Formulation and evaluation of anti-ulcer oral disintegrating film by using tridax procumbent and turmeric (curcuma longa)

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***Abstract*—Among the drug delivery routes, oral route is one of the most convenient, cost-effective and preferred Route of drug administration. But some patients, especially pediatric and geriatric patients, have difficulties in swallowing or chewing some oral solid dosage forms like tablets and hard gelatine capsules because of the fear of choking; they are unable to take these dosage forms. To overcome this, several Oral Disintegrating Films (ODFs) have been developed. Buccal drug delivery is an important route of drug administration. These films disintegrate or dissolve within seconds to release the active agent without drinking and chewing.**

***Index Terms*—oral route, dissolve within seconds, ODF, buccal drug delivery.**

I. INTRODUCTION

Oral disintegrating films (ODFs) are thin, flexible strips designed to be placed on the tongue, where they rapidly disintegrate or dissolve in saliva without the need for water. This drug delivery system is gaining popularity as an alternative to conventional tablets and capsules are especially useful for patients who have difficulty swallowing (dysphagia), such as children, elderly individuals, and bedridden patients. Once the film dissolves, the drug is released and can be absorbed through the oral mucosa or swallowed with saliva for systemic action. These films are typically made using hydrophilic polymers (such as pullulan, HPMC, or PVA), along with plasticizers, sweeteners, flavoring agents, and active pharmaceutical ingredients (APIs). The formulation ensures rapid disintegration (usually within seconds), pleasant taste, and ease of administration.

1.1 Advantages ODF

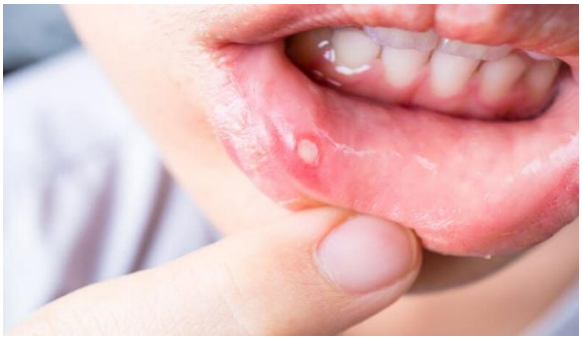
Oral disintegrating films are thin strips that dissolve quickly on the tongue without the need for water. They offer several benefits:

- Fast action: Rapid dissolution leads to quicker absorption and faster onset of effect.
- No need for water: Convenient for use anytime, anywhere.
- Easy to use: Ideal for children, elderly patients, and those with swallowing difficulties (dysphagia).
- Accurate dosing: Each film contains a precise amount of medication.
- Improved patient compliance: Pleasant taste and ease of administration increase acceptance.
- Reduced choking risk: Safer than tablets or capsules.
- Better stability and portability: Lightweight, compact, and easy to carry.
- Bypasses first-pass metabolism (partially): Some drugs can be absorbed directly through the oral mucosa, improving bioavailability.

1.2 Mouth Ulcer

A Mouth ulcer is a small, painful sore that develops inside the mouth, commonly on the lips, cheeks, tongue, or gums. It is usually caused by minor injuries, stress, spicy foods, or vitamin deficiencies. The ulcer

appears as a round or oval lesion with a white or yellow center and a red border. Most mouth ulcers heal on their own within 1–2 weeks. Simple treatments like saltwater rinses, avoiding irritating foods, and applying gels such as Benzocaine can help reduce pain and speed up healing.



1.3 Plant profile
A. Name: Tridax procumbens
Common name: Coat buttons, Triad daisy
Kingdom: Plantae
Family: Asteraceae
Species: procumbens

B. Name: Turmeric
Common: Haldi (Hindi/Marathi)
Kingdom: Plantae
Family: Zingiberoside
Genus: Curcuma
Species: longa

II. MATERIAL AND METHOD

Procurement and Authentication of the sample.
The Tridax procumbens power sample was collected from megadeals Market Nanded. It was well dried and light brown in color, and the authentication of sample is done from Sant Shree Gadge Maharaj Jr. College, Loha, Nanded.
Physicochemical characterization of Triad procumbens powder sample.
The different sample grades were evaluated for properties like Carr's index, Hausner's Ratio, solubility, and angle of repose Bulk Density, and Tapped Density. The evaluation was carried as per the procedure reported.

