Studi literatur dan pengembangan formula sediaan drop suplemen zat besi = Literature study and formula development of iron supplement drops

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Abstrak

PT. Indofarma Tbk sebagai salah satu industri produsen produk obat di Indonesia pada hal ini mengembangkan ide dan gagasannya dengan membuat sediaan produk suplemen zat besi untuk anak-anak dalam bentuk sediaan drop. Pada pengembangan formula sediaan yang dibuat ditemukan masih adanya kendala pada kelarutan zat aktif sediaan yang digunakan yaitu Sodium Feredetate. Hal ini mendorong adanya studi literatur lebih jauh serta pengembangan formula yang dilakukan untuk mencapai hasil formula sediaan drop suplemen zat besi yang stabil dan memenuhi standar spesifikasi. Metode penelitian dibagi 3 tahap yaitu studi literatur, pembuatan dan trial formula skala laboratorium, evaluasi sediaan berupa pengamatan stabilitas fisik sediaan setelah 24 jam. Hasil percobaan menunjukkan kelarutan zat aktif Sodium Feredetate dalam formula sediaan drop suplemen zat besi masih belum dapat diatasi dimana dengan penambahan konsentrasi asam sitrat dalam rancangan formula belum mampu mengatasi masalah kelarutan dalam rancangan formula sediaan. Asam askorbat berpengaruh membantu zat aktif sodium feredetate dalam formula sediaan terlarut, namun kestabilan fisiknya tidak terpenuhi. Tween 80 sebagai surfaktan dalan formula uji tidak berpengaruh signifikan terhadap hasil sediaan yang didapat. Modifikasi prosedur pengerjaan berupa pemanasan suhu 50-60°C mampu membantu zat aktif larut, namun stabilitas fisiknya tidak terjaga saat penyimpanan ± 24 jam. Pada rentang suhu 70-80°C sediaan mengental dan menimbulkan endapan baru.

..... PT. Indofarma Tbk, as one of the industrial drug product manufacturers in Indonesia, is developing its ideas and thoughts by making iron supplement products for children in drop form. In the development of the formulation of the preparation made, it was found that there were still problems with the solubility of the active substance of the preparation used, namely Sodium Feredetate. This prompted further literature studies and formula development to achieve stable iron supplement drop formulas that met specification standards. The research method was divided into 3 stages: literature study, preparation & trial of a laboratory scale formula and evaluation of the preparation in the form of observing the physical stability of the preparation after 24 hours. The experimental results showed that the solubility of the active substance Sodium Feredetate in the iron supplement drop preparation formula still could not be resolved, whereas adding the concentration of citric acid in the formula design was not able to overcome the solubility problem in the preparation formula design. Ascorbic acid has a helpful effect on the active substance sodium feredetate in the soluble preparation formula, but its physical stability is not met. Tween 80 as a surfactant in the test formula did not have a significant effect on the results obtained. Modification of the working procedure in the form of heating to a temperature of 50-60°C can help the active substance dissolve, but its physical stability is not maintained when stored for ± 24 hours. In the temperature range of 70-80°C the preparation thickens and creates new sediment.