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Formulation and Evaluation of Transdermal Patch of Pirfenidone

Deepti D. Bobade[1], Shailesh G. Jawarkar[2], Koshish B. Gabhane[3], Madhuri D. Game[4]
Department of Quality Assurance
Vidyabharati College of Pharmacy, Amravati, Maharashtra, India[1,2,3,4]

Abstract: *The purpose this research was to formulate a transdermal patch therapeutic system containing Pirfenidone with different ratios of polymeric systems by the solvent evaporation method. Different concentrations of plasticizer and penetration enhancer were used. In this work the physicochemical compatibility of the drug and the polymer were studied using infrared spectroscopy which showed absence of any interaction of the drug with the excipients. The formulated transdermal patches were subjected for evaluation with regard to physical appearance, weight variation, thickness, drug content, flatness, and folding endurance. All the prepared formulations indicated 0 % constriction of the transdermal patches and indicating % flatness of the transdermal patches.*

Keywords: Pirfenidone, Transdermal Patch, etc.

I. INTRODUCTION

A transdermal patch is a medicated patch that is placed on the skin which delivers the medication (specific amount of dose) through the skin and into the blood stream. An advantage of a transdermal patch over the other types of dosage form is that this type of dosage form (transdermal drug delivery system) provides a controlled release of the medication into the patient thereby preventing/ avoiding first pass metabolism. Also ease of application. Provide suitability for self-administration. It is of great advantages in patients who are nauseated or unconscious [1]. Idiopathic pulmonary fibrosis (IPF) is an irreversible, chronic, and progressive pulmonary disorder characterized by thickening and scarring of the lung tissue. Idiopathic pulmonary fibrosis (IPF) may also be defined as an unpredictable, irreversible, progressive, and fatal lung disease developing from an unknown cause that affects the tissue surrounding the air sacs or alveoli. Common symptoms involve shortness of breath and a persistent dry, hacking cough. Although the cause of IPF is unknown, risk factors for the development of IPF include smoking, certain genetic mutations, and possibly gastro oesophageal reflux disease. Management of IPF is multifaceted and may include the use of the anti-fibrotic agent's Nintedanib and Pirfenidone, smoking cessation, and supportive care, including oxygen therapy, pulmonary rehabilitation, and in some cases, lung transplantation. Pharmacists can enlighten patients about therapy for IPF and make clinical suggestions when warranted that are customized to patient-specific needs [2].

II. MATERIALS AND METHOD

Materials

Pirfenidone was obtained as a gift sample form Raks Pharma Pvt. Ltd. Gujarat. The following materials were procured from indicated sources: HPMC E 15 LV - Loba Chemie Pvt. Ltd.,Mumbai; HPMC 5 cPs LR - S D Fine- Chem Limited, Mumbai; Methanol - Thermo Fisher Scientific India Pvt. Ltd,Mumbai; PEG 400 - S D Fine- Chem Limited, Mumbai; Tween 20 - S D Fine- Chem Limited, Mumbai; Chloroform - S D Fine- Chem Limited, Mumbai; Potassium hydrogen phosphate - S D Fine- Chem Limited, Mumbai; Disodium hydrogen phosphate - S D Fine- Chem Limited, Mumbai; Sodium chloride - S D Fine- Chem Limited, Mumbai.

Methods

Matrix-type transdermal patches containing Pirfenidone were prepared by solvent evaporation technique. The polymers were weighed in requisite ratio and they were further dissolved in solvents (Methanol: chloroform). The plasticizer and penetration enhancer used were PEG 400 and Tween 20 respectively. The drug was then added in the homogeneous

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solution thereby stirring with the magnetic stirrer. This was further poured on a petri plate and the solvent was further allowed to evaporate for about 24 hrs without disturbing. Then the dried patches were taken out and kept in desiccator for further studies. Composition of formulated patch is shown in Table 1.

III. EVALUATION OF TRANSDERMAL PATCHES

Determination of λmax: About, 0.1 g of the drug was dissolved in 100 ml of phosphate buffer (pH 7.4) to prepare 100 mg/ml of solution. From this solution, 0.1 ml was withdrawn and the volume was made up to 10 ml with phosphate buffer (pH 7.4) for preparing the stock solution. The solution containing a concentration of 10 µg/ml Pirfenidone was scanned over the wavelength of 200–400 nm in UV-Vis spectrophotometer to determine the wavelength of maximum absorbance [3].