III. REFORMULATION STUDIES

A. Bulk density
The bulk density is the weight of a volume unit of powder and is usually expressed in g/cm3, kg/m3 or g/100 ml. Bulk Density is usually determined by measuring the volume of 3 g of powder sample in a 10 ml measuring cylinder after exposure to compaction by standardized tapping.

The bulk density is calculated by the formula:
Bulk density = weight/bulk volume
Tapped Density
The Tapped Density is an increased bulk density attained after mechanically tapping a container containing the powder sample. The Tapped Density is obtained by mechanically tapping a graduated measuring cylinder containing a powder sample.
The Tapped Density is calculated by the formula –
Tapped density: weight / Tapped volume
Carr's Index
It is an indicator of compressibility of a powder; the car's index is frequently used in pharmaceutics as an indication of the compressibility of a powder sample.
The car's index is calculated by formula –
Carr's index: (TD – BD / TD) 10
Hausner's Ratio
The Hausner's ratio is a number that correlated to the flow ability of powder or granular material.
The Hausner's Ratio is calculated by formula
Hausner's Ratio: Tapped density / bulk density

B. Angle of Repose
The angle of repose is the maximum possible angle between the surface of the pile of powder and the horizontal plane. It is determined by the formula – Angle of Repose = tan-1 (h/r). Method for determination of angle of repose –

- Fixed funnel method
- Tilting box method
- Revolving cylinder method.

C. Porosity
Porosity is the measure of the void spaces in a material and is a fraction of the volume of void over the total volume, between 0 and 1.
The porosity is calculated by formula –
Porosity: (BV – TV / BV)100

D. Results and Discussion

Table no. 1: Reformulation studies for trade procumbent

Sr. No.	Sieve no. #	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index %	Hausner's Ration	Angel of repose	Porosity %
1.	60	0.30	0.41	26.82	1.36	43.3	25.77
2.	80	0.31	0.44	29.54	1.41	40.43	28.42
3.	100	0.33	0.45	26.66	1.36	43.13	26.66

Table no. 2 solubility

Solution/ sieve no.	#60	#80	#100
Water	Partially soluble	Freely soluble	Freely soluble
Ethanol	Partially soluble	Soluble	Soluble
Aceton	Partially soluble	Soluble	Soluble

Table no. 3. Composition of ODF

Ingredients (mg)	F1	F2	F3
Triad procumbent	6mg	5mg	7mg
Turmeric	6mg	7mg	5mg
Sodium alginate	28mg	27mg	26mg
Glycerol	3ml	3ml	3ml
Citric acid	1mg	2mg	2.5mg
Sucrose	3mg	2mg	3mg
Coloring agent	qasr	qasr	qasr

IV. EVALUATION

Table No. 4 Evaluation of ODF

Batch	Weight variation (%)	Folding endurance	Thickness(mm)	pH	Disintegration (Sec)
F1	4.76	294.6	0.11	6.2	22
F2	16.23	295.6	0.2	6.3	21
F3	4.76	306.6	0.11	6.1	23

A. Organoleptic evaluations

Formulated films were evaluated for organoleptic Evaluations like color, odor, odor, and taste.

Weight Variation Test

Weight variation was determined by individually weighing 5 randomly selected films and the average weight was calculated. The weight of each film was measured using a digital weighing balance.

B. Folding Endurance Test

Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance Value.

C. Thickness Test

To ensure accuracy, the thickness is measured at three or more different locations (e.g., corners and center) of the film.

D. PH Test

A 2x2 cm^2 film is placed in a Petri dish, wetted with 0.5 ml of distilled water, and left for a set time (e.g., 1 hour) before testing.

E. Disintegration Test

A film is placed in a petri dish containing 2-10 mL of distilled water or artificial saliva, often with the dish swirled at intervals to simulate oral movement.

V. RESULTS AND DISCUSSION

A. Authentication of plant

Authentication of the plant is done by Dr S. V. Mandge Sir from Sant Shree Gadge Maharaj Jr. College, Loha Nanded. This authentication of the plant proved that the plant specimen is Tridax procumbent power.

