JCARR
JOURNAL OF CLINICAL ADVANCES AND RESEARCH REVIEWS

Available online on http://www.jcarr.in/
Journal of Clinical Advances and Research Reviews 2024; 01(03); 01-09
ISSN: 3048-6556

Research

Herbal Extraction, Characterization and Evolution of Film Coating by Natural Polymer *Trigonella Foenumgraceum L.* (Methi)

Ritu Verma[*1], Priya Bharti[2], Amit Singh[3], Garima Gupta[4], Mohd Shuaib[5], Ambika Shakya[6], Arabind Kumar[7]

[1]*Assistant professor, Monad University, NH-9, Delhi-Hapur Road, P.O Pilkhuwa-245304, Dist. Hapur (U.P.)*
[3]*Director, Monad University, NH-9, Delhi-Hapur Road, P.O Pilkhuwa-245304, Dist. Hapur (U.P.)*
[4]*Principal, Monad University, NH-9, Delhi-Hapur road, P.O Pilkhuwa-245304, Dist. Hapur(U.P.)*
[2,5,6]*Assistant Professor, Kalka Institute for research & Advanced studies, Partapur bypass, Meerut, (UP.) India.*
[7]*Principal, Kalka Pharmacy Institute for Advanced Studies, Partapur bypass, Meerut, (UP.) India.*

Received: 22-08-2024 / Revised: 23-09-2024 / Accepted: 15-10-2024
Corresponding Author: Ritu Verma
Conflict of interest: Nil

Abstract:

Nowadays' home grown (normal) items are more utilized than to artificially engineered items as a result of they have low harmfulness, biocompatibility, less expensive and biodegradable. We attempting to plan and portray buccal movies of glimepiride by utilizing the normal polymer, the regular polymer were extricated from seeds of trigonella foenumgraceum L (methi). Dissolvable extraction strategy was utilized for extraction and was portrayed for various boundaries i.e., pH, expanding file, Carr's list, tapped thickness, mass thickness, actual attributes, and point of rest. It was observed that the adhesive was insoluble in cool water however dissolvable in steaming hot water with various dissolvable. The buccal movies were formed utilizing dissolvable projecting method. The principal polymer utilized was Methi adhesive polymer. Various centralizations of polymer were utilized in the advancement of buccal film. The planned movies were assessed for various boundaries like deterioration, enlarging record, elasticity, surface pH, and weight consistency, in vitro drug discharge, drug content, thickness and collapsing perseverance. pH of the figured out films was between 6.5 to 7.5. The medication content of movies was in the scope of 7.3-9.3. In vitro drug discharge study showed a typical 84% medication discharge from every one of the figured out films up to 6 hrs. Expanding record of the planned movies showed great ballooning to 2 hrs. It was seen that Plan F4 was the best detailing out of all definitions. In the entire bunch the polymer focus was 300 mg/25 ml. The buccal movies of glimepride were ready by dissolvable projecting method.

Keyword: Natural polymer, trigonella foenumgraceum L (methi), solvent casting technique

Introduction

Microspheres might be characterized as microspheres are the substances or mixtures which having free streaming property (powders). Microspheres are comprising of proteins or manufactured polymers which are biodegradable in nature and preferably having a molecule size from 1-1000µm. Microspheres are additionally called as microparticals. Microsphere can be made by different sort of material like glass, polymers, and artistic microspheres. They are utilized in various applications; their utilization relies upon their material and molecule size utilized in

development. Miniature circle are two sorts microcapsules and micrometrics, which are portrayed as, miniature containers are those where ensnared substance is particularly encircled by unmistakable case wall. Furthermore, micrometrics in which ensnared substance is scattered all through the grid (see figure 1). Microsphere assumes a significant part to further develop bioavailability of customary medications and limiting secondary effect [1,2].

Fig.1: Phyto-constituents benefits of *Trigonella Foenumgraceum L. (Methi).*

Diabetes mellitus normally known as diabetes, is a gathering of metabolic problems described by high glucose levels over a delayed period. Blood glucose is the sort of glucose which are acquired from the eat or foot. Which give energy during the digestion within the sight of oxygen. Diabetes is the term which may likewise characterized as the glucose level of the blood is expanded to typical, because of diminishing the level or creation of insulin chemical.

