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# Appendix

## 시험정보

### 임상시험 계획서

Refer to ISF

### 증례기록서 양식

Refer to ISF

### 임상시험 심사위원회의 명단 및 심사기록, 서면동의서와 동의를 위한 설명서 양식

Refer to ISF

### 시험책임자 및 담당자, 공동연구자의 명단 및 시험수행에 적합한 약력

Refer to ISF

### 시험책임자 및 공동연구자 또는 시험 의뢰자의 서명

Refer to section 1.2

### 2가지 이상의 batch에서 제조된 임상시험용의약품을 투여 받았을 경우 그 제조번호 목록 및 각 batch별 투여된 피험자의 명단

Not Applicable

### 무작위 배정 방법 및 배정표

Refer to ISF

### 점검확인서

Refer to Audit Certificates

### 통계적 방법에 관한 문서

Refer to statistical analysis plan

### 각 실시기관의 실험실간 표준화 방법, 기타 자료의 질적 보증을 위해 사용한 방법

Refer to ISF

### 임상시험결과를 출판하였을 경우 출판물

Not Applicable

### 임상시험결과의 평가에 절대적 영향을 미친 참고문헌

Not Applicable

## 시험대상자 자료 목록

### 중도탈락자

| **SID** | **RID** | **Sex** | **Age** | **Final\_visit** | **Reason\_for\_discontinuation** |
| --- | --- | --- | --- | --- | --- |
| S01 | R010 | 남 | 20 | 2022-06-13 | 대상자가 임상시험용 의약품의 투약 중단을 요구하거나, 시험 참여 동의를 철회하는 경우 |
| S07 | R040 | 남 | 32 | 2022-06-14 | 대상자가 임상시험용 의약품의 투약 중단을 요구하거나, 시험 참여 동의를 철회하는 경우 |

### 시험계획서 이탈

Refer to section 10.2

### 약동학 평가에서 제외된 시험대상자

Not Applicable

### 시험대상자 특성표

| **SID** | **RID** | **Screening Date** | **Age** | **Sex** | **Smoking** | **Alcohol** | **Caffeine** | **Height** | **Weight** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 2022-05-30 | 20 | 남 | 10개피/일 이하 | 210g/주 이하 | 5컵/일 이하 | 173.4 | 62.4 |
| S02 | R020 | 2022-05-31 | 29 | 남 | 아니오 | 아니오 | 5컵/일 이하 | 171.4 | 71.7 |
| S04 | R030 | 2022-05-31 | 40 | 남 | 아니오 | 아니오 | 5컵/일 이하 | 169.2 | 68.1 |
| S07 | R040 | 2022-06-02 | 32 | 남 | 아니오 | 아니오 | 5컵/일 이하 | 177.3 | 83.2 |
| S09 | R050 | 2022-06-03 | 27 | 남 | 10개피/일 이하 | 210g/주 이하 | 5컵/일 이하 | 161.1 | 65.6 |
| S10 | R060 | 2022-06-03 | 26 | 남 | 아니오 | 아니오 | 아니오 | 181.6 | 88.0 |
| S11 | R070 | 2022-06-03 | 23 | 남 | 10개피/일 이하 | 210g/주 이하 | 5컵/일 이하 | 172.2 | 75.6 |
| S15 | R080 | 2022-06-20 | 22 | 남 | 아니오 | 210g/주 이하 | 아니오 | 176.7 | 63.5 |

### 순응도 및 혈중농도 자료

16.2.5.1 시험대상자별 개별 투약 시간

| **SID** | **RID** | **투여일(1d)\_1회** | **투여일(1d)\_2회** | **투여일(1d)\_3회** | **투여일(1d)\_4회** | **투여일(2d)\_1회** | **투여일(2d)\_2회** | **투여일(2d)\_3회** | **투여일(2d)\_4회** | **투여일(3d)\_1회** | **투여일(3d)\_2회** | **투여일(3d)\_3회** | **투여일(3d)\_4회** | **투여일(4d)\_1회** | **투여일(4d)\_2회** | **투여일(4d)\_3회** | **투여일(4d)\_4회** | **투여일(5d)\_1회** | **투여일(5d)\_2회** | **투여일(5d)\_3회** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 | NA | NA | NA | NA | NA | NA | NA | NA |
| S02 | R020 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 |
| S04 | R030 | 08:04 | 12:04 | 16:04 | 20:04 | 08:04 | 12:04 | 16:04 | 20:04 | 08:04 | 12:04 | 16:04 | 20:04 | 08:04 | 12:04 | 16:04 | 20:04 | 08:04 | 12:04 | 16:04 |
| S07 | R040 | 08:06 | 12:06 | 16:06 | 20:06 | 08:06 | 12:06 | 16:06 | 20:06 | 08:06 | 12:06 | 16:06 | 20:06 | 08:06 | 12:06 | NA | NA | NA | NA | NA |
| S09 | R050 | 08:08 | 12:08 | 16:08 | 20:08 | 08:08 | 12:08 | 16:08 | 20:08 | 08:08 | 12:08 | 16:08 | 20:08 | 08:08 | 12:08 | 16:08 | 20:08 | 08:08 | 12:08 | 16:08 |
| S10 | R060 | 08:10 | 12:10 | 16:10 | 20:10 | 08:10 | 12:10 | 16:10 | 20:10 | 08:10 | 12:10 | 16:10 | 20:10 | 08:10 | 12:10 | 16:10 | 20:10 | 08:10 | 12:10 | 16:10 |
| S11 | R070 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 | 20:00 | 08:00 | 12:00 | 16:00 |
| S15 | R080 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 | 20:02 | 08:02 | 12:02 | 16:02 |