B. Grinding and sieving

Dried Tridax procumbent powder sample was grinded well and sieved to have desired particle size of number #60, #80, #100

Physiochemical Properties of Triad procumbens Powder

Sample Powder characteristics, such as bulk density, Hausner's ratio, angle of repose, Carr's index of Tridax procumbent powder, are given in Table 01

C. Summary

The present work is mainly focused on preparing an oral disintegrating solid dispersion of Curcumin, since Curcumin is a poorly soluble drug. The main aim of this is to provide quick Onset of action, improved bioavailability and also to increase the patient convenience of Administration. The rate of dissolution can be increased by incorporating the solid dispersed Drug into film which is prepared by sodium Alginate as a polymer, glycerine as a plasticiser, citric acid as saliva stimulating agent and sucrose as a sweetening agent.

VI. CONCLUSION

In the present work efforts have been made to evaluate the anti-ulcer property of Tridax procumbens and turmeric powder by formulating oral disintegrating film powder with the use of sodium alginate as a Hydrophilic Polymer, glycerol as Plasticizer, Citric Acid as a Saliva Stimulating Agent and other excipients are used. The solvent casting method.

FUTURE PROSPECTS

In future we are willing to carried out clinical trials of this oral disintegrating film.

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REFERENCE

[1] Geetham, T. K., and M. M. Manju, "Characterisation and evaluation of mouth dissolving films of atenolol," European Journal of Biomedical and Pharmaceutical Sciences, vol. 3, pp. 373–380, 2016.

[2] B. Shen, C. Shen, X. Yuan, J. Bai, and Q. Lv, "Development and characterization of registerable film containing drug nanoparticles," European Journal of Pharmaceutics and Biopharmaceutics, vol. 85, pp. 1348–1356, 2013.

[3] S. Saini, A. Nanda, M. Hooda, and H. M. Komal, "Fast dissolving films (FDF): Innovative drug delivery system," Pharmacologyonline, vol. 2, pp. 919–928, 2011.

[4] J. B. Katsande, S. S. Murad, R. V. Trivedi, and M. J. Umeki, "Formulation and characterization of lornoxicam fast dissolving tablet using natural super disintegrants," International Journal of Research in Pharmaceutical and Biomedical Sciences, vol. 4, pp. 459–464, 2013.

[5] U. Kamalesh, K. Lalit, P. A. Suttie, and C. Viney, "Formulation and evaluation of mouth dissolving film of paracetamol," International Journal of Pharmacy and Pharmaceutical Sciences, vol. 6, pp. 199–202, 2014.

[6] A. K. Gali, "Fast-dissolving dosage forms," International Journal of Pharmaceutical Science Invention, vol. 2, no. 11, pp. 14–17, 2013.

[7] P. P. Ghodake, K. M. Karande, R. A. Osmani, R. R. Bhosale, and B. R. Harkare, "Mouth dissolving films: Innovative vehicle for oral drug delivery," International Journal of Pharmaceutical Research, vol. 2, pp. 41–47, 2013.

[8] A. S. Mundada and B. K. Shrikhande, "Design and evaluation of a soluble ocular drug insert for controlled release of ciprofloxacin hydrochloride," Drug Development and Industrial Pharmacy, vol. 32, pp. 443–448, 2006.

[9] S. D. Komaragiri, F. Shaik, C. Yerram, V. R. Vishnu, V. Amaravathi, and A. Uttaradi, "Formulation and characterisation of atenolol fast dissolving films," International Journal of Pharmaceutical Sciences and Research, vol. 22, pp. 58–62, 2012.

[10] G. E. Yassin and H. A. Abass, "Design and evaluation of fast dissolving oro-dispersible

films of metoclopramide hydrochloride using 3^2 multifactorial designs," International Journal of Pharmacy and Pharmaceutical Sciences, vol. 8, pp. 218–241, 2016.

[11] P. K. Pallavi and T. Pallavi, "Formulation and evaluation of fast dissolving films of eletriptan hydrobromide," International Journal of Current Pharmaceutical Research, vol. 9, pp. 59–63, 2017.

[12] M. A. Tamer, S. N. Hammid, and B. Ahmed, "Formulation and in-vitro evaluation of bromocriptine mesylate as a fast-dissolving oral film," International Journal of Applied Pharmaceutics, vol. 10, pp. 7–20, 2018.