The two types of hormones are secreted from the pancreas-

- Insulin-helps in the carring the blood glucose to all body cell or tissue, Glucagon-it helps in the controlling the glucose level and increment the blood glucose, Now and again, when the pancreas doesn't make or deliver an adequate number of these chemicals, (Insulin and glucagon) insulin doesn't utilized in conveying blood glucose, Then, at that point, glucose stays in the blood and doesn't arrive at in the phones or tissues
- Kinds of the diabetes-there are principal three sorts of diabetes.
- Type-1
- Type-2
- And gestational

Type-1

Assuming that we have type-1, our body doesn't make insulin. Our safe framework assaults and obliterates the cells in your pancreas that make insulin. Type 1 diabetes is normally analyzed in kids and youthful grown-ups, despite the fact that it can show up at whatever stage in life. Individuals with type 1 diabetes need to take insulin consistently to remain alive.

Type-2

Assuming that we have type 2 diabetes, our body doesn't make or utilize insulin well. also, we can foster sort 2 diabetes at whatever stage in life, in any event, during youth. Be that as it may, this kind of diabetes happens most frequently in moderately aged and more seasoned individuals. Type 2 is the most well-known kind of diabetes.

Gestational

Gestational diabetes develops in some women when they are pregnant. Most of the time, this type of diabetes goes away after the baby is born. However, if we've had gestational diabetes, we have a greater chance of developing type 2 diabetes later in life. Sometimes diabetes diagnosed during pregnancy is actually type 2 diabetes. [6,7].

Material and methods:

Methi was collected from the market of greater noida (in india). And authenticated by biotechnology, gautambudha nagar, greater noida. Glimpride drug was acquired or obtained from the zee Laboratories, Himachal Pradesh, India.

Extraction and isolation mucilage of Methi

Extraction

Solvent extraction method was used for the extraction of the mucilage of methi, first of all the seeds of the methi are washed with water and dried at room temperature and boiled with hot water for 10-12 hours at 45^{o}C to release their mucilage into water. The material was then squeezed in a muslin cloth(it is a cotton fabric plain weave) to remove the marc from the filtrate, For the cooling the filtrate was kept in the refrigerator.

Isolation

Double volume of ethyl alcohol was added to the filtrate that causes precipitate, then the mucilage was separated out, and dried in oven at about 50-55^{o}C and powdered. The powdered mucilage was packed up an air tight container [12, 13].

pH of mucilage

For getting 1% w/v solution of mucilage was weighted and dissolved in water, and determine the pH of solution by using pH meter.

Organoleptic Evaluation of Isolated Mucilage

The isolated mucilage was checking the organoleptic properties such as color, odor, fracture and texture [14, 15].

Bulk & Tapped Density

In graduated cylinder pre-weighed quantities of mucilage were poured and the volume was recorded and then the powder was subjected to tapping in a bulk density apparatus until constant volume was obtained [17].

Powder Flow Property

It is also known as angle of repose in which Fixed height funnel method was used to determine the angle of repose [13].

Powder Compressibility and Hausner's Ratio

Powder compressibility is also known as Carr's index. Carr's index and Hausner's ratio were calculated from the bulk and tapped densities [13]

Carr's index-

$$\text{carr's index}(\%) = \frac{\text{tapped density-poured/bulk density}}{\text{tapped density}} \times 100$$

Hausner ratio-

$$\text{hausner ratio} = \frac{\text{tapped density}}{\text{bulk density}}$$

Identification Tests for Carbohydrate, Fat, Gum and Mucilag.

When the aqueous Solution of methi mucilage was performed the tests for carbohydrate, gums, fat, tannins and oil according to standard procedure. Test for carbohydrate showed positive result and other tests showed negative results for the presence of tannins, oils and fats in isolated mucilage.

Swelling Index of Isolated Mucilage

The swelling index is the volume in ml absorbed or consumed by 1 gm of the substance. The swelling characteristics of methi seed mucilage were evaluated in distilled water.for the determination of swelling index of methi mucilage, weight accurately 1 gm mucilage of methi and transfer it in 25 ml stoppered measuring cylinder add 20 ml of distilled water stirring continuously for 10 minutes and allow to stand for 24 hr at room temperature and The volume occupied by the mucilage was measured. The procedure was repeated thrice and then the mean values were calculated [17]

Infrared Spectra of the Isolated Mucilage

Powdered adhesive (100 mg) and potassium bromide (400 mg) were combined as one and afterward water powered press at 15 tons pressure was utilized to pack this blend to shape a pellet. Bruker FTIR spectrophotometer was utilized to filter the pellets between 4000-400 cm-1 [12] and the outcome is portrayed

Scanning Electron Microscopy of Isolated Mucilage

For surface investigation of removed polymer SEM was finished with the ZIESS device of Indian Foundation of Innovation, New Delhi was utilized and the subsequent picture is portrayed in Fig. Polymer was covered with gold

covering utilizing EMITECH (K550X) Falter at vacuum of 10-3Torr for expanding conductivity to kill charge of test.

