Formulation and evaluation Procyclidine hydrochloride mouth dissolving oral film using solvent casting method

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Abstract

The present investigation was undertaken to formulate Procyclidine HCL oral films for the treatment of Parkinson. Among all the formulations F3 showed good mechanical properties and less disintegration time of 24 seconds. All the parameters of film were found to be satisfactory. The dissolution profile was found to be desirable and reproducible. The morphological study (SEM) of F3 shows more porous. The rapid drug release was achieved for the immediate onset of action.

The film (F3) samples evaluated gave maximum release within 03 minutes indicating the rapid drug release profile which entails in faster onset of action for the medicament. Therefore the oral films have considerable advantage over the conventional dosage forms

Keywords: Oral Film, Mouth dissolving film, HPMC, Procyclidine Hydrochloride.

Introduction

Oral administration is the most popular route without sterility Conditions, so it is less expensive to create. This is because it is simple to consume, avoids pain, is versatile (to adapt to many types of drug candidates), and most importantly, patient compliance.Recently, a number of innovative technologies for oral administration have been developed that can be used to improve patient compliance while addressing the physicochemical and pharmacokinetic features of medications [1].

Recent developments include computer-aided 3D printing (3DP) tableting and electrostatic drug deposition and coating. In order to provide pediatric and elderly patients with an alternative to pills, capsules, and syrups, the quick dissolving medication delivery system was originally created in the late 1970s [2].

Swallowing issues with conventional oral solid dose forms, Fast-dissolving, fast-melting, and fast-disintegrating tablets are the new term for quickly dissolving dosage forms.

However, all of these dosage forms have the same principles and purposes. A solid dosage form is defined as one that dissolves or disintegrates quickly in the mouth to create a solution or suspension without the need for water to be administered. A fast-dispersing oral dose form is known as Dysphagia (dysphagia) can happen when ingesting ordinary tablets and capsules and is common in all age groups, but is most prevalent in the elderly [3-4].

Numerous illnesses, such as stroke, Parkinson's disease, AIDS, thyroid surgery, head and neck thyroid therapy, and other neurological conditions, such as cerebral palsy, are linked to dysphagia. The size of the tablet is the most often mentioned problem, followed by the surface, shape, and flavor. Elderly and young patients, those who travel frequently, and those who do not have easy access to water all experience difficulties taking pills [5].

Materials and methods

Procyclidine Hydrochloride was provided Pharma Tech Solutions, India. HPMC E15, HPMC E5 and PEG (Accent microcell industries) were used as components of the Mouth dissolving film. All other ingredients and reagents were of analytical grade and were used as received.

Results and Discussion

The water-soluble polymer and plasticizer are dissolved in distilled water. Stir the solution on a magnetic stirrer for 2 hours and set aside to remove all trapped air bubbles. At the same time, dissolve the excipients and drugs and fully stir for 30 minutes. After the stirring is completed, mix the two solutions. Finally, the solution is poured on a suitable petrochemical plate to form a thin film. The plate was kept in a hot air oven at 60°C for 1 hour. The dried film is gently peeled from the glass plate and cut to the required size [6]. An FTIR study was conducted to check the compatibility of the drug with the polymer. The infrared spectrum of Procyclidine hydrochloride was measured on a Fourier transform infrared spectrophotometer using the KBr scattering method.

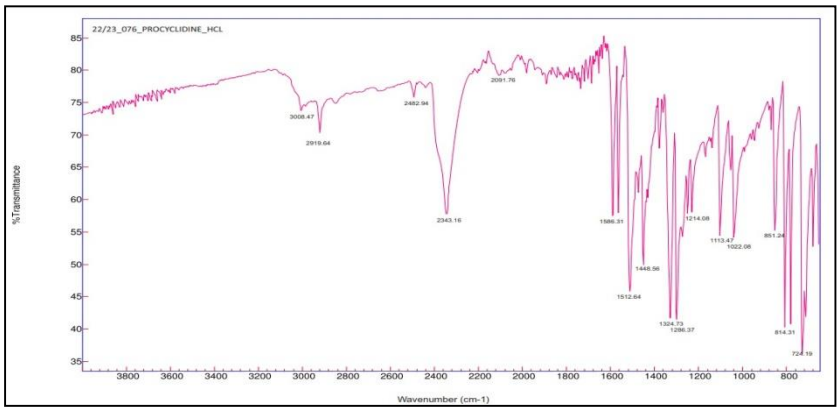

Figure 1. IR Spectra of Procyclidine HCl

From the Infrared spectrometer it was found that all the principal peaks in Procyclidine HCl is represent in FTIR of physical mixture; Hence it is concluded that no significant interaction was found in drug and excipients.

