

9. Stability Study

9.1 Introduction

The stability of pharmaceutical products is a key indicator of quality and must be rigorously assessed to recommend proper storage conditions and ascertain shelf life. Products are often tested under various environmental conditions such as temperature, humidity, and light to monitor any alterations in critical quality attributes over time. Stability testing, in accordance with the ICH guidelines-Q1A (R2), was conducted on all formulated products to ensure their integrity. (1)

9.2 Materials

In-house developed formulations including Luliconazole and Tavaborole loaded nanoemulsion and NLC based gels were prepared for evaluation.

9.3 Stability study

The stability of the aforementioned formulations was investigated at conditions mentioned in ICH guidelines – Q1A (R2) i.e. $30\pm 2^{\circ}\text{C}$ with $65\pm 5\%$ RH. The study was done over a three-month period and sampling was done every month. Parameters such as particle size, zeta potential, and entrapment efficiency were monitored as key indicators of stability. Formulations were stored in sealed glass vials within a stability chamber set to the specified conditions. Monthly assessments were conducted on these parameters using previously described methods.

9.4 Results and Discussion

Table 9.1 Stability study of Luliconazole and Tavaborole loaded developed formulations at storage condition $30\pm 2^{\circ}\text{C}/65\pm 5\%\text{RH}$

Formulation	Time (months)	Globule/Particle Size (nm)	Zeta Potential (mV)	%Entrapment efficiency
Luliconazole loaded nanoemulsion based gel	Initial	223.4 \pm 0.70	-28.54 \pm 0.94	80.20 \pm 0.14
	1 Month	222.3 \pm 0.84	-27.03 \pm 0.12	80.05 \pm 2.07
	2 nd Month	223.9 \pm 2.81	-26.01 \pm 1.82	79.91 \pm 1.67
	3 rd Month	224.8 \pm 2.49	-26.29 \pm 2.06	79.07 \pm 0.03
Luliconazole loaded NLCs based gel	Initial	240.3 \pm 0.87	-14.32 \pm 1.76	80.24 \pm 1.87
	1 Month	241.7 \pm 0.12	-14.07 \pm 0.39	79.92 \pm 1.44
	2 nd Month	239.9 \pm 2.32	-13.81 \pm 0.92	79.73 \pm 2.07
	3 rd Month	240.6 \pm 1.27	-12.73 \pm 1.64	79.23 \pm 0.67
Tavaborole loaded nanoemulsion based gel	Initial	226.8 \pm 0.64	-26.12 \pm 1.32	79.75 \pm 0.72
	1 Month	227.2 \pm 1.54	-26.03 \pm 0.27	79.32 \pm 0.95
	2 nd Month	227.9 \pm 2.31	-25.87 \pm 0.08	78.19 \pm 2.06
	3 rd Month	229.4 \pm 1.27	-24.05 \pm 1.86	78.06 \pm 1.97
Tavaborole loaded NLCs based gel	Initial	234.3 \pm 1.54	-23.12 \pm 1.43	79.21 \pm 0.98
	1 Month	235.1 \pm 0.75	-22.57 \pm 0.82	79.03 \pm 0.37
	2 nd Month	236.8 \pm 0.18	-22.04 \pm 2.10	78.25 \pm 0.42
	3 rd Month	237.2 \pm 1.62	-21.28 \pm 1.58	78.06 \pm 2.07