16.2.5.2 시험대상자별 혈장 내 농도 (Period 1 Tamsulosin)

16.2.5.3 시험대상자별 혈장 내 농도 (Period 2 Mirabegron)

16.2.5.4 시험대상자별 혈장 내 농도 (Period 3 Tamsulosin)

16.2.5.5 시험대상자별 혈장 내 농도 (Period 3 Mirabegron)

### 시험대상자별 약동학 결과

16.2.6.1 시험대상자별 비구획 분석 결과 (Tamsulosin)

16.2.6.2 시험대상자별 비구획 분석 결과 (Mirabegron)

16.2.6.3 시험대상자별 혈중농도 프로파일 (Tamsulosin)

16.2.6.4 시험대상자별 혈중농도 프로파일 (Mirabegron)

16.2.6.5 시험대상자별 채혈수행시각

| **SID** | **RID** | **투여일(1d)\_첫 투여 직전 0 hr** | **투여일(1d)\_0.33hr** | **투여일(1d)\_0.67hr** | **투여일(1d)\_1hr** | **투여일(1d)\_1.5hr** | **투여일(1d)\_2hr** | **투여일(1d)\_3hr** | **투여일(1d)\_4hr** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 07:55 | 08:20 | 08:40 | 09:00 | 09:30 | 10:00 | 11:00 | 11:55 |
| S02 | R020 | 07:57 | 08:22 | 08:42 | 09:02 | 09:32 | 10:02 | 11:02 | 11:57 |
| S04 | R030 | 07:59 | 08:24 | 08:44 | 09:04 | 09:34 | 10:04 | 11:04 | 11:59 |
| S07 | R040 | 08:01 | 08:26 | 08:46 | 09:06 | 09:36 | 10:06 | 11:06 | 12:01 |
| S09 | R050 | 08:03 | 08:28 | 08:48 | 09:08 | 09:38 | 10:08 | 11:08 | 12:03 |
| S10 | R060 | 08:05 | 08:30 | 08:50 | 09:10 | 09:40 | 10:10 | 11:10 | 12:05 |
| S11 | R070 | 07:55 | 08:20 | 08:40 | 09:00 | 09:30 | 10:00 | 11:00 | 11:55 |
| S15 | R080 | 07:57 | 08:22 | 08:42 | 09:02 | 09:32 | 10:02 | 11:02 | 11:57 |

| **SID** | **RID** | **투여일(5d)\_첫 투여 직전 0hr** | **투여일(5d)\_마지막 투여 직전 0hr** | **투여일(5d)\_0.33hr** | **투여일(5d)\_0.67hr** | **투여일(5d)\_1hr** | **투여일(5d)\_1.5hr** | **투여일(5d)\_2hr** | **투여일(5d)\_3hr** | **투여일(5d)\_4hr** | **투여일(5d)\_6hr** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| S02 | R020 | 07:57 | 15:57 | 16:22 | 16:42 | 17:02 | 17:32 | 18:02 | 19:02 | 20:02 | 22:02 |
| S04 | R030 | 07:59 | 15:59 | 16:24 | 16:44 | 17:04 | 17:34 | 18:04 | 19:04 | 20:04 | 22:04 |
| S07 | R040 | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| S09 | R050 | 08:03 | 16:03 | 16:28 | 16:48 | 17:08 | 17:38 | 18:08 | 19:08 | 20:08 | 22:08 |
| S10 | R060 | 08:05 | 16:05 | 16:30 | 16:50 | 17:10 | 17:40 | 18:10 | 19:10 | 20:10 | 22:10 |
| S11 | R070 | 07:55 | 15:55 | 16:20 | 16:40 | 17:00 | 17:30 | 18:00 | 19:00 | 20:00 | 22:00 |
| S15 | R080 | 07:57 | 15:57 | 16:22 | 16:42 | 17:02 | 17:30 | 18:02 | 19:02 | 20:02 | 22:02 |

### 시험대상자별 이상반응 목록

### 피험자별 임상검사 비정상치 자료

## 증례기록서

### 사망, 또는 다른 중대한 이상반응, 다른 유의성 있는 이상반응에 대한 증례기록서

Not Applicable

### 이외의 증례기록서

Not Applicable

## 시험대상자별 자료 목록

### 선행약물 또는 병행 약물

### 실험실적 검사

16.4.2.1 혈액학 검사

| **SID** | **WBC\_RID** | **WBC\_Screening Visit** | **WBC\_투여일(5d)** | **WBC\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 5.36 | NA | 5.23 |
| S02 | R020 | 6.81 | 8.19 | NA |
| S04 | R030 | 5.12 | 4.23 | NA |
| S07 | R040 | 5.44 | NA | 6.38 |
| S09 | R050 | 6.48 | 5.01 | NA |
| S10 | R060 | 5.73 | 5.09 | NA |
| S11 | R070 | 4.45 | 4.49 | NA |
| S15 | R080 | 5.51 | 6.43 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 5.475 | 5.05 | 5.805 |
| Min | - | 4.45 | 4.23 | 5.23 |
| Max | - | 6.81 | 8.19 | 6.38 |
| Mean | - | 5.61 | 5.57 | 5.8 |
| SD | - | 0.75 | 1.49 | 0.81 |
| CV | - | 0.13 | 0.27 | 0.14 |

