2009, 8,161–72.
9. Chang RK, Guo X, Burnside BA, Couch RA, Fast dissolving tablets, Pharm Tech, 2000, 24, 52–9.
10. Koizumi K, Watanabe Y, Morita K, Utoguchi N, Matsurnoto M, New method of preparing high porosity rapidly saliva soluble compressed tablets using mannitol with camphor, a subliming material, Int J Pharm, 1997, 152,127–31.
11. Kuchekar BS, Badhan AC, Mahajan HS, Mouth dissolving tablets, A Novel Drug Delivery System, Pharma Times, 2003, 35, 7-9.
12. Ravi K, Swati P, Patil MB, Patil SR, Paschapur MS, Isolation and evaluation of disintegrant properties of fenugreek seed mucilage, Int J Pharm Tech Res 2009, 1, 982–96.
13. Wade A, Paul J. Handbook of pharmaceutical excipients, 2nd ed. London, UK: Pharmaceutical Press; 1994.
14. Harshal AP, Priscilla DM, Spectrophotometric estimation of total polysaccharides in Cassia tora gum, J Applied Pharm Sci, 2011, 01, 93–5.20
15. Sugimoto M, Matsubara K, Koida Y and Kobayashi M, The preparation and evaluation of rapidly disintegrating tablets in the mouth, Pharm devlopment Tech, 2001, 6(4), 487-93.
16. Patel DM, Patel MM and Sharma MG, Design and optimization of fast dissolving etoricoxib tablets prepared by sublimation technique, Indian J Pharma Sci, 2008, 70(1),71-6.

17. Divekar VB, Kalaskar MG, Chougule PD, Redasani VK and Baheti DG, Isolation and characterization of mucilage from Lepidium sativum linn seeds, Int J Pharma Res devlopment 2010, 2(1),1-5.
18. Mehta KK, Patel HH, Patel ND, Vora CN and Patel NJ, Comparative evaluation of natural and synthetic superdisintegrant for promoting Nimesulide dissolution for fast dissolving technology, Int J Pharma and Applied Sci, 2011, 2(1),52-62.
19. Quadir A, Kolter K and Robin SD, A comparative study of current superdisintegrants, Int J Pharma Sci, 2006, 1(4), 45-50.
20. Udupa N, Venkatesh, Mutalik S and Venugopal K, Nimesulide dispersible tablets from direct compression method, Indian Drugs 2001, 38(4), 208-10.
21. Kuchekar BS, Badhan AC and Mahajan HS, Mouth dissolving tablets of salbutamol sulphate: A novel drug delivery system, Indian Drugs, 2004, 4(10), 592-8.
22. Government of India ministry of health & family welfare published by the Indian pharmacopoeia commission Ghaziabad Vol 3; 2007, 1605.
23. Punit S and Rajshree M, Stability testing of Pharmaceuticals, A prospective J Pharm Res 2007, 6(1),1-9.

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