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FORMULATION AND EVALUATION OF IBUPROFEN PERORAL SUSPENSION 100 mg/5 ml

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Abstract

Ibuprofen is a widely used medicine from the group of non-steroidal anti-inflammatory drugs (NSAIDs) and its development. The development of Ibuprofen oral suspension was in accordance with the requirements
prescribed in possesses analgesic, antipyretic and anti-inflammatory properties. Based on the market analysis, the
properties of the active substance and the intention to cover a pediatric group of patients as a product for
development, an oral suspension was chosen. Due to their thermodynamic instability, formulating a stable
suspension is a complex process followed by many challenges during the ICH Q8 guideline for pharmaceutical
development.
In order to understand the problem of suspensions, as well as to enable easier facing of the challenges during its
development, already in the early phase of the pre-formulation research, risk-based analyzes of changing variables
and process parameters were made on the defined critical characteristics of the product. The realization of the
experiments and all the tests required for the purpose of this paper were carried out in the laboratory

premises of the
pharmaceutical company GALAFARM DOO, Skopje, Republic of North Macedonia.
The aim of this paper is the development of a liquid dosage form – a suspension for oral administration, which will
ensure the appropriate release of the prescribed dose of the active substance in the human body. At the same time, it
will meet the prescribed requirements according to the appearance, viscosity, color, smell and taste to be acceptable
to the target group of patients - children from 3 months to 12 years, as well as chemical and physical characteristics
and to ensure the stability of the active substance. For this purpose, four formulations of Ibuprofen oral suspension
100 mg /5 ml were made where the main variables were the suspending agents/viscosity adjustment. The anionic
surfactant polysorbate 80 was also taken as a variable, which is of crucial importance, primarily because it is a class
II active substance according to the biopharmaceutical classification of drugs. The samples were evaluated
according to the appropriate tests prescribed in the current editions of the European Pharmacopoeia [PhEur.], the
British Pharmacopoeia [BP] and the United States Pharmacopoeia [USP], and some of the parameters were also
tested according to the company's internal methods. From the tested formulations, only with formulation 2, 3 and 4
were obtained results that satisfy the requirements prescribed in the quality specification for Ibuprofen oral
suspension 100 mg/5 ml, but the most acceptable organoleptic characteristics, appearance, consistency and taste
were achieved by formulation 3, which was chosen for further and additional investigations.

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