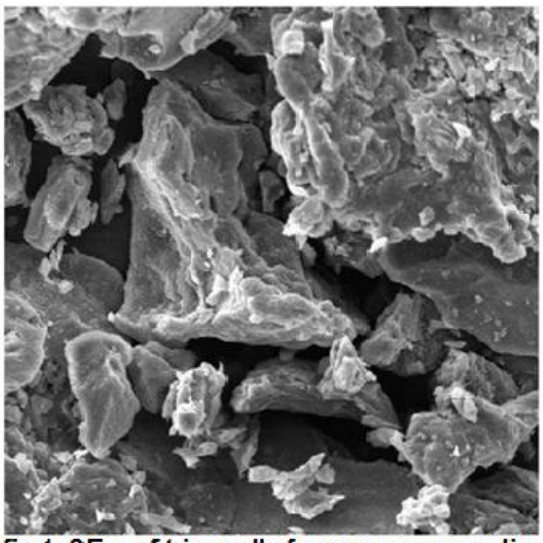


fig.1. SEm of trigonella foenum graecum linn seed mucilage

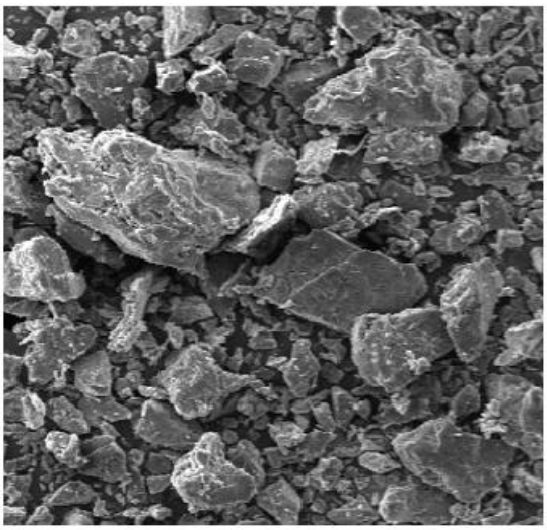


fig.2.SEM of trigonella foenum graecum linn seed mucilage

Fabrication of Mucoadhesive Buccal Films of Glimepirid

For the readiness mucoadhesive buccal movies of glimepiride dissolvable projecting technique was utilized. Here two arrangement was arranged solution(A) and solution(B). arrangement (A) was ready by dissolving methi adhesive in adequate measure of water by adding sodium alginate powder, and added the glycerol that goes about as a plasticizer, and the blend was mixed for 2 hrs. Various convergences of excipients were utilized to plan arrangement A by a similar strategy referenced above and used to figure out buccal movies having various centralizations of excipients.

Arrangement (B) was ready by dissolving drug (glimepiride) in 1 ml of chloroform according to detailing outline (Table 1) in suitable amounts, and both arrangement (A) and arrangement B was combined as one and mixed for 2 hrs. during mixing stayed away from the bobble development. In the wake of blending two arrangements, degassing was finished to eliminate air bubbles lastly the arrangement was casted into pre manufactured petridish and dried for the time being. The dried film was then cut into suitable sizes for additional assessment.

Evaluation of Physicho-chemical Parameters of Mucoadhesive Buccal Films of Glimepiride:

