

Table 14.4.4.5  
Summary of Slit Lamp Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Orbit (Right Eye) Screening				
n	15	0	0	15
Normal	13/ 15 ( 86.7%)	0/ 0	0/ 0	13/ 15 ( 86.7%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
Orbit (Right Eye) Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	11/ 14 ( 78.6%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	2/ 5 ( 40.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	3/ 14 ( 21.4%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Orbit (Left Eye) Screening				
n	15	0	0	15
Normal	13/ 15 ( 86.7%)	0/ 0	0/ 0	13/ 15 ( 86.7%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
Orbit (Left Eye) Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	11/ 14 ( 78.6%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	2/ 5 ( 40.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	3/ 14 ( 21.4%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Eyelids (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
 Eyelids (Right Eye)				
Week 24				
n	5	3	6	14
Normal	4/ 5 ( 80.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	13/ 14 ( 92.9%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Eyelids (Left Eye)				
Screening				
n	15	0	0	15
Normal	14/ 15 ( 93.3%)	0/ 0	0/ 0	14/ 15 ( 93.3%)
Abnormal, NCS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
 Eyelids (Left Eye)				
Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	2/ 3 ( 66.7%)	6/ 6 (100.0%)	11/ 14 ( 78.6%)
Abnormal, NCS	2/ 5 ( 40.0%)	1/ 3 ( 33.3%)	0/ 6 ( 0.0%)	3/ 14 ( 21.4%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lashes (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Lashes (Right Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lashes (Left Eye) Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Lashes (Left Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	2/ 3 ( 66.7%)	6/ 6 (100.0%)	13/ 14 ( 92.9%)
Abnormal, NCS	0/ 5 ( 0.0%)	1/ 3 ( 33.3%)	0/ 6 ( 0.0%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lacrimal Glands (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Lacrimal Glands (Right Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Lacrimal Glands (Left Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Lacrimal Glands (Left Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Conjunctiva (Right Eye) Screening				
n	15	0	0	15
Normal	12/ 15 ( 80.0%)	0/ 0	0/ 0	12/ 15 ( 80.0%)
Abnormal, NCS	3/ 15 ( 20.0%)	0/ 0	0/ 0	3/ 15 ( 20.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Conjunctiva (Right Eye) Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	2/ 3 ( 66.7%)	5/ 6 ( 83.3%)	10/ 14 ( 71.4%)
Abnormal, NCS	2/ 5 ( 40.0%)	1/ 3 ( 33.3%)	1/ 6 ( 16.7%)	4/ 14 ( 28.6%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Conjunctiva (Left Eye) Screening				
n	15	0	0	15
Normal	13/ 15 ( 86.7%)	0/ 0	0/ 0	13/ 15 ( 86.7%)
Abnormal, NCS	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Conjunctiva (Left Eye) Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	11/ 14 ( 78.6%)
Abnormal, NCS	2/ 5 ( 40.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	3/ 14 ( 21.4%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Cornea (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Cornea (Right Eye)				
Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	11/ 14 ( 78.6%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Abnormal, CS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	1/ 14 ( 7.1%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Cornea (Left Eye) Screening				
n	15	0	0	15
Normal	14/ 15 ( 93.3%)	0/ 0	0/ 0	14/ 15 ( 93.3%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Cornea (Left Eye) Week 24				
n	5	3	6	14
Normal	3/ 5 ( 60.0%)	3/ 3 (100.0%)	4/ 6 ( 66.7%)	10/ 14 ( 71.4%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Abnormal, CS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Sclera (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Sclera (Right Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Sclera (Left Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Sclera (Left Eye)				
Week 24				
n	5	3	6	14
Normal	4/ 5 ( 80.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	13/ 14 ( 92.9%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Summary of Slit Lamp Examination  
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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Anterior Chamber (Right Eye)				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Anterior Chamber (Right Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Anterior Chamber (Left Eye)				
Screening				
n	15	0	0	15
Normal	14/ 15 ( 93.3%)	0/ 0	0/ 0	14/ 15 ( 93.3%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Anterior Chamber (Left Eye)				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	13/ 14 ( 92.9%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

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Summary of Slit Lamp Examination  
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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Iris (Right Eye) Screening				
n	15	0	0	15
Normal	14/ 15 ( 93.3%)	0/ 0	0/ 0	14/ 15 ( 93.3%)
Abnormal, NCS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
 Iris (Right Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	13/ 14 ( 92.9%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