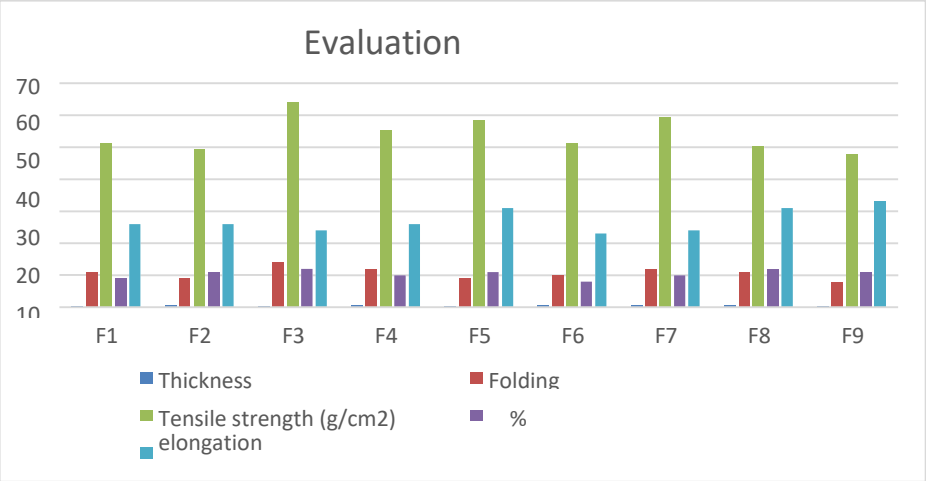

Figure 2. Bar chart of evaluation parameters

From the evaluation of thickness of F1 to F9 batches was found in between 0.52 mm - 0.56 mm, Folding endurance of F1 to F9 batches was found in between 8 to 144, tensile strength of F1 to F9 batches was found in between 47.86 to 59.36 gm/cm2, % elongation of F1 to F9 batches was found in between 8 to 12 and *in vitro* evaluation of F1 to F9 batches was found in between 23 to 33 sec. Ten films are randomly selected and their average weight is weighed. From the evaluations of weight variation of F1 to F9 batches was found in between 118.3 to 124.3 mg.

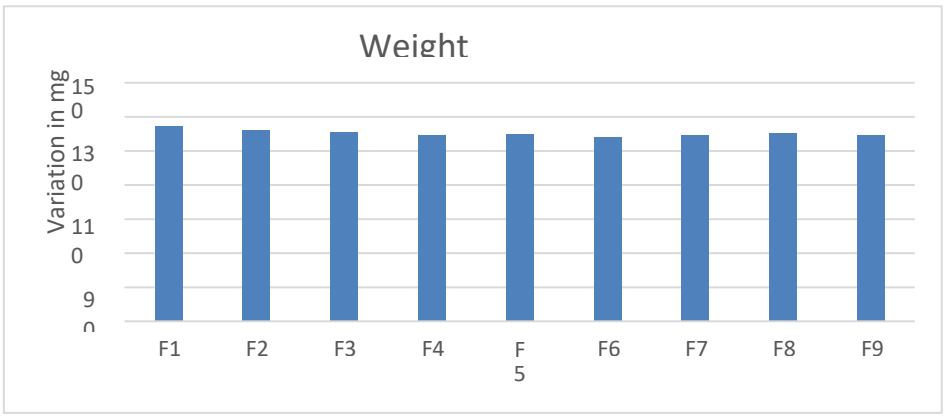

Figure 3. Bar chart of weight variation

In-vitro dissolution

Use 900 ml Phosphate buffer 6.8 as the medium and keep it at 37±0.5°C while setting the basket to 100 rpm. Cut 4 cm2 (2 x 2 cm) film sample and place five films in the basket. Take 5 ml samples every 30 seconds and replace the same amount of samples with fresh Phosphate buffer 6.8. The extracted samples were filtered and analyzed using an ultraviolet spectrometer at a wavelength of 212 nm. The cumulative drug release percentage of F1-F9.

