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Formulation and validation of herbal oral disintegrating film for toothache

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Abstract

The oral film is a new invention with the fastest processing time and improved patient consistency. When placed in the mouth, the film will damage or broken within minutes without water. It improves API capabilities and enables better planning. This formula is suitable for colds, allergy, mouth infection asthma and central nervous system diseases that need to be treated quickly. Oral film disintegrates faster and release drug faster compare to other oral dosage form. This formulation is suitable for minor toothache which can be cause by infection or cavities. This article provides an overview of formulation of oral film.

Keywords: Oral patch; Onset of action; Patented technology; Toothache

1. Introduction

Over the past few years, interest in leading-edge technology has increased in efforts to improve effectiveness, safety, and patient convenience. Since the discovery and development of new drugs is difficult, expensive and time-consuming, the trend has recently shifted towards the design and development of new drugs to complement existing drugs. Among these the most famous drug delivery in the field of paediatrics and geriatrics is oral. Among oral diseases, oral patches are gaining popularity in paediatrics and geriatrics due to the fastest onset of action and better patient compliance. The oral patch is placed on the tongue, breaks within a second by immersion in saliva, and releases the medication from the dosage form. [1-2]

Oral patches, capsules, tablets etc. It is an alternative to oral prescriptions such as the technology behind the development of the oral patch is the transdermal patch. Hydrophilic polymers play an important role in the rapid preparation of oral patches; Release of the drug into the body system through the oral mucosa. Due to the oral mucosal film, the drug is absorbed directly into the systemic circulation and has instant bioavailability and rapid onset of action. [3-4]

2. Materials and methods

2.1. Materials

Thymus Vulgarise and clove Extracts was gifted by Schwabe, India. Eudragit RS 200, HPMC k100, PEG 400, UV - spectrophotometer, magnetic steer.

2.2. Formulation of Film

Oral Film was prepared by solvent casting method using different polymer combination of HPMC K 100, Eudragit RS 200. EUD· 50 mg eudragit was dissolved in ethanol and 400 mg of HPMC was dissolved in water. The calculated amount

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of Thymus Vulgaris and clove was added in EUD solution. According to the solution given above solutions were mixed thoroughly. PEG 400 was added as a plasticizer and stirred on a magnetic stirrer until obtaining a clear and homogenous mixture. These solutions were poured in Petry dish and let it set for 12 h. [5,6]

Figure 1 Image of Formulation (oral film)

2.3. Development and validation

UV spectroscopy is widely used for quantitative analysis and quality control in various industries due to its distinct advantages over traditional absorbance methods. One key advantage is its capability to differentiate sharp spectral features from larger bands, enhancing the resolution of overlapping spectra. This feature allows for more precise identification and quantification of substances in samples, making UV spectroscopy a valuable tool in ensuring product quality and safety across different sectors.

2.4. UV analysis of Thymus vulgaris

The standard stock solution was prepared of thymus vulgaris the stock solution was dissolved separately in 20mL of water in a volumetric flask and absorbance was measured at 274nm.

2.5. Validation parameter of oral film

2.5.1. Linearity

The linearity of this method was determined at concentration levels ranging between 0.5 mg/ml and 2.5 mg/ml. The plot of absorbance v/s concentration (Fig. 2) of formulation was found to be linear in the range

Table 1 Standard calibration curve of thymus vulgaris at 274 nm

X-Axis (concentration)	Y-Axis (Absorbance)
0.5	0.56
1	0.76
1.5	1.02
2	1.18
2.5	1.37