16.4.2.2 혈액학 검사

| **SID** | **RBC\_RID** | **RBC\_Screening Visit** | **RBC\_투여일(5d)** | **RBC\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 4.86 | NA | 4.89 |
| S02 | R020 | 4.54 | 4.7 | NA |
| S04 | R030 | 5.19 | 5.13 | NA |
| S07 | R040 | 4.79 | NA | 4.74 |
| S09 | R050 | 4.72 | 4.66 | NA |
| S10 | R060 | 5.31 | 5.05 | NA |
| S11 | R070 | 5.12 | 5.06 | NA |
| S15 | R080 | 4.92 | 4.61 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 4.89 | 4.875 | 4.815 |
| Min | - | 4.54 | 4.61 | 4.74 |
| Max | - | 5.31 | 5.13 | 4.89 |
| Mean | - | 4.93 | 4.87 | 4.81 |
| SD | - | 0.26 | 0.24 | 0.11 |
| CV | - | 0.05 | 0.05 | 0.02 |

16.4.2.3 혈액학 검사

| **SID** | **Hemoglobin\_RID** | **Hemoglobin\_Screening Visit** | **Hemoglobin\_투여일(5d)** | **Hemoglobin\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 15 | NA | 15.6 |
| S02 | R020 | 13.4 | 14.4 | NA |
| S04 | R030 | 15.5 | 15.2 | NA |
| S07 | R040 | 14.2 | NA | 13.9 |
| S09 | R050 | 14.1 | 14 | NA |
| S10 | R060 | 15.5 | 15.2 | NA |
| S11 | R070 | 15.2 | 15.3 | NA |
| S15 | R080 | 14.4 | 13.9 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 14.7 | 14.8 | 14.75 |
| Min | - | 13.4 | 13.9 | 13.9 |
| Max | - | 15.5 | 15.3 | 15.6 |
| Mean | - | 14.66 | 14.67 | 14.75 |
| SD | - | 0.76 | 0.64 | 1.2 |
| CV | - | 0.05 | 0.04 | 0.08 |

16.4.2.4 혈액학 검사

| **SID** | **Hematocrit\_RID** | **Hematocrit\_Screening Visit** | **Hematocrit\_투여일(5d)** | **Hematocrit\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 45 | NA | 44.1 |
| S02 | R020 | 41.6 | 41.7 | NA |
| S04 | R030 | 45.4 | 43.4 | NA |
| S07 | R040 | 41.9 | NA | 42.6 |
| S09 | R050 | 43 | 41.8 | NA |
| S10 | R060 | 46.9 | 42.8 | NA |
| S11 | R070 | 45.3 | 45 | NA |
| S15 | R080 | 42.4 | 39.7 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 44 | 42.3 | 43.35 |
| Min | - | 41.6 | 39.7 | 42.6 |
| Max | - | 46.9 | 45 | 44.1 |
| Mean | - | 43.94 | 42.4 | 43.35 |
| SD | - | 1.96 | 1.79 | 1.06 |
| CV | - | 0.04 | 0.04 | 0.02 |

16.4.2.5 혈액학 검사

| **SID** | **Platelets\_RID** | **Platelets\_Screening Visit** | **Platelets\_투여일(5d)** | **Platelets\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 283 | NA | 287 |
| S02 | R020 | 223 | 220 | NA |
| S04 | R030 | 240 | 241 | NA |
| S07 | R040 | 324 | NA | 300 |
| S09 | R050 | 242 | 241 | NA |
| S10 | R060 | 219 | 227 | NA |
| S11 | R070 | 284 | 306 | NA |
| S15 | R080 | 274 | 283 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 258 | 241 | 293.5 |
| Min | - | 219 | 220 | 287 |
| Max | - | 324 | 306 | 300 |
| Mean | - | 261.12 | 253 | 293.5 |
| SD | - | 36.18 | 33.95 | 9.19 |
| CV | - | 0.14 | 0.13 | 0.03 |

16.4.2.6 혈액학 검사

| **SID** | **Seg.neutrophils\_RID** | **Seg.neutrophils\_Screening Visit** | **Seg.neutrophils\_투여일(5d)** | **Seg.neutrophils\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 56.1 | NA | 43.8 |
| S02 | R020 | 57 | 61.3 | NA |
| S04 | R030 | 69.1 | 51 | NA |
| S07 | R040 | 67.5 | NA | 60.4 |
| S09 | R050 | 49.6 | 50.1 | NA |
| S10 | R060 | 45.6 | 44.4 | NA |
| S11 | R070 | 49 | 41.4 | NA |
| S15 | R080 | 46.6 | 49.8 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 52.85 | 49.95 | 52.1 |
| Min | - | 45.6 | 41.4 | 43.8 |
| Max | - | 69.1 | 61.3 | 60.4 |
| Mean | - | 55.06 | 49.67 | 52.1 |
| SD | - | 9.14 | 6.83 | 11.74 |
| CV | - | 0.17 | 0.14 | 0.23 |

16.4.2.7 혈액학 검사

| **SID** | **Lympho\_RID** | **Lympho\_Screening Visit** | **Lympho\_투여일(5d)** | **Lympho\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 33.4 | NA | 44.6 |
| S02 | R020 | 33.3 | 29.9 | NA |
| S04 | R030 | 25.6 | 40.7 | NA |
| S07 | R040 | 26.3 | NA | 30.6 |
| S09 | R050 | 38.3 | 38.9 | NA |
| S10 | R060 | 43.8 | 45.4 | NA |
| S11 | R070 | 40.9 | 49.2 | NA |
| S15 | R080 | 40.3 | 38.1 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 35.85 | 39.8 | 37.6 |
| Min | - | 25.6 | 29.9 | 30.6 |
| Max | - | 43.8 | 49.2 | 44.6 |
| Mean | - | 35.24 | 40.37 | 37.6 |
| SD | - | 6.76 | 6.64 | 9.9 |
| CV | - | 0.19 | 0.16 | 0.26 |

