



## Evaluation of Stability Studies on Transdermal Patches of Econazole and Luliconazole

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### Abstract

TDDS i.e. transdermal drug delivery system has been an increased interest in the drug administration on diseased skin (topical delivery) as well as for systemic delivery of drugs. Econazole and Luliconazole is synthetic antifungal agent used for most kinds of fungal infections including superficial and invasive fungal infections. The formulated patches of the drug were evaluated for stability studies. Stability studies were carried out as per ICH guidelines at three different temperature and RH for 3 months for the optimized formulations of transdermal patches of econazole. The results indicates that the transdermal patches of econazole and luliconazole showing better results at  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$ .

**Keywords:** Transdermal Patches; Econazole; Luliconazole; Transdermal Patches

### Introduction

The topical route offers a large and varied surface in addition to the ease of application via self-administration and provides an alternative to oral delivery of drugs as well as hypodermic injection. The rate and extent of drug absorption through skin depends on the skin physiology and physicochemical properties of drugs as well as the delivery system. The current dosage forms, i.e. patches, ointments, creams, etc., are associated with several limitations. Patches have various disadvantages, most commonly skin irritation, because of their occlusive properties causing obstruction of sweat ducts, which in turn prevents loss of water vapor from skin surface, difficulty in applying on the curved surfaces, pain while peeling off and poor aesthetic appeal. Semisolid preparations like creams and ointments overcome some of these drawbacks but have other limitations. These do not ensure persistent contact with the skin surface and can be easily wiped off by patient's clothes. Hence repeated application is required in case of chronic diseases like athlete's foot, ringworm and candidiasis [1,2]. Also, these leave a sticky and greasy feel after application leading to poor patient compliance. Therefore, there is a need for development of a dosage form which permits less frequent dosing by maintaining a close contact with the skin for prolonged time period thereby improving the patient compliance [3-6].

### Objective of the Study

The objective of the present study was to evaluated stability studies of developed transdermal matrix patch of econazole and luliconazole an antifungal drugs and assess its feasibility for transdermal application.

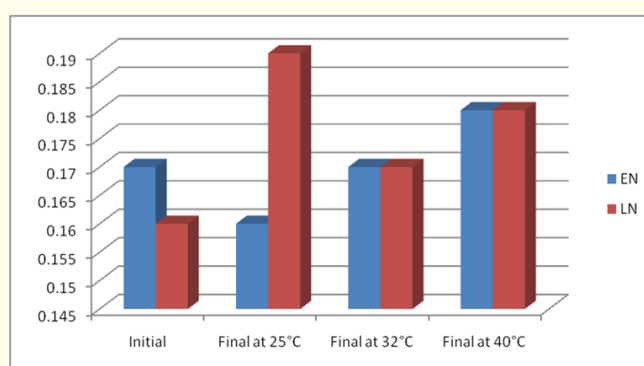
### Methodology

Stability studies were carried out as per ICH guidelines at three different temperature and RH for 3 months. The optimized for-

mulation of the drug containing Econazole and Luliconazole were subjected to accelerated stability studies at specified conditions of temperature and relative humidity of  $25^{\circ}\text{C}/60\% \text{RH}$ ,  $30^{\circ}\text{C}/60\% \text{RH}$  and  $40^{\circ}\text{C}/75\% \text{RH}$  for 3 months. After the completion of three month the samples were analyzed visually for any color changes due to physical and chemical interaction within excipients and with the drug [7].

### Results and Discussion

The optimized formulation of Econazole and luliconazole formulations were subjected for stability studies. Stability studies were carried out as per ICH guidelines at three different temperature and RH for 3 months for the optimized formulations of transdermal patches of econazole and luliconazole. From the results table 1 and 2 it was found that the transdermal patches of econazole showing better results at  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$  whereas it was found that the transdermal patches of luliconazole showing better results at  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$ .



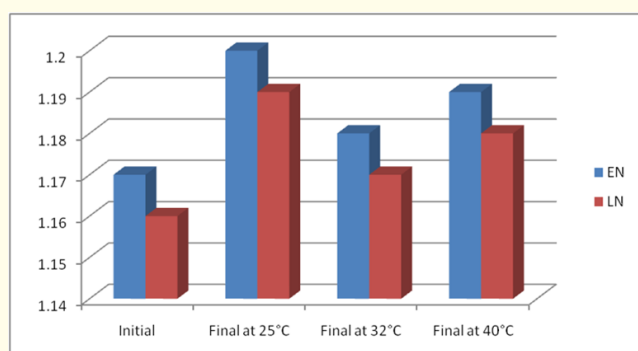
**Graph 1:** Thickness of transdermal patches of econazole and luliconazole at  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$ ,  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$  and  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \text{RH} \pm 5\%$  RH.

