STANDARDISATION OF NEW EYE DROPS BASED ON POLYSACCHARIDES OF ALOE

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Introduction. The development and expansion of the range of Ukrainian ophthalmic products, in particular, eye drops with a multivalent effect based on polysaccharides of Aloe, is of current interest and relevance. Acemannan is a polysaccharide that is contained in aloe plants. It has anti-inflammatory, antibacterial, antifungal, antioxidant, and neuroprotective effects, and activates the immune response, thus providing antiviral and antitumour activity, etc (Sierra-García G.D.et al, 2014; Mukherjee P. K. et al, 2014; Chang Liu et al, 2019; Hęś M. et al, 2019).

The development of eye drops based on the polysaccharides of aloe, which to a certain extent determine the high biological activity of the plant, requires a reliable and efficient method of standardisation following the requirements of Good Practice, verification, validation and justification of the manufacturing process.

Purpose. To develop the standardisation of new eye drops based on polysaccharides of Aloe (Aloe arborescens) in order to study the ophthalmic safety and specific activity of the new drug.

Material and methods. The study included pharmacological, chemical, physicochemical**,** pharmacognostic, pharmaco-technological, mathematical methods using an SF-46 spectrophotometer, an AXIS BTU210 analytical balance, centrifuge Opn-8UHL4.2, chamber and plates for thin-layer chromatography "Sorbfil" PTSH-AF-V, Hamilton microsyringe 10.0 μl, software Spekwin 32, Qplot, ImageJ, Graph Digitizer, Plot Digitizer.

Results. The methods for determining the amount of acemannan, which is the main indicator of standardisation for new ophthalmic eye drops based on Aloe, were compared. The method of quantitative determination by dehydration of polysaccharides to hydroxymethylfurfural followed by spectrophotometric measurement at 490 nm was shown to have a sensitivity of 60 μg/ml to 120 μg/ml and to allow the introduction to the formula of a complex molar coefficient for converting standard monosaccharides (mannose and/or glucose) into acetylated aloe glucomannans. The introduction of a polycomponent molar coefficient will

improve the determination of the quantitative content of bioactive aloe polymers in the ready-to-use product.

It was shown that the thin-layer chromatography method improved by the software calculation of the amount and retention factor (Rf) may complicate the interpretation of routine analysis results, although being more informative for scientific research of a new drug.

The number of polysaccharides converted into acemannan is rationally carried out in the 1:4 ratio of aqueous extraction to ethyl alcohol. In this case, the experimental procedure for obtaining the number of polysaccharides is as close as possible to the analytical value recommended by the International Aloe Science Council (≥ 5 %).

Conclusions. A standard operating procedure was created for the analysis of plant raw materials as well as research samples of substance and ready-to-use product, which allows unifying quality analysis in the laboratory and predicting the potential pharmacotherapeutic activity of research samples, source materials and plant raw materials at the initial stages of new drug development.

Key words: aloe, tissue therapy preparations for ophthalmology, analytical methods to determine polysaccharides, acemannan, standardisation of plant raw materials