Supplementary File A

Exclusion criteria:

1. Patients who had an established daily routine of using their artificial tear drop in either eye for ≥1 week prior to the screening visit.

2. Patients who used the provided artificial teardrops routinely during the run-in phase.

3. Patients who had ever used artificial tears, in either eye, >4 times a day within 1 year prior to the screening visit.

4. Patients who used the provided assigned artificial tears, >4 times a day on any day during the run-in phase, in either eye.

5. Patients who had a change in TOSS score of ≥3 or IDEEL symptom-bother score of ≥10 between the screening and baseline visits (end of run-in phase), in either eye.

6. Used any topical ocular medication preserved with benzalkonium chloride, in either eye, within 3 months prior to the screening visit.

7. Best corrected visual acuity of 55 or lower in both eyes, as measured by ETDRS chart at the screening visit.

8. Women of childbearing potential (those who were not surgically sterilized or postmenopausal for ≥2 years) were excluded from participating in the study if they met any of the following conditions:

   • They were currently pregnant

   • They had a positive result on a pregnancy test at the screening visit

   • They were breastfeeding
• They planned to get pregnant during the study

• They were not in agreement to use adequate birth control methods to prevent pregnancy throughout the study

9. Any hypersensitivity to the use of the study product formulations or an allergy to any ingredient(s) contained within the product formulations.

10. Ocular abnormalities, in either eye, that could have adversely affected the safety or efficacy outcome such as:

• Eyelid anomalies that affected proper lid closure or proper blink function (for example, extropion or entropion)

• Corneal disorders or abnormalities such as active corneal ulcer, current corneal abrasion, keratoconus, or corneal dystrophies, which actively changed or affected vision

• Metaplasia of the ocular surface

• Current filamentous keratitis

• Evidence of corneal neovascularization

• Any history of Herpes Simplex or Herpes Zoster keratitis

11. Active ocular infection (bacterial, viral, or fungal) and active inflammation not associated with dry eye such as uveitis, iritis, active blepharitis, active allergic conjunctivitis, etc., in either eye.
12. Uncontrolled systemic disease. These conditions may have included, but were not limited to, unstable diabetes, thyroid disease, autoimmune disease, and poorly controlled hypertension.

13. Additional excluded diseases were clinically significant congestive heart failure, renal failure, hepatic dysfunction, previous cerebrovascular accident with a significant residual motor or sensory defect, progressive neurologic disorders (Parkinsonism, dementias, multiple sclerosis, unstable acquired seizure disorders, etc.).

14. Participated in an investigational drug or device trial within 30 days of entering the study at the screening visit.

15. Patients who were taking chronic systemic medications: (prescription, over-the-counter, vitamins/supplements), who had been on a stable dose for <30 days prior to the screening visit, and who had any anticipated change in dosing regimen during the course of the study.

16. Patients with a history, in either eye, of ocular or intraocular surgery or serious ocular trauma, within the past 6 months prior to the screening visit.

17. Patients who demonstrated any medical condition (systemic or ophthalmic) that may have, in the opinion of the investigator, precluded the safe administration of test article or safe participation in this study.

18. Punctal occlusion or diathermy, in either eye, initiated within 1 month prior to the screening visit.

19. Use of any topical ocular over-the-counter or prescribed medications (with the exception of artificial tears/gels/lubricants) 2 weeks prior to the screening visit.
20. Contact lens use within 2 weeks prior to the screening visit, and unwillingness to avoid contact lens use during the course of the study.

21. Unwillingness to avoid use of additional artificial tears (other than study treatment) throughout the study starting at the screening visit.