Chapter 9
Stability Study

Dermal Delivery of Protein/Peptide Based Antimicrobial to Treat Secondary Infection in Psoriasis and Eczema

9.1 Introduction

The aim of stability study is to offer indication on how the quality of drug product differs with time under the impact of a diverse environmental factors i.e., humidity, temperature, and light [1]. ICH Q1A (R2) and Q1C provides guidance for stability testing of new drug products and new dosage forms, respectively [2]. Additionally, the stability of nanocarriers is a foremost attention in all stages of their manufacture and administration, from development phases to storage to delivery. Stability of nanocarriers and their controlled release at the time of their usage is a serious issue [3]. A successful introduction of any of the new dosage forms into market place depends upon a defined stability study that can establish product's integrity. In designing a stability study, one must consider to evaluate physical and chemical parameters.

9.2 Short term stability study of Omiganan and DPK 060 loaded formulations

Short term stability of all developed formulations i.e., Omiganan liposomal and NLC gel, Omiganan lotion, DPK 060 NLC gel, and DPK lotion) was performed at 30±2 °C/65±5 % RH for 3 months [3, 4]. % Drug content and vesicle/particle size of Omiganan/DPK-060 loaded nanocarriers were considered decisive and thus chosen as stability-indicating parameters for the developed formulations. Samples were withdrawn on 0, 1, 2 and 3 months and examined for stability-indicating parameters using the techniques described in the previous chapters.

9.3 Results and Discussion

Table 9.1 shows the results of stability data:

Table 9.1 Stability study of Omiganan and DPK 060 loaded formulations

Formulation	Time (months)	Vesicle/particle size	Drug content (%)
Omiganan Liposomes	Initial	121.7 ± 2.50	72.52 ± 1.12
	1 month	125.4 ± 2.24	71.99 ± 1.34
	2 month	128.9 ± 3.02	71.25 ± 1.46
	3 month	130.1 ± 2.77	70.68 ± 1.73
Omiganan NLCs	Initial	118.7 ± 2.01	79.82 ± 1.37
	1 month	121.5 ± 2.49	79.15 ± 1.30
	2 month	124.2 ± 3.25	78.89 ± 1.62
	3 month	125.9 ± 3.12	78.41 ± 1.49
Omiganan lotion	Initial	--	99.78 ± 1.58
	1 month		98.91 ± 2.10
	2 month		98.15 ± 1.84
	3 month		97.07 ± 1.93
DPK 060 NLCs	Initial	126.9 ± 2.32	84.68 ± 1.27
	1 month	128.7 ± 2.76	83.96 ± 1.75
	2 month	129.2 ± 3.31	83.24 ± 1.64
	3 month	134.3 ± 3.18	82.88 ± 1.78
DPK lotion	Initial	--	99.91 ± 1.45
	1 month		99.07 ± 1.78
	2 month		98.19 ± 1.44
	3 month		96.53 ± 2.07

The results of the stability studies indicated a slight increase in vesicle/particle size as well as a slight decrease in % drug content. However, the values observed after 3 months were found within desirable limits required for formulations to perform effectively.

9.4 References

1. Huynh-Ba, K., *Handbook of stability testing in pharmaceutical development: regulations, methodologies, and best practices*. 2008: Springer Science & Business Media.
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3. Muthu, M.S. and S.-S. Feng, *Pharmaceutical stability aspects of nanomedicines.* Nanomedicine, 2009. **4**(8): p. 857-860.
4. Singh, D.K., S. Singh, and S. Bajaj, *Regulatory Guidelines on Stability Testing and Trending of Requirements*, in *Methods for Stability Testing of Pharmaceuticals*. 2018, Springer. p. 1-30.