Parameters	TPE5			
	Initial	Final at 25°C	Final at 32°C	Final at 40°C
Thickness (mm)	0.17 ± 0.09	0.16 ± 0.05	0.17 ± 0.01	0.18 ± 0.19
Weight Variation (mg)	± 1.17	± 1.20	± 1.18	± 1.19
Flatness	100	100	100	100
Folding Endurance	254.7 ± 0.20	250.6 ± 0.18	253.7 ± 0.11	250.1 ± 0.11
Tensile Strength (kg/mm <sup>2</sup> )	12.92 ± 0.04	12.27 ± 0.12	12.87 ± 0.10	12.20 ± 0.11
pH	6.2	6.1	6.2	6.1
% Moisture Content	1.98 ± 0.01	2.13 ± 0.03	1.99 ± 0.10	2.19 ± 0.29
% Moisture Uptake	3.11 ± 0.29	3.19 ± 0.27	3.14 ± 0.07	3.21 ± 0.87
% Drug Content	98.34 ± 0.92	97.91 ± 0.02	97.91 ± 0.02	97.81 ± 0.17
% Drug Release	83.92	81.86	81.86	80.01

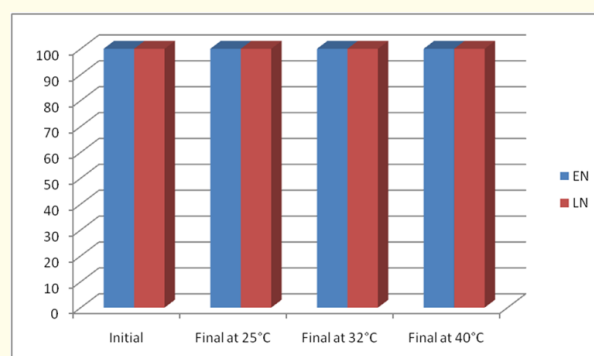
**Table 1:** Stability testing of transdermal patches of econazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.

Parameters	TPE5			
	Initial	Final at 25°C	Final at 32°C	Final at 40°C
Thickness (mm)	0.16 ± 0.08	0.19 ± 0.20	0.17 ± 0.11	0.18 ± 0.28
Weight Variation (mg)	± 1.16	± 1.19	± 1.17	± 1.18
Flatness	100	100	100	100
Folding Endurance	255.8 ± 0.22	250.7 ± 0.02	254.8 ± 0.12	251.8 ± 0.12
Tensile Strength (kg/mm <sup>2</sup> )	12.96 ± 0.02	10.97 ± 0.12	12.87 ± 0.10	11.07 ± 0.22
pH	6.3	6.4	6.3	6.4
% Moisture Content	1.96 ± 0.29	2.09 ± 0.92	1.98 ± 0.02	2.08 ± 0.02
% Moisture Uptake	3.12 ± 0.19	4.78 ± 0.18	3.15 ± 0.01	4.88 ± 0.08
% Drug Content	98.96 ± 0.12	97.01 ± 0.29	98.19 ± 0.09	97.05 ± 0.91
% Drug Release	84.90	82.91	84.21	83.11

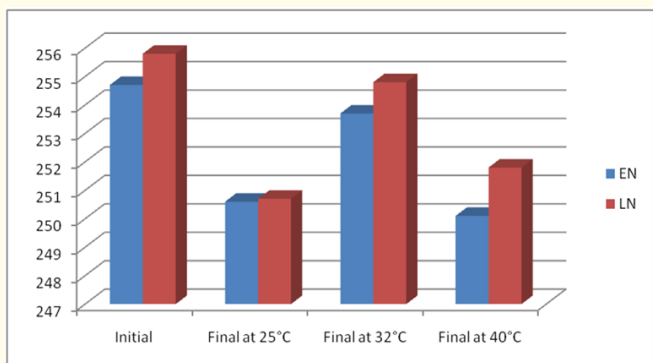
**Table 2:** Stability testing of transdermal patches of luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



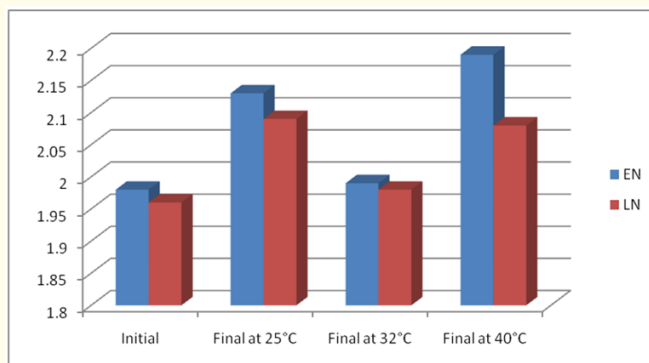
**Graph 2:** Weight variation of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