- **Physical Appearance:** Formulated patches were evaluated for their physical appearance [4].
- **Thickness:** Thickness of Transdermal patch was measured by using digital micrometre screw gauze. Thickness of patch was determined at three different points and average thickness was further calculated. The same procedure was performed for other patches also. Thickness of each individual patch should not deviate significantly from each other [4].
- **Weight Variation:** This was studied by individually weighing 10 randomly selected patches and the average weight was calculated. The individual weight shouldn't deviate significantly from the average weight [4].
- **Folding endurance:** A strip of 2 cm × 2 cm was subjected to folding endurance by folding the patch at the same place repeatedly several times until a visible crack was observed and the values were reported [5].
- **Flatness:** A transdermal patch must possess a smooth surface and shouldn't constrict with time. This can be well demonstrated with the flatness study. For this determination, one strip is cut from the centre and two from each side of patches. The length of each strip is measured and variation in length is measured by determining % constriction. 0% constriction is equivalent to 100% flatness [6].
- **Drug content:** For determining the drug content of the transdermal patches, an area of 10 cm2 of the patch was cut and dissolved in 10 ml of phosphate buffer (pH 7.4). After which, 0.1 ml volume was withdrawn from the solution and diluted with the phosphate buffer to 10 ml in a volumetric flask. The absorbance of the prepared solution was taken at 311 nm by using UV spectrophotometer [7].

IV. RESULTS AND DISCUSSION

All the formulated transdermal patches were transparent, smooth and flat.

- **Fourier Transforms Infrared Spectroscopy (FTIR):** Fourier Transforms Infrared spectra of Pirfenidone, Pirfenidone and HPMC E 15 LV, Pirfenidone and HPMC 5 cPs LR are shown in Fig 1 a), Fig 1 b), and Fig 1 c). This study showed that there was absence of interaction in between the drug and the polymer. The FT-IR spectra demonstrated the presence of characteristic peaks of drugs and polymers.
- The λmax of the drug was found to be 311 nm the results of which are shown in Fig 2 and Fig 3.
- Thickness of the transdermal patches was found to be good which is shown in Table 2.
- However, a slight variation in weight among the formulation F1–F8 was observed shown in Table 2.
- All formulations exhibited a little variation in drug content ranging from 91.65% to 96.50% shown in Table 2. Formulation F2 shows the highest drug content of 96.50% while the batch F1 presented the lowest drug content of 91.65%. All formulations found to be satisfactory with reference to the drug content shown in Table 2.
- The folding endurance was found out manually in order to estimate/ determine the plasticity of the prepared patches. The number of times the patch could be folded at the same place without breaking gave the value of folding endurance. The folding endurance was satisfactory in all the formulated batches of Pirfenidone shown in Table 2.
- All formulations have shown 0 % constriction of the transdermal patches. No amount of constriction in the formulated transdermal patches ensured their 100% flatness. Thus, these prepared formulations can maintain a smooth and uniform surface when they are functional onto skin shown in Table 2.

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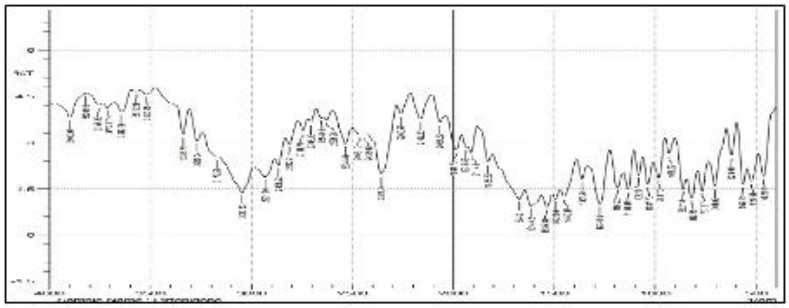

Figure 1: a) FTIR Spectrum of Pirfenidone.

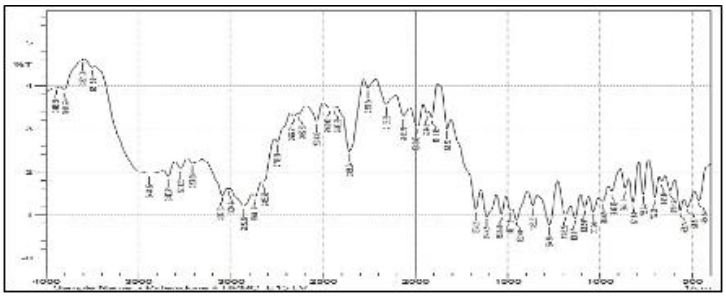

Figure 1: b) FTIR Spectrum of Pirfenidone + HPMC E 15 LV.

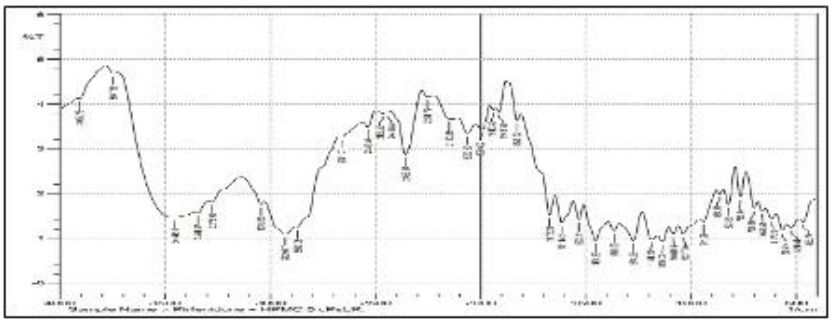

Figure 1: c) FTIR Spectrum of Pirfenidone + HPMC 5 cPs LR.

