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10.1. INTRODUCTION

Stability of pharmaceutical product is critical to product quality and needs to be thoroughly investigated to recommend an appropriate storage condition and to establish the shelf-life. These studies commonly involve evaluation of any change in products' critical quality attributes with respect to time when exposed to different environmental conditions such as of temperature, relative humidity and light [1]. ICH Q1A (R2) and Q1C provides guidance for stability testing of new drug products and new dosage forms, respectively [2].

10.2. MATERIALS & METHODS

10.2.1 Materials

VPN UDL MNP, NPT UDL MNP, VPN PNP MNP, NPT PNP MNP were developed and characterized in-house. Sorbipak (Silica gel sachets) was purchased from Sorbead India. Calcium oxide was purchased from LobaChemie Pvt. Ltd., India. Double distilled water was prepared in lab, filtered through 0.2μ membrane filter in glass bottle and consumed within a maximum of 7 days.

10.2.2 Short term stability study of nanocarriers loaded MNP

Short term stability of all four nanocarriers loaded fast dissolving MNP was studied at 30±2 °C/65±5 %RH for three months. Axial needle fracture force of MNP together with particle/vesicle size of loaded nanocarriers and drug retained within nanocarriers were considered critical and therefore selected as stability indicating characteristics of nanocarriers loaded MNP. Patches were hermetically packed in airtight containers along with silica gel and calcium oxide as desiccant. These containers were stored in stability chamber operating at 30±2 °C/65±5

%RH for three months. Samples were withdrawn every month and evaluated for critical stability indicating parameters using the methods described earlier in this chapter.

10.3. RESULTS & DISCUSSION

10.3.1 Short term stability study

The ANFF, vesicle/particle size and percent drug retained data of samples stored for up to three months are summarized in **Table 10-1**.

Table 10-1. Three months' stability data of nanocarriers loaded MNP

Formulation	Time (months)	ANFF (N)*	Vesicle / Particle size (nm)*	Drug Retained (%)*
VPN UDL MNP	Initial	0.686 ± 0.03	76.27 ± 2.52	86.60 ± 1.86
	1M	0.681 ± 0.05	77.85 ± 2.47	85.94 ± 2.16
	2M	0.673 ± 0.03	79.42 ± 2.25	85.27 ± 1.97
	3M	0.667 ± 0.04	82.46 ± 2.73	84.18 ± 1.84
NPT UDL MNP	Initial	0.688 ± 0.05	68.15 ± 3.04	82.09 ± 1.39
	1M	0.684 ±0.05	73.72 ± 2.86	81.54 ± 1.53
	2M	0.680 ± 0.04	79.28 ± 2.94	80.78 ± 1.76
	3M	0.674 ± 0.03	84.61 ± 2.88	80.26 ± 1.64
VPN PNP MNP	Initial	0.711 ± 0.05	103.91 ± 3.05	71.22 ± 1.49
	1M	0.709 ±0.06	104.43 ± 2.92	71.05 ± 1.38
	2M	0.706 ±0.03	105.75 ± 3.11	70.48 ± 1.74
	3M	0.702 ±0.05	107.35 ± 3.17	70.23 ± 1.58
NPT PNP MNP	Initial	0.704 ± 0.06	81.31 ± 2.44	69.79 ± 1.56
	1M	0.699 ±0.05	83.04 ± 2.61	69.58 ± 1.57
	2M	0.698 ±0.06	84.81 ± 2.37	68.96 ± 1.49
	3M	0.693 ±0.03	86.73 ± 3.04	68.38± 1.66

* Values represented as mean ± SD

On storage, ANFF was slightly decreased in all four formulations. Similarly, a slight increase in vesicle/particle size as well as a slight decrease in drug retained was evident on storage in all four formulations. However, the values observed after three months were found within desirable limits required for formulations to perform effectively. Such observation at intermediate temperature and high relative humidity could be attributed to the solid physical form of MNP and their effective packaging.

REFERENCES

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