Evaluation of Kollicoat® SR 30D as a sustained release polymer dispersion

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Abstract

Kollicoat SR 30D is a sustained release polymer dispersion used in the pharmaceutical industry. This study evaluates the effects of spray rate, inlet temperature, and air velocity on the granulation and coating process of a selected drug using a factorial design. The results of the evaluation studies prove the effectiveness of Kollicoat SR 30D as a sustained release polymer dispersion for sustained release formulation. In addition to the evaluation process, optimization of process variables is paramount to achieve a successful sustained release preparation.

Introduction

Evaluation of new polymers is crucial for development of novel sustained release formulations. In addition, the suitability of a polymer as a sustained release material is determined by its properties such as spray rate, air temperature and inlet air velocity. Statistical model selected was General Linear Model:

\[ \text{yield versus Spray rate, Inlet temp and Air velo} \]

Objective

The objective of this study is to evaluate the sustained release of Ibuprofen SR 30D as a sustained release polymer dispersion for the driven classes of novel pharmaceutical formulations. The use of similar scale-up procedures (specifically, scale-down testing and scale-up trials, cGMP compliant), characterization of polymer by dilution process optimization of process variables, establishment of the most effective process parameters and process conditions are critical to the large-scale manufacturing of the drug.

Background

Kollicoat SR 30D (BASF) is a hydroxypropyl methyl cellulose (HPMC) polymer (Methocel E5 Prem LV) stabilized by polyvinyl pyrrolidone and sodium lauryl sulfate \{PVA = 27%, PVP = 2.7% and SLS = 0.3% (solids 30% w/w)\}. The GPCG-1 Fluid Bed Dryer/Granulator (GLATT Inc.) and Hanson Dissolution Tester, Shimadzu UV 160 analyze the samples for dissolution studies. The results of the evaluation studies prove the effectiveness of Kollicoat SR 30D as a sustained release polymer dispersion for sustained release formulation.

Results and Discussion

The results and discussion showed that the factors involved in granulation, the air velocity and the spray rate are the most effective on the granulated and coated particles. The ANOVA table showed all three factors had significant effect on the granulation and coating process of the selected drug. Statistical model selected was General Linear Model: yield versus Spray rate, Inlet temp and Air velo. It was seen that more than 90% of the granules were retained on a No. 10 screen. In the case of Ibuprofen granules which were coated by top spray method in the fluid bed coater, total polymer content of 45 g/m² is required to produce a sustained release coating dispersion. The evaluation studies prove the effectiveness of Kollicoat SR 30D as a sustained release polymer dispersion for sustained release formulation. In addition to the evaluation process, optimization of process variables is paramount to achieve a successful sustained release preparation.

Sustained release studies of Kollicoat SR 30D coating:

Materials:

Kollicoat SR 30D (BASF), HPMC (Methocel E5 Prem LV) (Dow Chemical), Talc (BASF), Ibuprofen (BASF), HPMC (Methocel E5 Prem LV), and Polyvinylpyrrolidone.

Apparatus:

DPS-2 (BASF) Fluid Bed Dryer/Granulator (GLATT Inc.), Hanson Dissolution Tester, Shimadzu UV 160.

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Apparatus:

DPS-2 (BASF) Fluid Bed Dryer/Granulator (GLATT Inc.), Hanson Dissolution Tester, Shimadzu UV 160.

References:


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