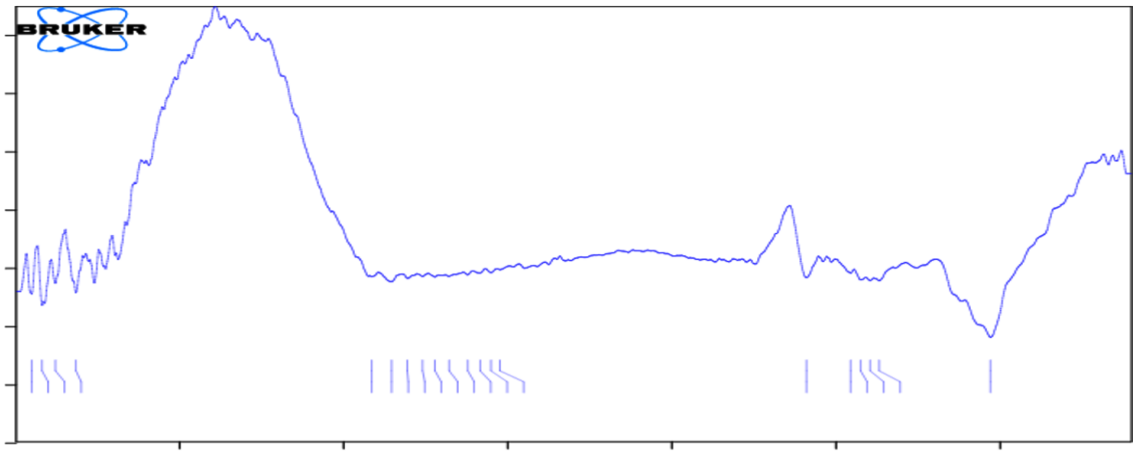


Figure 2. FTIR Spectroscopy of *Trigonella foenum graecum L.* seed mucilage.

Swelling Index- swelling index was prepared by following formula.

$$\textbf{Swelling index} = \text{Final weight-initial weight/initial weight} \times 100 \quad \text{Eq. (1)}$$

Accurately weighed buccal films ($1cm^2$) from each formulation were placed in petridish containing 50 ml distilled water and Films were removed at different time intervals i.e. 15 minutes, 30 minutes, 45 minutes, 1hour, 2 hours, 3hours, 4hours and 5hours, respectively and dried films (using filter paper) were weighed again. The swelling index was calculated by the above formula [19].

Surface pH

The surface pH of film was determined by dissolving film in 1ml of distilled water and allowed to swell for 1 hour in small glass beaker and The electrode of the pH meter was dipped into that small glass beaker containing film for 1 minute and the pH was noted down from the instrument. This procedure was repeated thrice to calculate the deviations and standard deviation was computed [18].

Drug Content Estimation- drug content was estimated by following formula.

$$\textbf{Drug Content} = \text{Concentration} \times \text{DF} \times \text{Bulk Volume}/1000 \quad \text{Eq. (2)}$$

where, DF is dissolution factor

Three pieces of a film in $1cm^2$ size was taken in a separate beaker, and 100 ml of phosphate buffer with pH 6.8 was added to the beaker and continuously stirred for 24 hrs. The solutions were filtered and diluted suitably with phosphate buffer and analyzed at 245 nm in a UV Spectrophotometer. The average of drug content of three films was taken as final reading [20].

Disintegration

Buccal films were evaluated for the disintegration studies with two methods:

i. Petridish Method

In the petridish method, the films were cut (1 cm2) and placed in petridish and 5 ml of phosphate buffer (6.8 pH) was added in petridish, separately. Time was noted when disintegration of the films started.

ii. Slide Frame Method-

In the slide frame method, the films were placed on two horizontal slides and 1-2 drops of phosphate buffer (6.8 pH) were placed on the film surface. Time was noted when disintegration of the films started.

Table 1. Composition of prepared mucoadhesive buccal films of glimepiride.

Ingredients	Formulation						
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**
Glimepiride (mg)	63.57	63.57	63.57	63.57	63.57	63.57	63.57
Glycerol	1	1	1	1	1	1	1
Chloroform (ml)	2	2	2	2	2	2	2
Mucilage (mg)	150	200	250	300	250	200	150
Sodium alginate	150	200	150	175	150	150	200
Water (ml)	30	30	30	30	30	30	30

Dissolution

The dissolution study was carried out using dissolution test apparatus USP type-II at 37oC at 50 rpm using 900 ml phosphate buffer (pH 6.8) as dissolution medium the films was submersed into dissolution medium phosphate buffer At different time intervals, the test samples were taken out and analyzed spectrophotometrically at wavelength 241 nm.

Tensile Strength- tensile strength was determined by following formula.