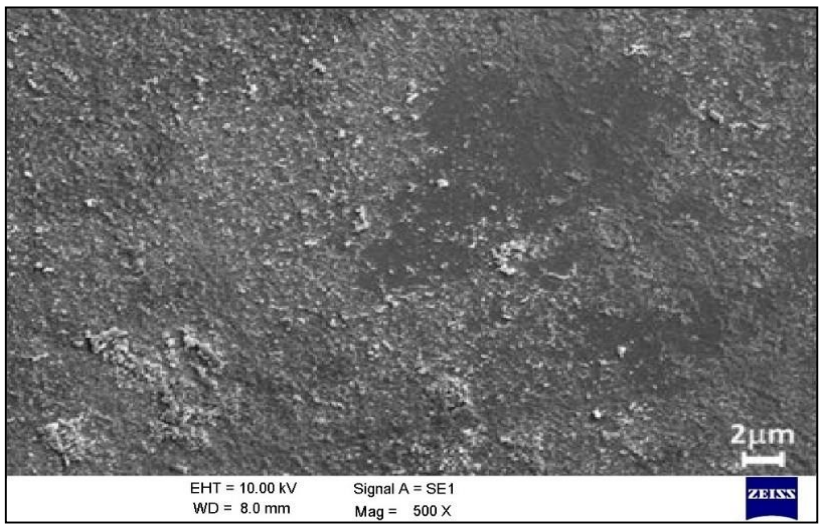

Fig 31: SEM images of F3 Batch

The morphological study of the oral film is carried out by scanning electron microscopy (SEM) at a prescribed magnification. The research involves the differencebetween the upper and lower surfaces of the film. It also helps determine API distribution.

Conclusion

The primary objective of this work was to develop a mouth dissolving film with Procyclidine HCl, along with basic ingredients like polymers, plasticizers, sweetener, saliva stimulating agent and flavor. The optimized formulation (F3) was shown good folding endurance, instant drug release as well as good mechanical properties. The F3, shown less disintegration time of 24 seconds and 98% drug released within 03 minutes. Therefore rapid drug release was achieved for immediate onset of action.

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References

1. Jyoti A, Singh G, Seema S, Rana AC. Fast dissolving films: A novel approach to oral drug delivery. Researchgate 2011 Dec 1; Available from:
2. Bhattarai M, Gupta AK. Fast dissolving Oral films: A novel trend to oral drug delivery system. Sunsari Technical College Journal 2016 Apr 28;2(1):58–68
3. Kaur P, Garg R. Oral dissolving film: present and future aspects. Journal of Drug Delivery and Therapeutics 2018 Nov 15;8(6):373–7.
4. Hoffmann EM, Breitenbach A, Breitkreutz J. Advances in orodispersible films for drug delivery. Expert Opinion on Drug Delivery 2011 Feb 2;8(3):299–316.

5. Van Riet-Nales DA, Ferreira JA, Schobben AFAM, De Neef BJ, Egberts TCG, Rademaker CMA. Methods of administering oral formulations and child acceptability. International Journal of Pharmaceutics 2015 Aug 1;491(1–2):261–7.
6. Bala R, Khanna S, Pawar P, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. International Journal of Pharmaceutical Investigation 2013 Jan 1;3(2):67.
7. Bala R, Khanna S, Pawar P, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. International Journal of Pharmaceutical Investigation Jan 1;3(2):67.
8. Singh S, Pawar R, Patidar S. A Review on Mouth Dissolving Film- a Novel Approach. International Journal of Pharmaceutical Sciences and Medicine 2024 Feb 28;9(2):36–51.
9. Al-Jarsha HYM, Ghareeb MM, Hussein AA. A review on film forming drug delivery systems. Research Journal of Pharmacy and Technology 2021 Oct 31;5579–88.
10. Bala R, Khanna S, Pawar P, Arora S. Orally dissolving strips: A new approach to oral drug delivery system. International Journal of Pharmaceutical Investigation 2013 Jan 1;3(2):67.
11. Schroeder IZ, Franke P, Schaefer UF, Lehr CM. Development and characterization of film forming polymeric solutions for skin drug delivery. European Journal of Pharmaceutics and Biopharmaceutics 2007 Jan 1;65(1):111–21.
12. Borges AF, Silva C, Coelho JFJ, Simões S. Oral films: Current status and future perspectives. Journal of Controlled Release 2015 May 1;206:1–19.
13. Bhattarai M, Gupta AK. Fast dissolving Oral films: A novel trend to oral drug delivery system. Sunsari Technical College Journal 2016 Apr 28;2(1):58–68.
14. Shimoda H, Taniguchi K, Nishimura M, Matsuura K, Tsukioka T, Yamashita H, et al. Preparation of a fast dissolving oral thin film containing dexamethasone: A possible application to antiemesis during cancer chemotherapy. European Journal of Pharmaceutics and Biopharmaceutics 2009 Nov 1;73(3):361–5.
15. Nagapudi K, Jona J. Amorphous Active Pharmaceutical Ingredients in preclinical Studies: Preparation, characterization, and Formulation. Current Bioactive Compounds 2008 Dec 1;4(4):213–24