

Table 14.3.5.12 Slit lamp examination analysis for all groups - Safety set

	Visit	Eye	Categories	Overall	CHL 3% gel	Vehicle
Anterior Chamber Flare	Screening	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 2 - Pre-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 2 - Post-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Screening	Right	None	95 (99.0)	66 (98.5)	29 (100.0)
			Mild	1 (1.0)	1 (1.5)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 2 - Pre-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 2 - Post-dose	Right	None	95 (99.0)	66 (98.5)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	1 (1.0)	1 (1.5)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Screening	Right	None	95 (99.0)	67 (100.0)	28 (96.6)
			Mild	1 (1.0)	0 (0.0)	1 (3.4)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Visit 2 - Pre-dose	Right	None	95 (99.0)	67 (100.0)	28 (96.6)
			Mild	1 (1.0)	0 (0.0)	1 (3.4)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Visit 2 - Post-dose	Right	None	74 (77.1)	50 (74.6)	24 (82.8)
			Mild	19 (19.8)	14 (20.9)	5 (17.2)
			Moderate	3 (3.1)	3 (4.5)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)

Conjunctival Redness	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Screening	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 2 - Pre-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 2 - Post-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Screening	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 2 - Pre-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 2 - Post-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Screening	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 2 - Pre-dose	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 2 - Post-dose	Right	None	95 (99.0)	66 (98.5)	29 (100.0)
			Mild	1 (1.0)	1 (1.5)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)

			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 4 - Follow-up	Right	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Screening	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Anterior Chamber Flare	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Screening	Left	None	95 (99.0)	66 (98.5)	29 (100.0)
			Mild	1 (1.0)	1 (1.5)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Chemosis	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Screening	Left	None	95 (99.0)	67 (100.0)	28 (96.6)
			Mild	1 (1.0)	0 (0.0)	1 (3.4)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)

			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival Redness	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Screening	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Cornea	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Screening	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Redness	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Screening	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 2 - Pre-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 2 - Post-dose	Left	None	96 (100.0)	67 (100.0)	29 (100.0)

			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid Swelling	Visit 4 - Follow-up	Left	None	96 (100.0)	67 (100.0)	29 (100.0)
			Mild	0 (0.0)	0 (0.0)	0 (0.0)
			Moderate	0 (0.0)	0 (0.0)	0 (0.0)
			Severe	0 (0.0)	0 (0.0)	0 (0.0)

Notes: Subjects are summarized according to the product they actually received.

The number and the proportion of subjects for each parameter in each category are reported.

The denominator for calculating the proportions is the number of subjects in the safety set.