Tensile Strength = Force at break/ cross sectional area of film × 100
Eq. (3)

The Tensile strength value of the films directly characterizes the flexibility of films. Tensile Strength of films was performed using tensile tester (Instron 1121, Japan). Hook was inserted in the paper holder which was connected to one end of the film while the other end of the film strip of dimension $1cm^2$ was fixed between the two iron screens to give support to the film. To this hook a thread was tied which was passed over the pulley and to hold the weight a small pan was attached to the other end. A small pointer, attached to the thread, which travels over the scale, was affixed on the base plate. Pulley system pulled the patch to determine tensile strength.

To increase the pulling force, weights were progressively added to the pan till the patch was broken. The weights which were necessary to break the film were considered as its tensile strength. The tensile strength was calculated in kg/cm2 using subsequent formula [22].

Stability Studies

To determine the stability, all the formulations were exposed at 40oC and 75% Rh. This also point out the effect of temperature on the drug content, pH, drug release etc in all the film formulations. The films were removed from the oven after 15, 30, 45, and 60 days and they were analyzed for different parameters [18].

Weight Variation Test

Four films were selected from each formulation. This time, the single pan balance was used to measure the weight and standard deviations were computed using the average weight of the films.

Figure3: Extraction, characterization and antioxidant activity of fenugreek (Trigonella-Foenum Graecum).

Folding Endurance

Three films of 1 cm2, taken from each formulation, were cut by using sharp blade. Folding endurance of the buccal films was determined by repeatedly folding a small strip of film at the same place till it broke. The number of times, the film could be folded at the same place without breaking which gave the value of folding endurance of film. This study was performed thrice and the average of three readings was calculated [23].

Table no-2 Organoleptic properties of isolated mucilage.

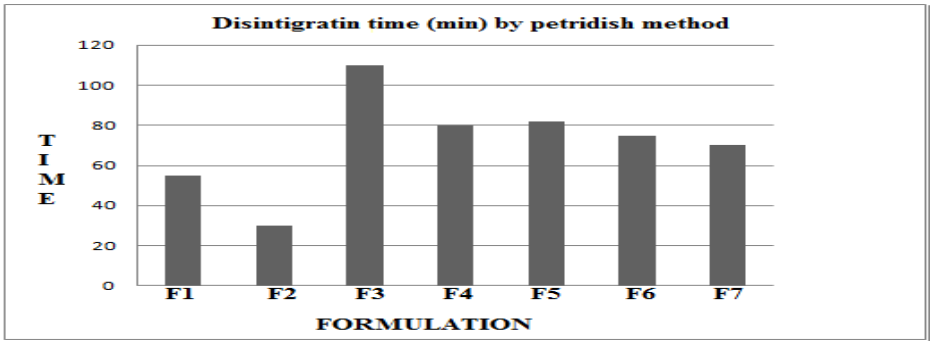
Parameter	Observation
Color	Light brown
Odor	Odorless
Taste	Tasteless
Texture	Rough and irregular
Fracture	Rough

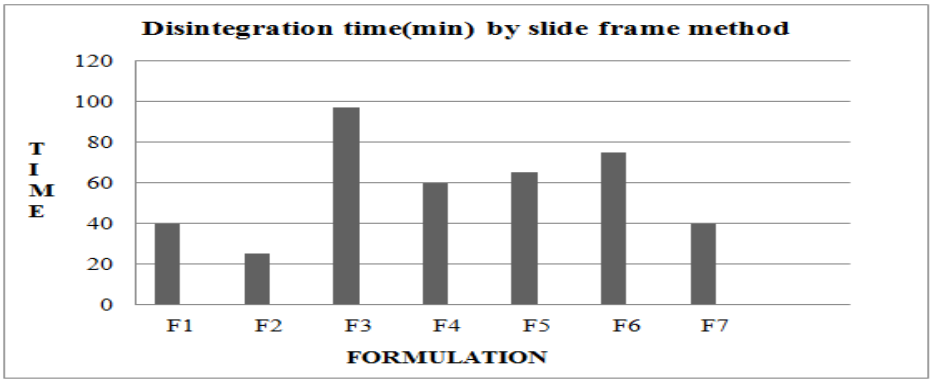
Both the isolated mucilages (Trigonella foenumgraecum L) were found to have good flow property with pH 7.9. Micromeretic studies, of isolated mucilages, like bulk density, tapped density, Carr's index etc., were carried out and are depicted in (Table 3). The solubility behavior of mucilages were analyzed using different solvents and it was found that isolated mucilages are soluble in hot water and swell to form gel in cold water.