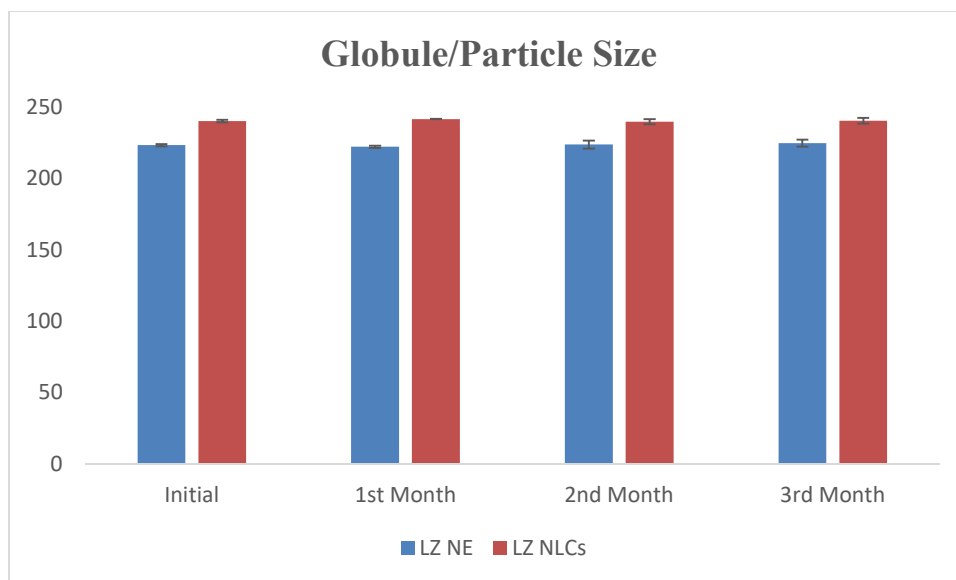


Figure 9.1: Effect on globule/particle size of Luciconazole formulations during stability studies

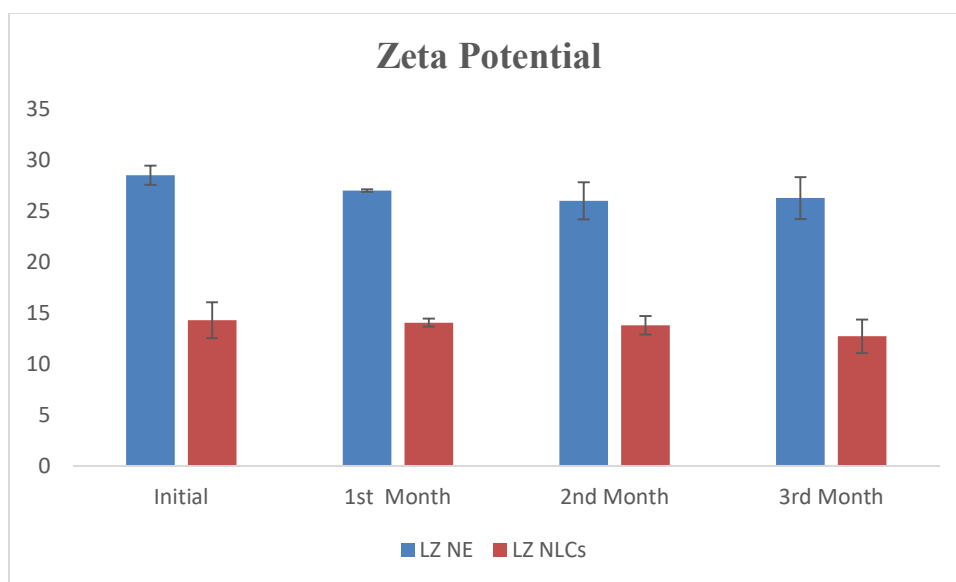


Figure 9.2: Effect on zeta potential of Luciconazole formulations during stability studies

