Application of Silicified Microcrystalline Cellulose in the formulation of Metronidazole Tablets

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Abstract

The influence of Silicified Microcystalline Cellulose on the powder, compaction and tableting properties of metronidazole was investigated. The study employed a medium grade of Silicifed Microcystalline Cellulose, commercially available as Prosolv SMCC$^{(R)}$ 90. Prosolv is a product, which resulted from co-processing of Microcrystalline Cellulose with colloidal Silicon dioxide. A similar grade of regular Microcystalline Cellulose (Emcocel) was used as reference. The bulk densities, Hausner quotient (H_f), Compressibility Index (CI) and angle of repose of formulations containing the drug and polymers were evaluated. Compacts of the amoebicidal drug, containing different concentrations of Prosolv or Emcocel within the range of 10 to 30 % w/w were made at compression forces between 20 to 30 KN. The compression and friability profiles of the compacts were evaluated.

The flow behaviour of the Drug:Prosolv mixtures was improved, with increase in poured bulk density of the drug, while angle of repose and compressibility index parameters decreased. Metronidazole formulations containing 25 % w/w of Prosolv had lower CI and H_f values than those made with 30 % w/w Emcocel. The crushing strength of the compacts increased with concentration of the polymers at all the compression forces used. At similar concentrations of the polymers, compacts of the formulations containing Prosolv exhibited higher crushing strength at the same compression pressure. Compacts of metronidzole containing 20 to 25 % of Prosolv exhibited disintegration and friability profiles comparable to those made with 30 % Emcocel. Prosolv may serve as a first choice excipient in direct compression formulation of metronidazole tablets, especially from mechanical and economic viewpoints.

Effect of moisture content of a herbal extract on the performance of SMCC as a direct compression agent.

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SMCC® 50 and 90 are widely used as direct compression agents in tablet formulation. This makes them quite useful in the formulation of tablets from herbal extracts since in some cases neither the chemical nature nor the interaction characteristics of the extract are well known, thus making direct compression with its use of few additives an attractive option. Herbal extracts however have relatively higher moisture content than synthetic drugs. This study investigates the effect of high drug moisture content on the direct compression properties of SMCC 50 and 90.

The moisture content of the freeze-dried hot water extract of NIPRISAN®, a herbal remedy used in the management of sickle cell anemia (1) was determined. Three moisture levels were then simulated by exposure to a saturated solution of Potassium nitrate for varying lengths of time. SMCC 50 and 90 respectively were then mixed with the extract and compressed at 4 compression levels. The hardness, friability and disintegration and dissolution times of the tablets were determined.

The results indicate that the untreated extract had relatively high moisture content of 14.2%. The physical strength (hardness and friability) of the tablets decreased with increased moisture content of the extract; while the release properties (disintegration and dissolution) improved at all the compression pressures used when compared with tablets of SMCC 50 and 90. It was also observed that at the lower compression pressures (21 and 25KN) tablets of unsuitable physical strength were obtained at all moisture levels. Increasing the compression pressure from 28KN to 30KN resulted in a dramatic increase in hardness.

It could be deduced from the results that SMCC 50 and 90 can both be used in the direct compression of the freeze dried extract of NIPRISAN. However, moisture content of not more than 16.2% and a compression pressure of at least 10units should be used to obtain suitable tablets.

Reference

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