

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

	Visit	Eye	Categories	Overall	CHL 3% gel	Vehicle
<b>Anterior Chamber Flare</b>	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)
<b>Anterior Chamber Flare</b>	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)
<b>Anterior Chamber Flare</b>	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)
<b>Anterior Chamber Flare</b>	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)
<b>Conjunctival Chemosis</b>	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)
<b>Conjunctival Chemosis</b>	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)
<b>Conjunctival Chemosis</b>	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)
<b>Conjunctival Chemosis</b>	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)
<b>Conjunctival Redness</b>	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)
<b>Conjunctival Redness</b>	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)
<b>Conjunctival Redness</b>	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)

<b>Conjunctival Redness</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Swelling</b>	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)
<b>Eyelid Swelling</b>	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)
<b>Eyelid Swelling</b>	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)

<b>Eyelid Swelling</b>	Visit 4 - Follow-up	Right	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Anterior Chamber Flare</b>	Screening	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Anterior Chamber Flare</b>	Visit 2 - Pre-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Anterior Chamber Flare</b>	Visit 2 - Post-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Anterior Chamber Flare</b>	Visit 4 - Follow-up	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Chemosis</b>	Screening	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Chemosis</b>	Visit 2 - Pre-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Chemosis</b>	Visit 2 - Post-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Chemosis</b>	Visit 4 - Follow-up	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Redness</b>	Screening	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Redness</b>	Visit 2 - Pre-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Redness</b>	Visit 2 - Post-dose	Left	Severe	0 (0.0)	0 (0.0)	0 (0.0)
			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)
<b>Conjunctival Redness</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Cornea</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Redness</b>	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)
<b>Eyelid Swelling</b>	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)
<b>Eyelid Swelling</b>	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)
<b>Eyelid Swelling</b>	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)
<b>Eyelid Swelling</b>	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.