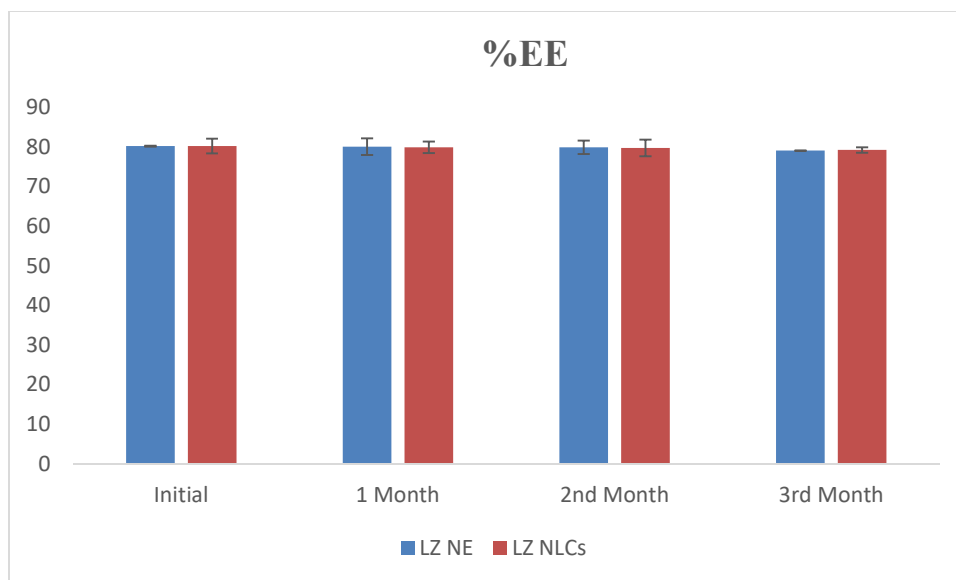


Figure 9.3: Effect on %EE of Luliconazole formulations during stability studies

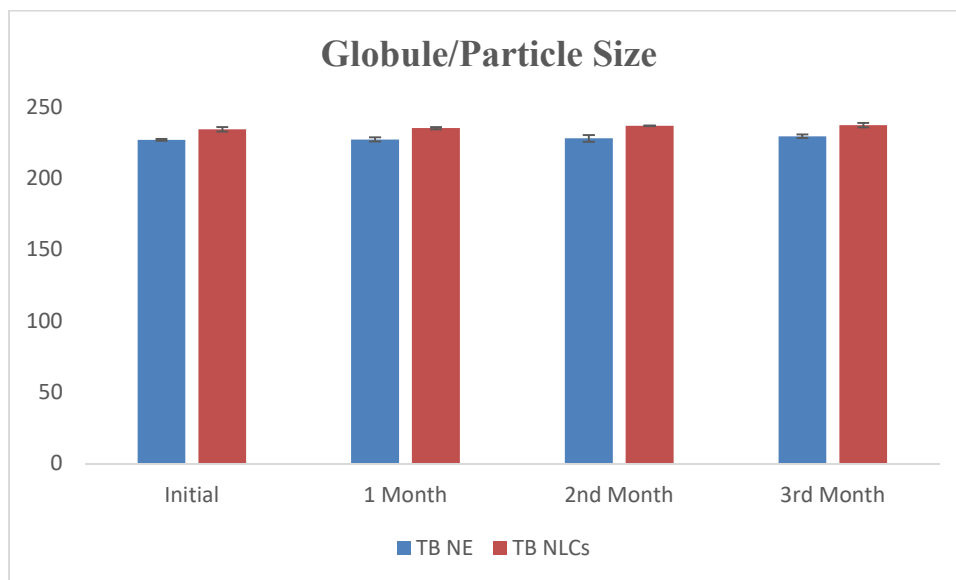


Figure 9.4: Effect on globule/particle size of Tavaborole formulations during stability studies