16.4.2.8 혈액학 검사

| **SID** | **Mono\_RID** | **Mono\_Screening Visit** | **Mono\_투여일(5d)** | **Mono\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 7.5 | NA | 8.4 |
| S02 | R020 | 8.2 | 7.3 | NA |
| S04 | R030 | 4.3 | 6.4 | NA |
| S07 | R040 | 5.1 | NA | 6.6 |
| S09 | R050 | 7.9 | 6.8 | NA |
| S10 | R060 | 7 | 6.3 | NA |
| S11 | R070 | 6.1 | 6.5 | NA |
| S15 | R080 | 9.3 | 8.7 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 7.25 | 6.65 | 7.5 |
| Min | - | 4.3 | 6.3 | 6.6 |
| Max | - | 9.3 | 8.7 | 8.4 |
| Mean | - | 6.92 | 7 | 7.5 |
| SD | - | 1.67 | 0.91 | 1.27 |
| CV | - | 0.24 | 0.13 | 0.17 |

16.4.2.9 혈액학 검사

| **SID** | **Eosino\_RID** | **Eosino\_Screening Visit** | **Eosino\_투여일(5d)** | **Eosino\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 2.1 | NA | 2.1 |
| S02 | R020 | 1.2 | 1 | NA |
| S04 | R030 | 0.4 | 0.7 | NA |
| S07 | R040 | 0.7 | NA | 1.9 |
| S09 | R050 | 3.7 | 3.6 | NA |
| S10 | R060 | 3.1 | 3.5 | NA |
| S11 | R070 | 3.6 | 2.2 | NA |
| S15 | R080 | 2.7 | 2.3 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 2.4 | 2.25 | 2 |
| Min | - | 0.4 | 0.7 | 1.9 |
| Max | - | 3.7 | 3.6 | 2.1 |
| Mean | - | 2.19 | 2.22 | 2 |
| SD | - | 1.3 | 1.21 | 0.14 |
| CV | - | 0.59 | 0.55 | 0.07 |

16.4.2.10 혈액학 검사

| **SID** | **Baso\_RID** | **Baso\_Screening Visit** | **Baso\_투여일(5d)** | **Baso\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0.9 | NA | 1.1 |
| S02 | R020 | 0.3 | 0.5 | NA |
| S04 | R030 | 0.6 | 1.2 | NA |
| S07 | R040 | 0.4 | NA | 0.5 |
| S09 | R050 | 0.5 | 0.6 | NA |
| S10 | R060 | 0.5 | 0.4 | NA |
| S11 | R070 | 0.4 | 0.7 | NA |
| S15 | R080 | 1.1 | 1.1 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 0.5 | 0.65 | 0.8 |
| Min | - | 0.3 | 0.4 | 0.5 |
| Max | - | 1.1 | 1.2 | 1.1 |
| Mean | - | 0.59 | 0.75 | 0.8 |
| SD | - | 0.27 | 0.33 | 0.42 |
| CV | - | 0.47 | 0.44 | 0.53 |

16.4.2.11 혈액학 검사

| **SID** | **MCV\_RID** | **MCV\_Screening Visit** | **MCV\_투여일(5d)** | **MCV\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 92.6 | NA | 90.2 |
| S02 | R020 | 91.6 | 88.7 | NA |
| S04 | R030 | 87.5 | 84.6 | NA |
| S07 | R040 | 87.5 | NA | 89.9 |
| S09 | R050 | 91.1 | 89.7 | NA |
| S10 | R060 | 88.3 | 84.8 | NA |
| S11 | R070 | 88.5 | 88.9 | NA |
| S15 | R080 | 86.2 | 86.1 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 88.4 | 87.4 | 90.05 |
| Min | - | 86.2 | 84.6 | 89.9 |
| Max | - | 92.6 | 89.7 | 90.2 |
| Mean | - | 89.16 | 87.13 | 90.05 |
| SD | - | 2.3 | 2.24 | 0.21 |
| CV | - | 0.03 | 0.03 | 0 |

16.4.2.12 혈액학 검사

| **SID** | **MCH\_RID** | **MCH\_Screening Visit** | **MCH\_투여일(5d)** | **MCH\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 30.9 | NA | 31.9 |
| S02 | R020 | 29.5 | 30.6 | NA |
| S04 | R030 | 29.9 | 29.6 | NA |
| S07 | R040 | 29.6 | NA | 29.3 |
| S09 | R050 | 29.9 | 30 | NA |
| S10 | R060 | 29.2 | 30.1 | NA |
| S11 | R070 | 29.7 | 30.2 | NA |
| S15 | R080 | 29.3 | 30.2 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 29.65 | 30.15 | 30.6 |
| Min | - | 29.2 | 29.6 | 29.3 |
| Max | - | 30.9 | 30.6 | 31.9 |
| Mean | - | 29.75 | 30.12 | 30.6 |
| SD | - | 0.53 | 0.33 | 1.84 |
| CV | - | 0.02 | 0.01 | 0.06 |

16.4.2.13 혈액학 검사

| **SID** | **MCHC\_RID** | **MCHC\_Screening Visit** | **MCHC\_투여일(5d)** | **MCHC\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 33.3 | NA | 35.4 |
| S02 | R020 | 32.2 | 34.5 | NA |
| S04 | R030 | 34.1 | 35 | NA |
| S07 | R040 | 33.9 | NA | 32.6 |
| S09 | R050 | 32.8 | 33.5 | NA |
| S10 | R060 | 33 | 35.5 | NA |
| S11 | R070 | 33.6 | 34 | NA |
| S15 | R080 | 34 | 35 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 33.45 | 34.75 | 34 |
| Min | - | 32.2 | 33.5 | 32.6 |
| Max | - | 34.1 | 35.5 | 35.4 |
| Mean | - | 33.36 | 34.58 | 34 |
| SD | - | 0.67 | 0.74 | 1.98 |
| CV | - | 0.02 | 0.02 | 0.06 |

