

the optimal formulation of ointment, the active substances have been incorporated into various excipients, of different nature. So it was investigated four compositions containing emulsion-type ointment bases O/W and W/O. It was established the manufacturing technology flow of the ointment. To select the optimal composition that would allow an effective therapeutic action and minimal side effects, first of all it was elaborated the optimal extraction method and after that it was used the dosage of active substances from the extract by UV-VIS spectrometry methods. So, it was analyzed the extraction with solution of 0.1% sodium hydroxide, dimethylformamide and the mixture: solution of 0.1% sodium hydroxide and dimethylformamide (1:3). It was recorded the absorption spectra in the region 250nm-450nm in the case of extraction with solution of 0.1% sodium hydroxide, 250-400nm in the case of extraction with dimethylformamide and 250-450nm in case of extraction with the mixture. Conclusions: 1. IZOHIDRAFURAL and METHYLURACIL have been incorporated into different excipients. As a result, it was investigated four compositions containing emulsion-type ointment bases O/W and W/O; 2. It was selected the optimal manufacturing technology for the compositions; 3. It was elaborated the extraction with solution of 0.1% sodium hydroxide, dimethylformamide and the mixture of these two substances; 4. It was concluded that the optimal extraction method is with dimethylformamide.

Robustness Testing of a Modified-Release Tablet Formulation Comprising Metformin and Glibenclamide

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It was recently ascertained that sulphonylureas and biguanides synergistically act for the control of blood glucose levels in patients with type II diabetes, by different pharmacological mechanisms. The aim of this study is to design a modified release formulation comprising metformin hydrochloride and glibenclamide, where one drug does not affect the release of the other drug. Due to a relatively high unit dose of metformin, the tablets should be size fitted for oral administration and should ensure the controlled release of the two active ingredients. Taking into consideration the poor flowability of metformin hydrochloride, in order to attain dose uniformity, a wet granulation manufacturing process was used. Glibenclamide was geometrically dispersed into the granules of metformin. The mixture was blended with soluble filler, a hydrophilic polymer, a disintegrant and a lubricant. The hydrophilic polymer used was: hydroxypropylcellulose (Klucel® HF, HXF) and hydroxymethylpropylcellulose (Methocel® K100 LV CR, K4M and E4M). The matrix tablets were evaluated for their robustness: hardness, friability, thickness, and weight variation and disintegration time. It was concluded that satisfactory robustness profiles can be achieved using all types of hydrophilic polymers, by wet granulation of the major active ingredient, followed by a direct compression into a modified release matrix. Keywords: metformin hydrochloride, glibenclamide, diabetes, formulation, matrix tablets.