

2013-14

WINNER

Rajnibhai V. Patel

**PharmInnova
Award**

Best M. Pharm Thesis

Runner-Up



Ms. Rasika Nikhade

Research Guide



Mrs. Shilpa Deshpande

Subject:
Quality Assurance

Thesis Title :
Formulation Evaluation & validation of ophthalmic emulsion of Docosahexaenoic acid

College:
Sharad Pawar College of Pharmacy, Nagpur

Novel fish oil formulation for Dry Eye Syndrome

Outcome of Research:

Dry Eye Syndrome (DES a condition due to lack of lubrication and moisture) is a common problem in the eye, secondary to enormous usage of information technology, exposure to dust, allergens, dry climate, hormonal imbalance and use of contact lenses. The study involved the formulation, evaluation and validation of ophthalmic oil in water emulsion of docosahexaenoic acid (DHA) for the treatment of DES. DHA was isolated from fish oil by column chromatography and confirmed by gas chromatography. The emulsion was examined for stability for 3 months. Significant anti-inflammatory effect, increased tear secretion and less irritancy was noticed on testing the product in experimental rats.

Thesis Title: Formulation Evaluation and Validation of Ophthalmic Emulsion of Docosahexaenoic Acid

ABSTRACT

The present study of the thesis is aimed at the formulation, evaluation and validation of ophthalmic emulsion of Docosahexaenoic Acid (DHA) for the treatment of dry eye syndrome. Dry eye syndrome (DES) is a chronic lack of sufficient lubrication and moisture on the ocular surface of the eye that typically develops from deficiencies of one or more components of the biologically complex pre-ocular tear film. When DHA is administered in capsule dosage form less amount of drug reaches the site of inflammation in the eye hence more dose is required, still inflammation is at risk. Hence, for the direct application of DHA to the eye it can be prepared in the form of ophthalmic dosage form. Preparation of oil-in-water (o/w) type emulsion is one of the approaches to formulate drugs that are poorly water-soluble. As the fish oil is the richest source of DHA it was isolated from fish oil. The isolated compound was identified by thin layer chromatography and gas chromatography. From the gas chromatography analysis it was found that retention time of isolated oil and standard DHA was at 5.73 and 5.01 respectively. The percentage purity of isolated compound was found out to be 95.21%. The oil in water emulsion was formulated containing 3% DHA oil, 1% tween 80 and 0.5% span 80. The appearance of the emulsion was milky white, the median particle size was 0.4 μm , viscosity was 30 cp. The emulsion was stable at 25°C and 40°C for more than 3 months. Furthermore, the formulated emulsion was validated for the same physical properties which are previously evaluated. The analysis of DHA in the emulsion was done by gas chromatography. The percentage purity of DHA in formulation was found to be 87.82%. The anti-inflammatory, tear secretion (Schirmer's test) and eye irritation studies of the formulated emulsion were performed on rats and it showed significant anti-inflammatory activity, increased tear secretion and less irritancy to eyes and hence the formulated DHA emulsion can be beneficial for the treatment of dry eye syndrome.