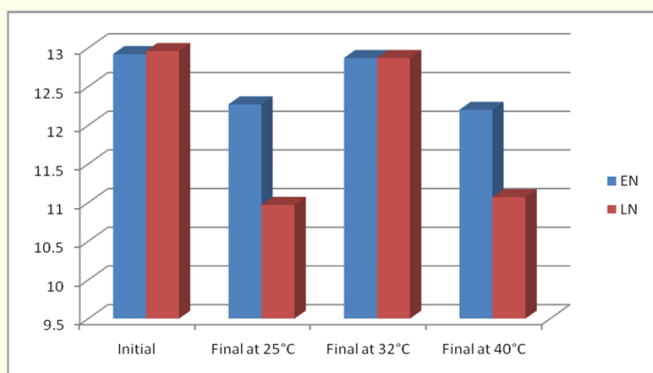
**Graph 3:** Flatness of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



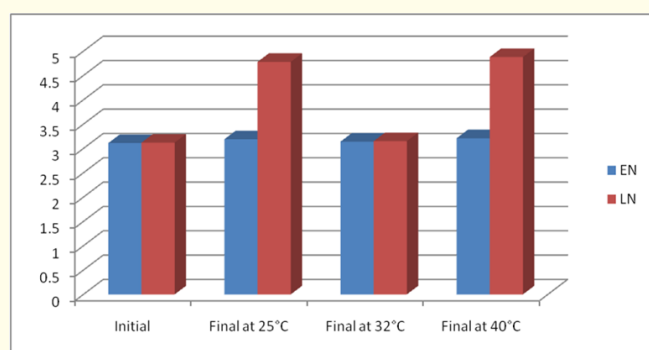
**Graph 4:** Folding endurance of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH



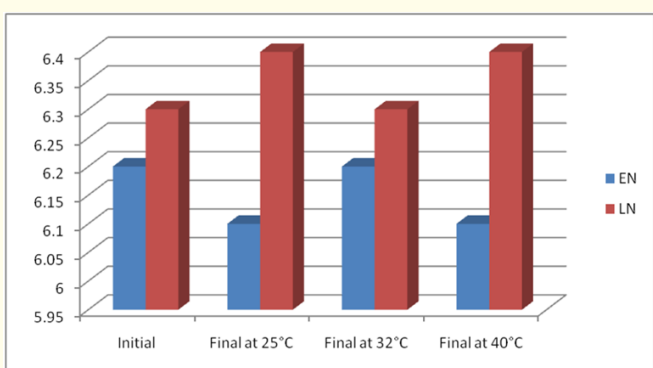
**Graph 7:** % Moisture content of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



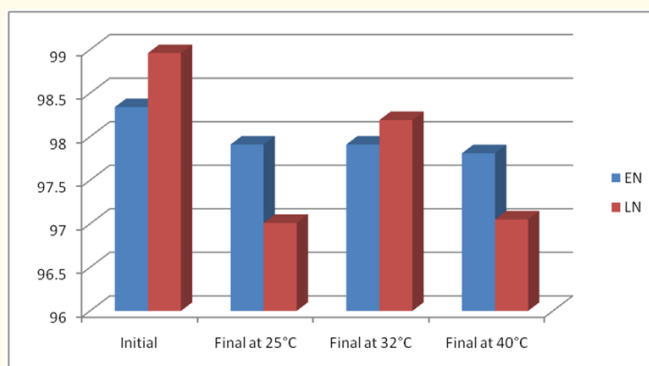
**Graph 5:** Tensile strength of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



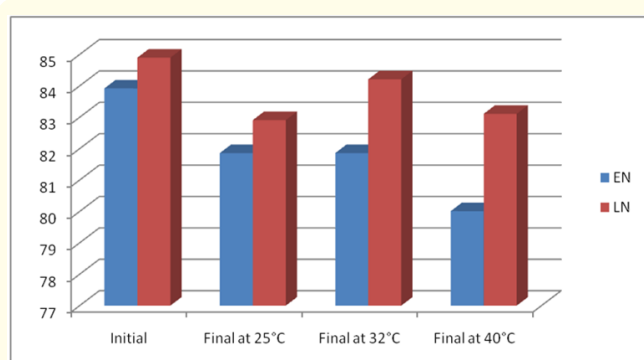
**Graph 8:** % Moisture uptake of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



**Graph 6:** pH of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



**Graph 9:** % Drug content of transdermal patches of econazole and luliconazole at 25°C ± 2°C/60% RH ± 5% RH, 32°C ± 2°C/60% RH ± 5% and 40°C ± 2°C/75% RH ± 5% RH.



**Graph 10:** % Drug release of transdermal patches of econazole and luliconazole at  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\% \text{RH}$ ,  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$  and  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \text{RH} \pm 5\% \text{RH}$ .

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## Conclusion

Econazole and Luliconazole are used as a cream to treat skin infections such as athlete's foot, tinea, pityriasis versicolor, ring-worm, and jock itch. Low dose maintenance therapy of drugs has the capability to reduce potential side effects and improved patient compliance which are more common with conventional drug delivery. Stability studies were carried out as per ICH guidelines at three different temperature and RH for 3 months for the optimized formulations of transdermal patches of Econazole and luliconazole. From the results it was found that the transdermal patches of econazole showing better results at  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$  whereas it the transdermal patches of luliconazole showing better results at  $32^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\%$ .

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