16.4.2.14 혈액화학 검사

| **SID** | **Glucose\_RID** | **Glucose\_Screening Visit** | **Glucose\_투여일(5d)** | **Glucose\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 83 | NA | 107 |
| S02 | R020 | 91 | 94 | NA |
| S04 | R030 | 88 | 87 | NA |
| S07 | R040 | 95 | NA | 93 |
| S09 | R050 | 91 | 95 | NA |
| S10 | R060 | 99 | 90 | NA |
| S11 | R070 | 83 | 92 | NA |
| S15 | R080 | 93 | 86 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 91 | 91 | 100 |
| Min | - | 83 | 86 | 93 |
| Max | - | 99 | 95 | 107 |
| Mean | - | 90.38 | 90.67 | 100 |
| SD | - | 5.58 | 3.67 | 9.9 |
| CV | - | 0.06 | 0.04 | 0.1 |

16.4.2.15 혈액화학 검사

| **SID** | **BUN\_RID** | **BUN\_Screening Visit** | **BUN\_투여일(5d)** | **BUN\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 10.4 | NA | 9.4 |
| S02 | R020 | 14.5 | 14.3 | NA |
| S04 | R030 | 11.4 | 13.7 | NA |
| S07 | R040 | 12 | NA | 7.7 |
| S09 | R050 | 9.4 | 9 | NA |
| S10 | R060 | 10.9 | 6.5 | NA |
| S11 | R070 | 10.9 | 12.2 | NA |
| S15 | R080 | 12.6 | 11.8 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 11.15 | 12 | 8.55 |
| Min | - | 9.4 | 6.5 | 7.7 |
| Max | - | 14.5 | 14.3 | 9.4 |
| Mean | - | 11.51 | 11.25 | 8.55 |
| SD | - | 1.55 | 2.97 | 1.2 |
| CV | - | 0.13 | 0.26 | 0.14 |

16.4.2.16 혈액화학 검사

| **SID** | **creatinine\_RID** | **creatinine\_Screening Visit** | **creatinine\_투여일(5d)** | **creatinine\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0.74 | NA | 0.85 |
| S02 | R020 | 0.96 | 0.9 | NA |
| S04 | R030 | 0.92 | 0.95 | NA |
| S07 | R040 | 0.94 | NA | 0.83 |
| S09 | R050 | 0.75 | 0.84 | NA |
| S10 | R060 | 0.77 | 0.73 | NA |
| S11 | R070 | 0.95 | 0.99 | NA |
| S15 | R080 | 1 | 0.98 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 0.93 | 0.925 | 0.84 |
| Min | - | 0.74 | 0.73 | 0.83 |
| Max | - | 1 | 0.99 | 0.85 |
| Mean | - | 0.88 | 0.9 | 0.84 |
| SD | - | 0.11 | 0.1 | 0.01 |
| CV | - | 0.12 | 0.11 | 0.02 |

16.4.2.17 혈액화학 검사

| **SID** | **MDRD-eGFR\_RID** | **MDRD-eGFR\_Screening Visit** | **MDRD-eGFR\_투여일(5d)** | **MDRD-eGFR\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 135 | NA | 115 |
| S02 | R020 | 93 | 100 | NA |
| S04 | R030 | 91 | 88 | NA |
| S07 | R040 | 93 | NA | 107 |
| S09 | R050 | 125 | 110 | NA |
| S10 | R060 | 122 | 130 | NA |
| S11 | R070 | 98 | 94 | NA |
| S15 | R080 | 93 | 96 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 95.5 | 98 | 111 |
| Min | - | 91 | 88 | 107 |
| Max | - | 135 | 130 | 115 |
| Mean | - | 106.25 | 103 | 111 |
| SD | - | 17.94 | 15.11 | 5.66 |
| CV | - | 0.17 | 0.15 | 0.05 |

16.4.2.18 혈액화학 검사

| **SID** | **total protein\_RID** | **total protein\_Screening Visit** | **total protein\_투여일(5d)** | **total protein\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 7 | NA | 7.3 |
| S02 | R020 | 7.4 | 7.5 | NA |
| S04 | R030 | 7.4 | 7.5 | NA |
| S07 | R040 | 7.6 | NA | 7.6 |
| S09 | R050 | 7.1 | 7.8 | NA |
| S10 | R060 | 6.8 | 7 | NA |
| S11 | R070 | 7.7 | 7.9 | NA |
| S15 | R080 | 7.3 | 7.2 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 7.35 | 7.5 | 7.45 |
| Min | - | 6.8 | 7 | 7.3 |
| Max | - | 7.7 | 7.9 | 7.6 |
| Mean | - | 7.29 | 7.48 | 7.45 |
| SD | - | 0.3 | 0.34 | 0.21 |
| CV | - | 0.04 | 0.05 | 0.03 |

