A NOVEL FILM COATING FORMULATION TO MINIMIZE COLOUR FADING

1.0 INTRODUCTION

It is common practice within the pharmaceutical industry to enhance the aesthetic appearance of dosage forms by using suitably colored film coatings [1]. Colored coatings increase patient acceptability and compliance, improve safety via easy identification and differentiation and may reduce degradation via increased opacity to light. Indigo Carmine (FD & C Blue #2) or Indigotine is approved in US and European Markets to be used as a colorant in oral and topical preparations. It is known to have good heat stability but poor stability to light and oxidizing agents. Thus formulations containing Indigo Carmine tend to fade with time.
Co-povidone is a one of the polymers which has been used to reduce colour fading issues in film coating systems [2].

2.0 PURPOSE

The objective of this study was to investigate the color stability, tested under different storage conditions, of tablets that were coated with HPMC and HPMC/ Copovidone coating formulations containing indigo carmine.

3.0 EXPERIMENTAL WORK

3.1 Coating formulation preparation

To investigate colour stability differences, HPMC-PEG based and HPMC-Copovidone based coating systems were prepared. Both formulations contained the same concentrations of Indigo Carmine. Laboratory scale mixers were used to prepare the coating formulations. The ingredients were added and blended together in the mixer until uniform powder blends were obtained.

3.2 Evaluation of Dry Powders

The powders were evaluated visually and samples were retained for stability studies packed in HDPE bottles at different conditions i.e. Ambient (25^0C± 2^0C/60% RH±5%) and Accelerated stability conditions (40^0C± 2^0C / 75% RH RH±5%) to evaluate the colour fading tendency.

3.3 Coating suspension preparation and tablet coating

The coating suspensions were prepared using a laboratory scale stirrer. Plain placebo tablets were coated using these suspensions in a 6 inch conventional coating pan with pre-determined coating parameters.

3.4 Evaluation of coated tablets and stability studies

Coated tablets were evaluated for appearance, colour uniformity, colour difference, disintegration time and coating defects. Tablets coated with both formulations were packed in polyethylene bags within HDPE bottles (screw capped). These were stored for stability studies at the following conditions:

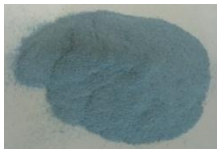
i. Ambient (25ºC± 2ºC/60% RH±5%)
ii. Accelerated (40ºC± 2ºC / 75% RH ±5%)

Open dish samples were exposed to ambient conditions. The tablets were evaluated for appearance and colour difference. Color difference was checked using a Reflectance Spectrophotometer. The dE values were measured over a 6 month period to evaluate colour fading over time.

4.0 RESULTS AND DISCUSSION

The HPMC-PEG and HPMC-Copovidone based formulations were prepared using a laboratory scale mixer. The plain placebo tablets were coated with both the formulations using the standard coating process parameters recommended for a HPMC based coating formulation. The coated tablets were evaluated for physical characteristics and found comparable. All samples stored under all conditions showed some color fading with time as shown in the photographs at Table No. 1,

Table No.1

Conditions	HPMC-PEG	HPMC-Copovidone	HPMC-PEG	HPMC-Copovidone
Initial				
After 6 months				
Open dish (Ambient)				
Ambient				
Accelerated (40ºC/75%RH)				

Colour differences between coated tablets stored under ambient and accelerated conditions for different time periods were measured using the Reflectance Spectrophotometer and expressed in terms of total colour difference (dE) with respect to initial samples. Copovidone based formulations exhibited good color stability at all the stability conditions as compared to other HPMC based formulation.

5.0 CONCLUSION

From the findings of this study, color fading was reduced with HPMC/Copovidone coating formulations compared with a standard HPMC based coating system. It is suggested that product stability may be improved by including copovidone in the coating formulations.

6.0 REFERENCES

1.Colorants-The Cosmetics for the Pharmaceutical Dosage Forms, Krishna Vamshi Allam, Gannu Praveen Kumar, *Int J Pharm Pharm Sci,* Vol 3, Suppl 3, 2011, Pg.No.13-21.

2.Moroni A.*et.al*, Pharmaceutical Tablet Coating Composition, US Patent 20040001884A1, January 1 2014.