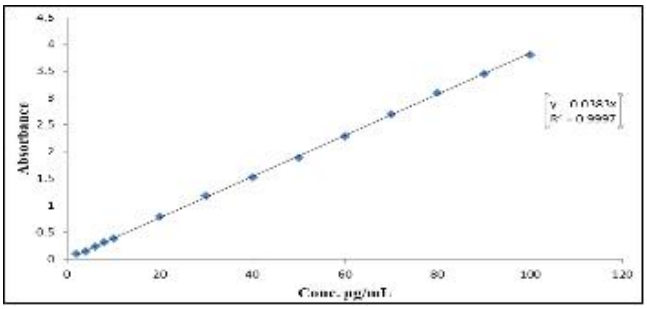

Figure 2: Standard calibration curve of Pirfenidone.

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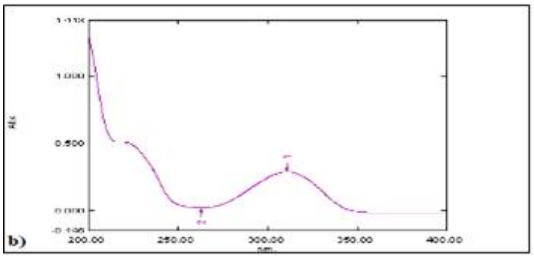

Figure 3: Absorbance of Pirfenidone at 311 nm.

Table 1: Composition of Transdermal Patches of Pirfenidone.

Batch code	Drug (mg)	Polymers (gm)	Plasticizer (ml)	Penetration enhancer (ml)	Solvents (ml)
F1	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F2	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F3	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F4	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F5	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F6	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F7	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol
F8	Pirfenidone	HPMC E 15 LV: HPMC 5 cPs LR	PEG 400	Tween 20	Chloroform: Methanol

Table 2: Evaluation of Transdermal Patches of Pirfenidone.

Batch code	Weight variation (mg)	Thickness (mm)	% Flatness	Folding endurance	Drug content %
F1	1669.42	0.108	100	171	91.65
F2	1661.01	0.010	100	240	96.50
F3	1550.23	0.028	100	203	94.75
F4	1733.52	0.091	100	211	92.13
F5	1662.68	0.071	100	146	91.93
F6	1651.12	0.030	100	101	93.46
F7	1620.51	0.101	100	188	91.98
F8	1579.15	0.043	100	87	96.38

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V. CONCLUSION

Transdermal patches of Pirfenidone were successfully formulated by using different concentrations of HPMC E 15 LV and HPMC 5 cPs LR along with penetration enhancers, solvents and plasticizers which were tween 20, methanol, chloroform and PEG 400. These prepared patches were found to have smooth as well as uniform surface onto the skin. All the evaluated parameters were found to be excellent such as weight variation, thickness, drug content, flatness, folding endurance, as well as its physical appearance.

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REFERENCES

[1] Wikimedia Foundation. (2022, May 15). Transdermal Patch. Wikipedia. Retrieved June 1, 2022, from https://en.wikipedia.org/wiki/Transdermal_patch

[2] https://www.uspharmacist.com/article/a-review-of-the-treatment-and-managementof-idiopathic-pulmonaryfibrosis#:~:text=There%20is%20no%20cure.,in%20some%20cases%2C%20lung%20 transplantation.

[3] Formulation development and evaluation of transdermal patch of Piroxicam for treating dysmenorrhoea. (2018). Journal of Applied Pharmaceutical Science, 8(11), 35–41. https://doi.org/10.7324/japs.2018.81105

[4] Formulation and evaluation of Transdermal Patch of pregabalin: International Journal of Pharmaceutical Sciences and research. IJPSR. (2022, March 2). Retrieved June 1, 2022, from https://ijpsr.com/bft-article/formulation-and-evaluation-of-transdermal-patch-of-pregabalin/

[5] Shah, S. S., Joshi, R., & Prabhakar, P. (2010). Formulation and evaluation of transdermal patches of papaverine hydrochloride. Asian Journal of Pharmaceutics, 4(1), 79. https://doi.org/10.4103/0973-8398.63974

[6] Kanabar, V. B. (n.d.). Formulation and evaluation of transdermal patch of Cefdinir with various polymers. https://www.thepharmajournal.com/archives/2015/vol4issue6/PartB/4-5-10.pdf.

[7] Formulation development and evaluation of transdermal patch of Piroxicam for treating dysmenorrhoea. (2018). Journal of Applied Pharmaceutical Science, 8(11), 35–41. https://doi.org/10.7324/japs.2018.81105