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Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Iris (Left Eye) Screening				
n	15	0	0	15
Normal	13/ 15 ( 86.7%)	0/ 0	0/ 0	13/ 15 ( 86.7%)
Abnormal, NCS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Abnormal, CS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Iris (Left Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	4/ 6 ( 66.7%)	12/ 14 ( 85.7%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.6  
Summary of Visual Acuity Examination  
(Safety Analysis Set)

Eye Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Visual Acuity (Right Eye)				
Screening				
n	15	0	0	15
20/15	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
20/16	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
20/20	8/ 15 ( 53.3%)	0/ 0	0/ 0	8/ 15 ( 53.3%)
20/25	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
20/32	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
20/40	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
20/50	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
20/80	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
20/400	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Visual Acuity (Right Eye)				
Week 24				
n	5	3	6	14
20/15	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
20/16	1/ 5 ( 20.0%)	1/ 3 ( 33.3%)	2/ 6 ( 33.3%)	4/ 14 ( 28.6%)
20/20	3/ 5 ( 60.0%)	1/ 3 ( 33.3%)	1/ 6 ( 16.7%)	5/ 14 ( 35.7%)
20/25	1/ 5 ( 20.0%)	1/ 3 ( 33.3%)	0/ 6 ( 0.0%)	2/ 14 ( 14.3%)
20/32	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
20/40	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
20/50	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
20/80	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
20/400	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.  
Overall percentages are based on the total number of patients in the Safety Analysis Set.

Table 14.4.4.6  
Summary of Visual Acuity Examination  
(Safety Analysis Set)

Eye Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Visual Acuity (Left Eye)				
Screening				
n	14	0	0	14
20/15	1/ 14 ( 7.1%)	0/ 0	0/ 0	1/ 14 ( 7.1%)
20/16	3/ 14 ( 21.4%)	0/ 0	0/ 0	3/ 14 ( 21.4%)
20/20	6/ 14 ( 42.9%)	0/ 0	0/ 0	6/ 14 ( 42.9%)
20/25	2/ 14 ( 14.3%)	0/ 0	0/ 0	2/ 14 ( 14.3%)
20/32	0/ 14 ( 0.0%)	0/ 0	0/ 0	0/ 14 ( 0.0%)
20/40	0/ 14 ( 0.0%)	0/ 0	0/ 0	0/ 14 ( 0.0%)
20/50	0/ 14 ( 0.0%)	0/ 0	0/ 0	0/ 14 ( 0.0%)
20/80	1/ 14 ( 7.1%)	0/ 0	0/ 0	1/ 14 ( 7.1%)
20/400	1/ 14 ( 7.1%)	0/ 0	0/ 0	1/ 14 ( 7.1%)
Visual Acuity (Left Eye)				
Week 24				
n	5	3	5	13
20/15	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 5 ( 0.0%)	0/ 13 ( 0.0%)
20/16	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 5 ( 20.0%)	2/ 13 ( 15.4%)
20/20	1/ 5 ( 20.0%)	2/ 3 ( 66.7%)	3/ 5 ( 60.0%)	6/ 13 ( 46.2%)
20/25	2/ 5 ( 40.0%)	1/ 3 ( 33.3%)	0/ 5 ( 0.0%)	3/ 13 ( 23.1%)
20/32	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 5 ( 0.0%)	0/ 13 ( 0.0%)
20/40	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 5 ( 0.0%)	0/ 13 ( 0.0%)
20/50	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 5 ( 20.0%)	1/ 13 ( 7.7%)
20/80	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 5 ( 0.0%)	0/ 13 ( 0.0%)
20/400	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	0/ 5 ( 0.0%)	1/ 13 ( 7.7%)

Patients are summarized under the dose received at the corresponding visit.  
Overall percentages are based on the total number of patients in the Safety Analysis Set.