Parameter	Result
Swelling index (%)	88
Angle of repose ('')	30.02
P^H	7.8
Bulkiness (ml/gm)	1.48±0.096
Bulk density (gm/ml)	0.68±0.041
Tapped density (gm/ml)	0.96±0.095
Carr's index	28.2±3.09
Hausner's ratio	1.37±0.059
Ash value (%)	1.06
Water-soluble ash	0.62
Yield%	15.11
Acid-value ash	0.58

Disintegration

Comparative studies of disintegration time of the formulated films using petridish method are depicted in (Fig.). Comparative studies of disintegration time of the formulated films using slide frame method are depicted in (Fig.). Disintegration study showed maximum time for disintegration in formulation F3 and the least in formulation F2.

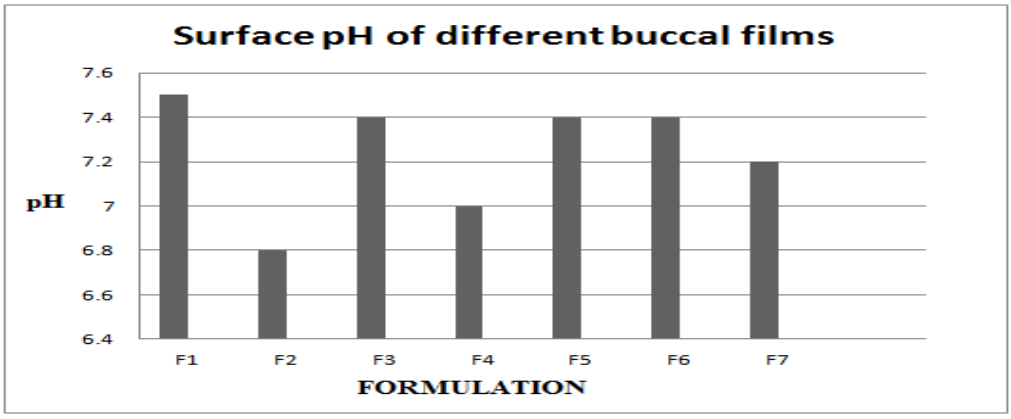




Surface pH

The surface pH of different buccal films was determined by pH meter (PC 510 Decibel). It was noticed that the change in concentration of the excipients caused the pH to change. The pH was found to be in the range of 6.5±0.09

to7.5±0.04indicating its compatibility with buccal pH. Hence, no mucosal irritation was expected and ultimately, patient compliance was achieved. The concentrations of chloroform, glycerol, water and drug were kept constant while the variation in the other excipients viz. sodium alginate and methi mucilage was influenced by further change in the characterization parameters. The comparative surface pH of the different buccal films has been given.



RESULTS AND DISCUSSION

After isolation, Trigonella foenumgraceum L. was subjected to identification. Isolated mucilage showed presence of carbohydrates while the remaining phytoconstituents such as tannins and fats were found to be absent in the mucilage. This result was considered as a proof for purity of isolated mucilage. The organoleptic properties of the isolated mucilage have been depicted in (Table 2) in which colors of both isolated mucilages were found to be light brown with characteristic odor.

CONCLUSION

The glimepiride buccal films were prepared by solvent casting technique. The ingredients used in the formulation of buccal films of glimepiride were sodium alginate, glycerol, methi polymer, water, chloroform. Seven formulations of different composition were prepared. To prepare film we have used methi as a polymer which is also an ant-diabetic agent so the methi showed synergistic effect of drug. The formulations were subjected to evaluation parameters. When evaluation parameters were correlated then it was concluded from the study that F3 was found to be best in comparison to the other formulation. It was also concluded that, in future methi can also be used as a film forming material.

REFERENCES:

[1] Saurabh, R. ; Malviya, R.; Sharma, P.K. Trends in buccal film:formulation, characteristics, recent studies and patents. *Eur. J.Appl. Sci*., 2011, *3*, 93-101.

[2] Mehnert, W.; Mader, K. Solid lipid nanoparticles: production, characterization and applications. *Adv. Drug Deliv. Rev*., 2001, *47*,165-196.

[3] Zhang, H.; Zhang, J.; Streisand, J.B. Oral mucosal drug delivery:clinical pharmacokinetics and therapeutic applications. *Clin. Pharmacokinetics*,2002, *41*(9), 661-680.

[4] Madhav, N.V.; Shakya, A.K.; Shakya, P.; Singh, K. Orotransmucosaldrug delivery systems: a review. *J. Control. Release*, 2009,*140*(1), 2-11.