16.4.2.19 혈액화학 검사

| **SID** | **albumin\_RID** | **albumin\_Screening Visit** | **albumin\_투여일(5d)** | **albumin\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 4.7 | NA | 4.9 |
| S02 | R020 | 4.5 | 4.4 | NA |
| S04 | R030 | 4.8 | 4.8 | NA |
| S07 | R040 | 4.7 | NA | 4.7 |
| S09 | R050 | 4.8 | 4.9 | NA |
| S10 | R060 | 4.8 | 4.8 | NA |
| S11 | R070 | 5.1 | 5.1 | NA |
| S15 | R080 | 4.8 | 4.8 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 4.8 | 4.8 | 4.8 |
| Min | - | 4.5 | 4.4 | 4.7 |
| Max | - | 5.1 | 5.1 | 4.9 |
| Mean | - | 4.78 | 4.8 | 4.8 |
| SD | - | 0.17 | 0.23 | 0.14 |
| CV | - | 0.03 | 0.05 | 0.03 |

16.4.2.20 혈액화학 검사

| **SID** | **AST\_RID** | **AST\_Screening Visit** | **AST\_투여일(5d)** | **AST\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 11 | NA | 16 |
| S02 | R020 | 37 | 23 | NA |
| S04 | R030 | 16 | 17 | NA |
| S07 | R040 | 12 | NA | 19 |
| S09 | R050 | 15 | 32 | NA |
| S10 | R060 | 14 | 13 | NA |
| S11 | R070 | 21 | 17 | NA |
| S15 | R080 | 22 | 17 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 15.5 | 17 | 17.5 |
| Min | - | 11 | 13 | 16 |
| Max | - | 37 | 32 | 19 |
| Mean | - | 18.5 | 19.83 | 17.5 |
| SD | - | 8.43 | 6.77 | 2.12 |
| CV | - | 0.46 | 0.34 | 0.12 |

16.4.2.21 혈액화학 검사

| **SID** | **ALT\_RID** | **ALT\_Screening Visit** | **ALT\_투여일(5d)** | **ALT\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 8 | NA | 14 |
| S02 | R020 | 28 | 29 | NA |
| S04 | R030 | 11 | 14 | NA |
| S07 | R040 | 11 | NA | 17 |
| S09 | R050 | 18 | 49 | NA |
| S10 | R060 | 16 | 17 | NA |
| S11 | R070 | 29 | 17 | NA |
| S15 | R080 | 11 | 8 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 13.5 | 17 | 15.5 |
| Min | - | 8 | 8 | 14 |
| Max | - | 29 | 49 | 17 |
| Mean | - | 16.5 | 22.33 | 15.5 |
| SD | - | 8.05 | 14.75 | 2.12 |
| CV | - | 0.49 | 0.66 | 0.14 |

16.4.2.22 혈액화학 검사

| **SID** | **alkaline phosphatase\_RID** | **alkaline phosphatase\_Screening Visit** | **alkaline phosphatase\_투여일(5d)** | **alkaline phosphatase\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 73 | NA | 74 |
| S02 | R020 | 89 | 86 | NA |
| S04 | R030 | 81 | 66 | NA |
| S07 | R040 | 68 | NA | 66 |
| S09 | R050 | 58 | 61 | NA |
| S10 | R060 | 42 | 43 | NA |
| S11 | R070 | 109 | 96 | NA |
| S15 | R080 | 55 | 53 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 70.5 | 63.5 | 70 |
| Min | - | 42 | 43 | 66 |
| Max | - | 109 | 96 | 74 |
| Mean | - | 71.88 | 67.5 | 70 |
| SD | - | 21.18 | 20.05 | 5.66 |
| CV | - | 0.29 | 0.3 | 0.08 |

16.4.2.23 혈액화학 검사

| **SID** | **total bilirubin\_RID** | **total bilirubin\_Screening Visit** | **total bilirubin\_투여일(5d)** | **total bilirubin\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0.65 | NA | 0.29 |
| S02 | R020 | 0.76 | 0.55 | NA |
| S04 | R030 | 0.61 | 0.57 | NA |
| S07 | R040 | 1.57 | NA | 0.61 |
| S09 | R050 | 0.59 | 0.41 | NA |
| S10 | R060 | 0.32 | 0.51 | NA |
| S11 | R070 | 1.2 | 0.73 | NA |
| S15 | R080 | 1.2 | 0.6 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 0.705 | 0.56 | 0.45 |
| Min | - | 0.32 | 0.41 | 0.29 |
| Max | - | 1.57 | 0.73 | 0.61 |
| Mean | - | 0.86 | 0.56 | 0.45 |
| SD | - | 0.42 | 0.11 | 0.23 |
| CV | - | 0.48 | 0.19 | 0.5 |

16.4.2.24 혈액화학 검사

| **SID** | **γ-GT\_RID** | **γ-GT\_Screening Visit** | **γ-GT\_투여일(5d)** | **γ-GT\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 19 | NA | 18 |
| S02 | R020 | 12 | 11 | NA |
| S04 | R030 | 12 | 11 | NA |
| S07 | R040 | 19 | NA | 20 |
| S09 | R050 | 34 | 37 | NA |
| S10 | R060 | 17 | 16 | NA |
| S11 | R070 | 44 | 30 | NA |
| S15 | R080 | 13 | 12 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 18 | 14 | 19 |
| Min | - | 12 | 11 | 18 |
| Max | - | 44 | 37 | 20 |
| Mean | - | 21.25 | 19.5 | 19 |
| SD | - | 11.63 | 11.22 | 1.41 |
| CV | - | 0.55 | 0.58 | 0.07 |