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<b>Vitreous (Right Eye)</b>				
Screening				
n	15	0	0	15
Normal	15/ 15 (100.0%)	0/ 0	0/ 0	15/ 15 (100.0%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
<b>Vitreous (Right Eye)</b>				
Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	6/ 6 (100.0%)	14/ 14 (100.0%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Vitreous (Left Eye) Screening				
n	15	0	0	15
Normal	14/ 15 ( 93.3%)	0/ 0	0/ 0	14/ 15 ( 93.3%)
Abnormal, NCS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
 Vitreous (Left Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	13/ 14 ( 92.9%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Lens (Right Eye) Screening				
n	15	0	0	15
Normal	13/ 15 ( 86.7%)	0/ 0	0/ 0	13/ 15 ( 86.7%)
Abnormal, NCS	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
 Lens (Right Eye) Week 24				
n	5	3	6	14
Normal	4/ 5 ( 80.0%)	3/ 3 (100.0%)	5/ 6 ( 83.3%)	12/ 14 ( 85.7%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
<hr/>				
Lens (Left Eye)				
Screening				
n	15	0	0	15
Normal	12/ 15 ( 80.0%)	0/ 0	0/ 0	12/ 15 ( 80.0%)
Abnormal, NCS	2/ 15 ( 13.3%)	0/ 0	0/ 0	2/ 15 ( 13.3%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
 Lens (Left Eye)				
Week 24				
n	5	3	6	14
Normal	4/ 5 ( 80.0%)	3/ 3 (100.0%)	4/ 6 ( 66.7%)	11/ 14 ( 78.6%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant



Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Optic Disc (Right Eye) Screening				
n	15	0	0	15
Normal	12/ 15 ( 80.0%)	0/ 0	0/ 0	12/ 15 ( 80.0%)
Abnormal, NCS	3/ 15 ( 20.0%)	0/ 0	0/ 0	3/ 15 ( 20.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Optic Disc (Right Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	4/ 6 ( 66.7%)	12/ 14 ( 85.7%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	2/ 6 ( 33.3%)	2/ 14 ( 14.3%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Optic Disc (Left Eye) Screening				
n	15	0	0	15
Normal	11/ 15 ( 73.3%)	0/ 0	0/ 0	11/ 15 ( 73.3%)
Abnormal, NCS	3/ 15 ( 20.0%)	0/ 0	0/ 0	3/ 15 ( 20.0%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Optic Disc (Left Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	3/ 6 ( 50.0%)	11/ 14 ( 78.6%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	2/ 6 ( 33.3%)	2/ 14 ( 14.3%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Retina (Right Eye) Screening				
n	15	0	0	15
Normal	10/ 15 ( 66.7%)	0/ 0	0/ 0	10/ 15 ( 66.7%)
Abnormal, NCS	4/ 15 ( 26.7%)	0/ 0	0/ 0	4/ 15 ( 26.7%)
Abnormal, CS	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Not Done	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Retina (Right Eye) Week 24				
n	5	3	6	14
Normal	4/ 5 ( 80.0%)	3/ 3 (100.0%)	4/ 6 ( 66.7%)	11/ 14 ( 78.6%)
Abnormal, NCS	1/ 5 ( 20.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	2/ 14 ( 14.3%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	0/ 6 ( 0.0%)	0/ 14 ( 0.0%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant

Table 14.4.4.7  
Summary of Dilated Fundus Examination  
(Safety Analysis Set)

Exam (Eye) Visit	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Retina (Left Eye) Screening				
n	15	0	0	15
Normal	9/ 15 ( 60.0%)	0/ 0	0/ 0	9/ 15 ( 60.0%)
Abnormal, NCS	5/ 15 ( 33.3%)	0/ 0	0/ 0	5/ 15 ( 33.3%)
Abnormal, CS	0/ 15 ( 0.0%)	0/ 0	0/ 0	0/ 15 ( 0.0%)
Not Done	1/ 15 ( 6.7%)	0/ 0	0/ 0	1/ 15 ( 6.7%)
Retina (Left Eye) Week 24				
n	5	3	6	14
Normal	5/ 5 (100.0%)	3/ 3 (100.0%)	3/ 6 ( 50.0%)	11/ 14 ( 78.6%)
Abnormal, NCS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Abnormal, CS	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)
Not Done	0/ 5 ( 0.0%)	0/ 3 ( 0.0%)	1/ 6 ( 16.7%)	1/ 14 ( 7.1%)

Patients are summarized under the dose received at the corresponding visit.

Overall percentages are based on the total number of patients in the Safety Analysis Set.

NCS = not clinically significant

CS = clinically significant