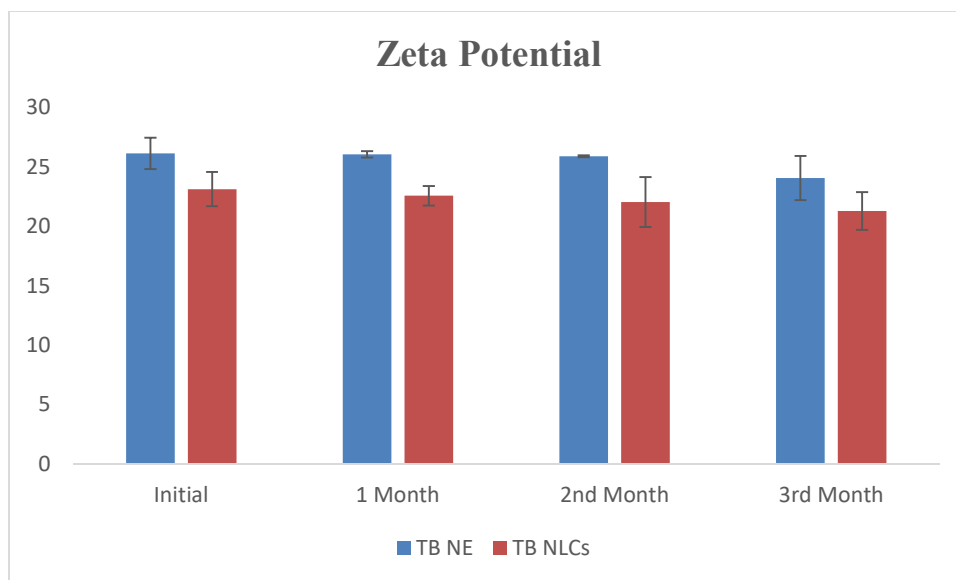


Figure 9.5: Effect on zeta potential of Tavaborole formulations during stability studies

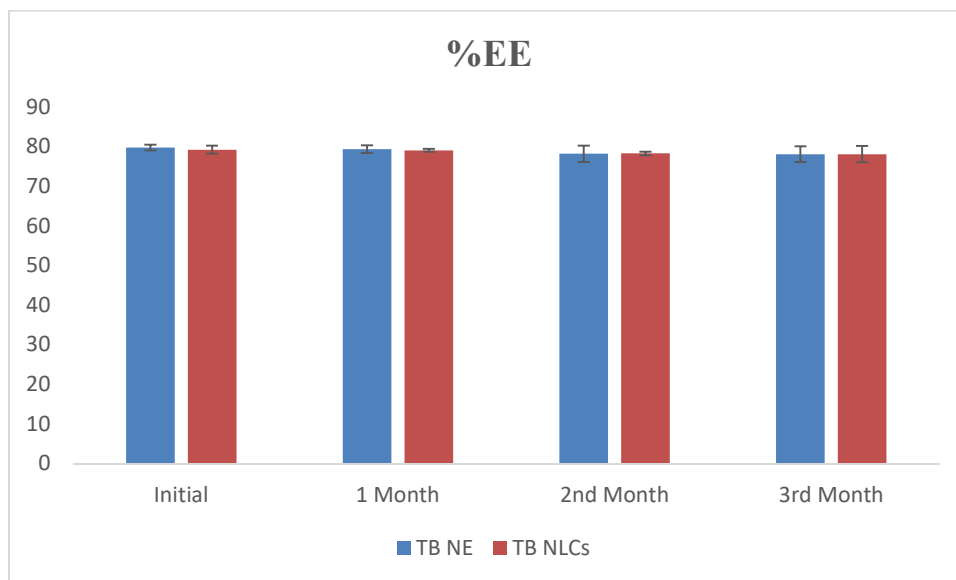


Figure 9.6: Effect on %EE of Tavaborole formulations during stability studies

Stability study outcomes revealed minor changes, including a marginal increase in vesicle/particle size and a slight reduction in zeta potential and entrapment efficiency percentages. Despite these variations, the measurements remained within the acceptable limits, demonstrating the formulations' stability over the three-month period.

9.5 References:

1. Guideline, I. H. T. "Stability testing of new drug substances and products." *QIA (R2), current step* 4.1-24 (2003).
2. Nagaraja, Sreeharsha, et al. "Topical nanoemulsion based gel for the treatment of skin cancer: Proof-of-technology." *Pharmaceutics* 13.6 (2021): 902.
3. Nagaich, Upendra, and Neha Gulati. "Nanostructured lipid carriers (NLC) based controlled release topical gel of clobetasol propionate: design and in vivo characterization." *Drug delivery and translational research* 6 (2016): 289-298.
4. Rabima, Rabima, and Metri Purnama Sari. "Entrapment efficiency and drug loading of curcumin nanostructured lipid carrier (NLC) formula." *Pharmaciana* 9.2 (2019): 299-306.