METHODS ANALYSIS OF PRESERVATIVES

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Introduction. Pharmaceutical preparations which need an aqueous vehicle such as eye drops are particularly susceptible to microbial growth because of the nature of their ingredients. That's why require safeguards from microbial contamination, which may affect product stability or infect the consumers. This is accomplished by the addition of anti-microbial agents in the formulation to destroy and inhibits the growth of those organisms that may contaminate the product during manufacture or use. There are several antimicrobial preservatives used in ocular preparations that may be classified as follows: quaternary ammoniums (Benzalkonium chloride); mercurials (Thimerosal); alcohols (Chlorobutanol, Benzyl alcohol); carboxylic acid (Sorbic acid); phenols (Methylparaben, Propylparaben); amidines (Chlorhexadine).

Aim. Methylparaben (Nipagine) and Propylparaben (Nipasol) are commonly used as preservatives in eye drops. These p-hydroxybenzoic acid esters are most commonly used to control bacterial growth due to their broad antimicrobial spectrum with good stability. Their typical allowed concentrations range from 0.1 to 0.2%.

Materials and methods. Nipagine enters in eye drops, such as "Taufone-Darnitsa" ("Pharmaceutical firm "Darnitsa" CJSC, Ukraine), "Pilocarpine hydrochloride" ("GNTSLS" PP, Ukraine), "Ocoferon" ("BioFarma" PP, Ukraine), "Fenistil, eye drops" ("Novartis Consumer Health" S.A., Switzerland), "Sanorine" ("IVAX", Czech Republic). Combination Nipagine with Nipasol includes in ocular drops "Oftanal" (PP "GNTSLS", Ukraine) and "Quinax" ("Alcon-Couvreur", USA).

Results and discussion. There are official monographs of Propylparaben and Methylparaben in leading world pharmacopoeias. *Monographs content "Identification" by Infrared spectroscopy and melting range of temperature, "Assay" and "Related impurities" by* liquid chromatography. Assay Propylparaben and Methylparaben in second edition of the Ukrainian Pharmacopoeia by titrimetric method analysis. But weight of sample is about 1.0 g, that is too much, that why we propose verificate liquid chromatography method, that will be apply to control substances and develop for assay parabens in eye drops a spectrophotometric method analysis, which is less weight as a substance, as well as time and available for pharmaceutical companies.

Conclusions. The purpose of this study is to incoming goods inspection and quality control of substance for quality assurance purposes finished drugs as well as for patient safety.