[5] Anders, R.; Merkle, H.P. Evaluation of laminated mucoadhesivepatches for buccal drug delivery. *Int. J. Pharm*., 1998, *34*, 498-502.

[6] Thimmasetty, J.; Pandey, G.S.; Satheesh Babu, P.R. Design and *invivo* evaluation of carvedilol buccal mucoadhesive patches. *Pak. J.Pharm. Sci*., 2008, *21*, 241□248.

[7] Shojaei, A.H.; Chang, R.K.; Guo, X.; Burnside, B.A.; Couch, R.A.Systemic drug delivery *via* the buccal mucosa route. *Pharm. Tech*.,2001, *6*, 70-81.

[8] Razavi, S.M.A.; Mortazavi, S.A.; Merino, L.M.; Parvar, S.H.H.;Motamedzadegan, A.; Khanipour, E. Optimization study of gum extraction from Basil seeds (*Ocimumbasilicum L.*). *Int. J. Food Sci.Technol*., 2009, *44*, 1755-1762.

[9] Sheth, N.S.; Shah, N.V.; Shah, N.C. Extraction of mucilage from *Occimumamericanum Linn* and its role as disintegrant in tablets formulation. *J. Global Pharm. Technol.*, 2010, *2*(12), 26-31.
[10] Verma, S.; Bansal, J.; Malviya, R.; Sharma, P.K. Isolation and characterization studies of mucilage obtained from *Trigonella foenumgreacum L.* seed and *Tamarindusindica* polysaccharide as a pharmaceutical excipient. *J. Drug Deliv. Ther*., 2014, *4*(3), 106-109.
[11] Harborne, J.B. Sugars and their derivatives. In: Phytochemical methods: *A guide to modern techniques of plant analysis*. 3rd ed. London: Chapman & Hall; 1998, pp. 235-290.
[12] Malviya, R. Extraction and characterization of selected mucilage as a pharmaceutical excipients. *Polim. Med*., 2011, *3*, 39-44.
[13] Kokate, C.K.; Purohit, A.P.; Gokhale, S.B. *Pharmacognosy*. 24th ed. Pune: Nirali Prakashan, 2003, p. 109.
[14] Indian Pharmacopoeia. Ministry of health and family welfare, Govt. of India. 4th ed. New Delhi: Controller of publications, 1996, p. A-54.
[15] Lala, P.K. *Practical Pharmacognosy*. Calcutta, Lina Guha, 1981, p. 135.
[16] Bal, T.; Murthy, P.N.; Sengupta, S. Isolation and analytical studies of mucilage obtained from the seeds of *Dilleniaindica* (family dilleniaceae) by use of various analytical techniques. *Asian J. Pharm. Clin. Res.*, 2012, *5*(3), 65-67.
[17] Pabon, C.V.; Frutos, P.; Lastres, J.L.; Frutos, G. *In vitro* study of mixed controlled release matrix tablets containing HPMC and polyamide. *Drug Develop. Ind. Pharm.*, 1992, *18*(20), 2163-2171.
[18] Khanna, R.; Agarwal, S.P.; Ahuja, A. Mucoadhesivebuccal drug delivery: A potential alternative to conventional therapy. Indian J. Pharm. Sci., 1998, 60(l), 1-11.
[19] Pavankumar, G.V.; Ramakrishna, V.; William, G.J.; Konde, A. Formulation and evaluation of buccal films of Salbutamol sulphate. Indian J. Pharm. Sci., 2005, 67(2), 160-164.
[20] Alagusundaram, M.; Chengaiah, B.; Ramkanth, S.; Angala, P.S. Formulation and evaluation of mucoadhesivebuccal films of Ranitidine. Int. J. Pharm. Tech. Res., 2009, 1(3), 557-563.
[21] Kumar, V.; Zakir, F.; Agarwal, G.; Choudhary, A. Formulation and Evaluation of Buccal Patches of Venlafaxine. Int. J. Pharm. Biol. Sci., 2011, 1(3), 170-182.
[22] Khanna, R.; Agrawal, S.P.; Ahuja, A. Preparation and Evaluation of Buccal Films of Clotrimazole for Oral Candida Infections. Indian J. Pharm. Sci., 1997, 59, 299-305.
[23] Amin, S.; Kohli, K. Stability studies. Indian Pharmacist, 2003, 4,11-12.

*****