16.4.2.25 혈액화학 검사

| **SID** | **uric acid\_RID** | **uric acid\_Screening Visit** | **uric acid\_투여일(5d)** | **uric acid\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 4.6 | NA | 5 |
| S02 | R020 | 5.4 | 4.6 | NA |
| S04 | R030 | 6.5 | 5.4 | NA |
| S07 | R040 | 6.4 | NA | 5.5 |
| S09 | R050 | 7.9 | 7 | NA |
| S10 | R060 | 7.6 | 6.2 | NA |
| S11 | R070 | 6.5 | 6.2 | NA |
| S15 | R080 | 7.6 | 5.7 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 6.5 | 5.95 | 5.25 |
| Min | - | 4.6 | 4.6 | 5 |
| Max | - | 7.9 | 7 | 5.5 |
| Mean | - | 6.56 | 5.85 | 5.25 |
| SD | - | 1.15 | 0.82 | 0.35 |
| CV | - | 0.17 | 0.14 | 0.07 |

16.4.2.26 혈액화학 검사

| **SID** | **Calcium\_RID** | **Calcium\_Screening Visit** | **Calcium\_투여일(5d)** | **Calcium\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 9.7 | NA | 9.6 |
| S02 | R020 | 8.9 | 8.8 | NA |
| S04 | R030 | 9.7 | 9.2 | NA |
| S07 | R040 | 9.6 | NA | 8.9 |
| S09 | R050 | 9.2 | 9 | NA |
| S10 | R060 | 10 | 9.2 | NA |
| S11 | R070 | 9.7 | 9.2 | NA |
| S15 | R080 | 9.7 | 9.2 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 9.7 | 9.2 | 9.25 |
| Min | - | 8.9 | 8.8 | 8.9 |
| Max | - | 10 | 9.2 | 9.6 |
| Mean | - | 9.56 | 9.1 | 9.25 |
| SD | - | 0.35 | 0.17 | 0.49 |
| CV | - | 0.04 | 0.02 | 0.05 |

16.4.2.27 혈액화학 검사

| **SID** | **phosphorus\_RID** | **phosphorus\_Screening Visit** | **phosphorus\_투여일(5d)** | **phosphorus\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 4 | NA | 3.5 |
| S02 | R020 | 3.2 | 3.1 | NA |
| S04 | R030 | 3.2 | 3.3 | NA |
| S07 | R040 | 3.9 | NA | 4.2 |
| S09 | R050 | 3 | 3 | NA |
| S10 | R060 | 4.6 | 3.7 | NA |
| S11 | R070 | 3.9 | 4.9 | NA |
| S15 | R080 | 3.3 | 4.1 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 3.6 | 3.5 | 3.85 |
| Min | - | 3 | 3 | 3.5 |
| Max | - | 4.6 | 4.9 | 4.2 |
| Mean | - | 3.64 | 3.68 | 3.85 |
| SD | - | 0.55 | 0.72 | 0.49 |
| CV | - | 0.15 | 0.2 | 0.13 |

16.4.2.28 혈액화학 검사

| **SID** | **Na\_RID** | **Na\_Screening Visit** | **Na\_투여일(5d)** | **Na\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 139 | NA | 139 |
| S02 | R020 | 142 | 139 | NA |
| S04 | R030 | 139 | 139 | NA |
| S07 | R040 | 138 | NA | 140 |
| S09 | R050 | 136 | 138 | NA |
| S10 | R060 | 141 | 142 | NA |
| S11 | R070 | 139 | 136 | NA |
| S15 | R080 | 138 | 139 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 139 | 139 | 139.5 |
| Min | - | 136 | 136 | 139 |
| Max | - | 142 | 142 | 140 |
| Mean | - | 139 | 138.83 | 139.5 |
| SD | - | 1.85 | 1.94 | 0.71 |
| CV | - | 0.01 | 0.01 | 0.01 |

16.4.2.29 혈액화학 검사

| **SID** | **K\_RID** | **K\_Screening Visit** | **K\_투여일(5d)** | **K\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 4.6 | NA | 4.6 |
| S02 | R020 | 5.1 | 4.1 | NA |
| S04 | R030 | 4.5 | 4.1 | NA |
| S07 | R040 | 4.1 | NA | 4 |
| S09 | R050 | 4.2 | 4.2 | NA |
| S10 | R060 | 4.3 | 4.1 | NA |
| S11 | R070 | 4.3 | 4.4 | NA |
| S15 | R080 | 4.1 | 3.8 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 4.3 | 4.1 | 4.3 |
| Min | - | 4.1 | 3.8 | 4 |
| Max | - | 5.1 | 4.4 | 4.6 |
| Mean | - | 4.4 | 4.12 | 4.3 |
| SD | - | 0.33 | 0.19 | 0.42 |
| CV | - | 0.08 | 0.05 | 0.1 |

16.4.2.30 혈액화학 검사

| **SID** | **Cl\_RID** | **Cl\_Screening Visit** | **Cl\_투여일(5d)** | **Cl\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 102 | NA | 103 |
| S02 | R020 | 105 | 103 | NA |
| S04 | R030 | 102 | 102 | NA |
| S07 | R040 | 103 | NA | 103 |
| S09 | R050 | 101 | 102 | NA |
| S10 | R060 | 103 | 105 | NA |
| S11 | R070 | 102 | 99 | NA |
| S15 | R080 | 103 | 103 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 102.5 | 102.5 | 103 |
| Min | - | 101 | 99 | 103 |
| Max | - | 105 | 105 | 103 |
| Mean | - | 102.62 | 102.33 | 103 |
| SD | - | 1.19 | 1.97 | 0 |
| CV | - | 0.01 | 0.02 | 0 |