[13] A. A. Kassem and G. S. Labib, "Flash dissolving sublingual almotriptan malate lyotabs for the management of migraine," International Journal of Pharmacy and Pharmaceutical Sciences, vol. 9, pp. 125–131, 2017.

[14] S. L. Patil, P. R. Mahaparale, M. A. Shivnikar, S. S. Tiwari, K. V. Pawar, and P. N. Sane, "Fast dissolving oral films: An innovative drug delivery system," International Journal of Research and Reviews in Pharmacy and Applied Sciences, vol. 2, pp. 482–496.

[15] Y. Rubia, Y. Firoz, C. Mouli, V. A. Vikram, M. Mahitha, and U. Aruna, "Preparation and evaluation of oral fast dissolving films of citalopram hydrobromide," International Journal of Biopharmaceutics, vol. 3, pp. 103–106, 2012.

[16] M. Arunachalam, S. Karthikeyan, A. Kumar, P. Kishore, K. P. Konam, and Hari Prasad, "Fast dissolving drug delivery system: A review," Journal of Global Trends in Pharmaceutical Sciences, vol. 1, pp. 92–110, 2010.

[17] S. V. Shubham, K. Nitin, and S. P. Kumar, "Buccal film: An advanced technology for oral drug delivery," Advanced Biological Research, vol. 8, pp. 260–267, 2014.

[18] R. N. G. Raghavendra, Shravani, and S. R. Mettu, "Overview on buccal drug delivery systems," Journal of Pharmaceutical Sciences and Research, vol. 5, pp. 80–88, 2013.

[19] P. Pallavi and S. K. Shrivastava, "Fast dissolving oral films: An innovative drug delivery system," International Journal of Science and Research, vol. 3, pp. 2088–2093, 2014.

[20] S. K. Shweta and M. Bansal, "Recent trends in the development of oral dissolving film," International Journal of PharmTech Research, vol. 4, pp. 725–733, 2012.

[21] N. G. N. Swamy and K. S. Shiva, "Formulation and evaluation of fast dissolving oral films of palonosetron hydrochloride using HPMC-E5," International Journal of Pharmaceutical and Chemical Sciences, vol. 3, pp. 145–150, 2014.

[22] D. H., G. A., and H. K., "Recent trends of fast dissolving drug delivery system—An overview of formulation technology," Pharmacophore, vol. 4, pp. 1–9, 2013.

[23] R. P. Dixit and S. P. Puthli, "Oral strip technology: Overview and future potential," Journal of Controlled Release, vol. 139, pp. 94–107, 2009.

[24] M. S. Rekha, S. S. K., K. Mahathi, P. Praveen, B. Prathima, and A. S. Devi, "Formulation and evaluation of fast dissolving buccal film containing isradipine solid dispersion," American Journal of PharmTech Research, vol. 5, pp. 91–107, 2015.

[25] M. Dahiya, S. Saha, and A. Shahiwala, "A review on mouth dissolving films," Current Drug Delivery, vol. 6, pp. 469–476, 2009.

[26] D. Nagendrakumar, G. G. Keshavshetti, P. Mogale, S. Swami, and H. Swami, "Formulation and evaluation of fast dissolving oral films of metoprolol succinate," International Journal of Engineering and Applied Sciences, vol. 6, pp. 28–38, 2015.

[27] S. Sandeep, A. Nanda, and M. H. Monika, "Fast dissolving films (FDF): Innovative drug delivery system," Pharmacologyonline, vol. 2, pp. 919–928, 2011.

[28] S. L. Patil, P. R. Mahaparale, M. A. Shivnikar, S. S. Tiwari, K. V. Pawar, and P. N. Sane, "Fast dissolving oral films: An innovative drug delivery system," International Journal of Research and Reviews in Pharmacy & Applied Sciences, vol. 2, no. 3, pp. 482–496, 2014.

[29] R. R. Zachariya, R. R. Shaha, A. R. Dole, and C. S. Magdum, "Preparation of novel biocompatible honey hydrogel with turmeric and aloe vera," Research Journal of Pharmacology and Pharmacodynamics, vol. 9, no. 2, pp. 1–4, 2017.