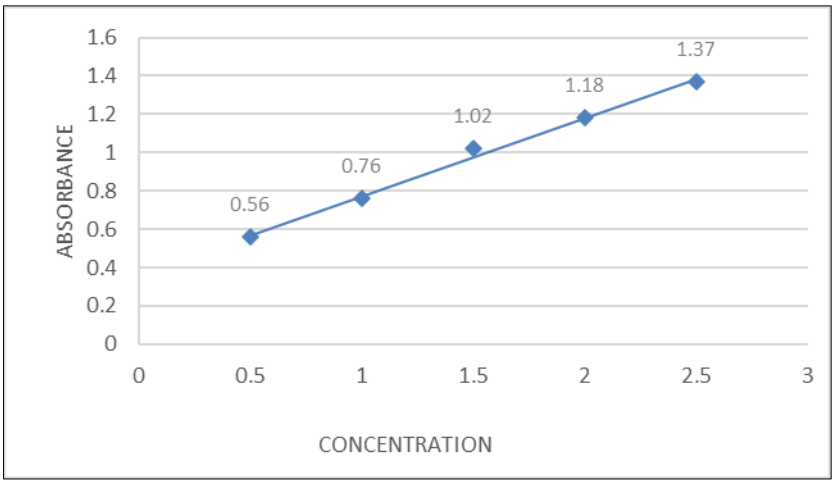

Figure 2 Calibration curve of formulation

2.5.2. Precision

The precision of the method was assessed by repeatability(intra-day) and intermediate precision (inter-day). Intra-day precision was determined by analysing 20 µg/ml s for three times within the day and average % RSD was calculated. Inter-day precision was determined by analysing the same concentration of solutions for three days and average % RSD was calculated. % RSD should not be more than 2 %.

Table 2 Intraday precision (On same Day)

Sr No	Concentration (µg/ml)		Absorbance	Mean	SD	% RSD
1	20	Morning	0.84	0.82	0.01247	1.52%
2	20		0.82			
3	20		0.81			
4	20	Afternoon	0.80	0.80	0.0081	1.01%
5	20		0.81			
6	20		0.79			
7	20	Evening	0.79	0.80	0.0124	1.55%
8	20		0.80			
9	20		0.82			

Table 3 Interday precision (On different day)

Sr No	Concentration (µg/ml)		Absorbance	Mean	SD	% RSD
1	20		0.83			
2	20	Day 1	0.81	0.81	0.0124	1.53%
3	20		0.80			
4	20		0.82			
5	20	Day 2	0.80	0.80	0.0251	1%

6	20		0.81			
7	20		0.81			
8	20	Day 3	0.78	0.80	0.0141	1.76%
9	20		0.81			

2.5.3. Accuracy:

Accuracy is defined as closeness of agreement between the actual (true) value and analytical value and obtained by applying test method for a number of times. Accuracy may often be expressed as % Recovery by the assay of known, added amount of analyte. It is measure of the exactness of the analytical method. The recovery experiments were carried out in triplicate by spiking previously analysed samples of with three different concentrations of sample.

Table 4 Accuracy Determination

Sr No	Concentration (%)	Original level (µg/ml)	Amount Added (µg/ml)	Recovery (µg/ml)	Recovery %	Avg. Recovery	% RSD
1	80	1.6	1.28	1.28	99.4	99.23	0.154
	80	1.6	1.28	1.19	99.1		
	80	1.6	1.28	1.22	99.2		
2	100	1.6	1.60	1.60	99.8	99.8	0.301
	100	1.6	1.60	1.62	100.1		
	100	1.6	1.60	1.59	99.5		
3	120	1.6	1.92	1.98	100.4	100.23	0.152
	120	1.6	1.92	1.95	100.2		
	120	1.6	1.92	1.93	100..1		

2.5.4. LOD & LOQ

Limit of detection (LOD)

LOD is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. LOD value was calculated from the calibration curve by using the equation.

$$LOD=3.3 \times \sigma/S$$

where, SD is standard deviation of the standard curve.

Limit of quantitation (LOQ)

LOQ is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. The quantitation limit is a parameter of quantitative assays for low levels of compounds in sample matrices, and is used particularly for the determination of impurities and/or degradation products.

LOQ value can also be calculated from the calibration curve using the equation.

$LOQ=10x\ \sigma/S$ Where, σ = Standard deviation of the response, S = Slope of the calibration curve.

3. Results and discussion

The oral film containing HPMC k100 and Eudragit RS 100 polymers were successfully prepared by the solvent casting method. Plasticizer PEG 400 was used to improve flexibility and reduce the brittleness of the film. The extract was dissolved in ethanol and the ʎmax was found to be 274 nm. from the result obtained from table 1, linearity was found in fig 2 and coefficient correlation was found to be 0.9972. The regression of the curve was y = 0.408X + 0.336. The precision (measurements of intra-day and inter-day) results showed (Table 2 and Table 3) significant reproducibility with percent relative standard deviation (% RSD) is below 2.0. The detection and quantitation limits as LOD (k ¼ 3.3) and LOQ (k ¼ 10) were calculated and these were found to be 2.63 mg/ml and 7.98 mg/ml respectively. this indicate that method is highly precise. The precent recovery value which was higher than 100% indicate the accuracy of the method.

4. Conclusion

The developed method was found to be simple, accurate, precise, reproducible and most importantly cost effective. The proposed method is specific in estimating commercial formulations without excipient interference.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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