16.4.2.31 혈액화학 검사

| **SID** | **LDH\_RID** | **LDH\_Screening Visit** | **LDH\_투여일(5d)** | **LDH\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 141 | NA | 140 |
| S02 | R020 | 222 | 181 | NA |
| S04 | R030 | 192 | 162 | NA |
| S07 | R040 | 135 | NA | 148 |
| S09 | R050 | 139 | 142 | NA |
| S10 | R060 | 170 | 146 | NA |
| S11 | R070 | 178 | 152 | NA |
| S15 | R080 | 182 | 141 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 174 | 149 | 144 |
| Min | - | 135 | 141 | 140 |
| Max | - | 222 | 181 | 148 |
| Mean | - | 169.88 | 154 | 144 |
| SD | - | 30.29 | 15.32 | 5.66 |
| CV | - | 0.18 | 0.1 | 0.04 |

16.4.2.32 혈액화학 검사

| **SID** | **Total cholesterol\_RID** | **Total cholesterol\_Screening Visit** | **Total cholesterol\_투여일(5d)** | **Total cholesterol\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 157 | NA | 151 |
| S02 | R020 | 154 | 190 | NA |
| S04 | R030 | 207 | 207 | NA |
| S07 | R040 | 209 | NA | 217 |
| S09 | R050 | 189 | 215 | NA |
| S10 | R060 | 152 | 159 | NA |
| S11 | R070 | 217 | 212 | NA |
| S15 | R080 | 162 | 163 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 175.5 | 198.5 | 184 |
| Min | - | 152 | 159 | 151 |
| Max | - | 217 | 215 | 217 |
| Mean | - | 180.88 | 191 | 184 |
| SD | - | 27.59 | 24.83 | 46.67 |
| CV | - | 0.15 | 0.13 | 0.25 |

16.4.2.34 소변검사

| **SID** | **Glucose\_RID** | **Glucose\_Screening Visit** | **Glucose\_투여일(5d)** | **Glucose\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Negative | Negative | NA |

16.4.2.35 소변검사

| **SID** | **Color\_RID** | **Color\_Screening Visit** | **Color\_투여일(5d)** | **Color\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | LT.YELLOW | NA | LT.YELLOW |
| S02 | R020 | LT.YELLOW | LT.YELLOW | NA |
| S04 | R030 | LT.YELLOW | LT.YELLOW | NA |
| S07 | R040 | LT.YELLOW | NA | LT.YELLOW |
| S09 | R050 | LT.YELLOW | LT.YELLOW | NA |
| S10 | R060 | LT.YELLOW | LT.YELLOW | NA |
| S11 | R070 | LT.YELLOW | LT.YELLOW | NA |
| S15 | R080 | YELLOW | LT.YELLOW | NA |

16.4.2.36 소변검사

| **SID** | **Leukocyte\_RID** | **Leukocyte\_Screening Visit** | **Leukocyte\_투여일(5d)** | **Leukocyte\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Negative | Negative | NA |

16.4.2.37 소변검사

| **SID** | **Bilirubin\_RID** | **Bilirubin\_Screening Visit** | **Bilirubin\_투여일(5d)** | **Bilirubin\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Negative | Negative | NA |

16.4.2.38 소변검사

| **SID** | **Ketone\_RID** | **Ketone\_Screening Visit** | **Ketone\_투여일(5d)** | **Ketone\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | 1+ | Negative | NA |

16.4.2.39 소변검사

| **SID** | **Specific gravity\_RID** | **Specific gravity\_Screening Visit** | **Specific gravity\_투여일(5d)** | **Specific gravity\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 1.015 | NA | 1.019 |
| S02 | R020 | 1.016 | 1.014 | NA |
| S04 | R030 | 1.019 | 1.018 | NA |
| S07 | R040 | 1.027 | NA | 1.004 |
| S09 | R050 | 1.015 | 1.007 | NA |
| S10 | R060 | 1.016 | 1.002 | NA |
| S11 | R070 | 1.020 | 1.015 | NA |
| S15 | R080 | 1.031 | 1.030 | NA |

16.4.2.40 소변검사

| **SID** | **Occult blood\_RID** | **Occult blood\_Screening Visit** | **Occult blood\_투여일(5d)** | **Occult blood\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Trace | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Trace | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Negative | 1+ | NA |

16.4.2.41 소변검사

| **SID** | **PH\_RID** | **PH\_Screening Visit** | **PH\_투여일(5d)** | **PH\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 6.0 | NA | 6.0 |
| S02 | R020 | 6.5 | 6.5 | NA |
| S04 | R030 | 5.5 | 5.5 | NA |
| S07 | R040 | 6.0 | NA | 7.0 |
| S09 | R050 | 5.5 | 6.5 | NA |
| S10 | R060 | 6.0 | 6.5 | NA |
| S11 | R070 | 6.0 | 6.0 | NA |
| S15 | R080 | 5.5 | 6.0 | NA |

16.4.2.42 소변검사

| **SID** | **Protein\_RID** | **Protein\_Screening Visit** | **Protein\_투여일(5d)** | **Protein\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Trace | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Trace | Negative | NA |

16.4.2.43 소변검사

| **SID** | **Urobilinogen\_RID** | **Urobilinogen\_Screening Visit** | **Urobilinogen\_투여일(5d)** | **Urobilinogen\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Trace | NA | Trace |
| S02 | R020 | Trace | Trace | NA |
| S04 | R030 | Trace | Trace | NA |
| S07 | R040 | Trace | NA | Trace |
| S09 | R050 | Trace | Trace | NA |
| S10 | R060 | Trace | Trace | NA |
| S11 | R070 | Trace | Trace | NA |
| S15 | R080 | Trace | Trace | NA |

16.4.2.44 소변검사

| **SID** | **Nitrite\_RID** | **Nitrite\_Screening Visit** | **Nitrite\_투여일(5d)** | **Nitrite\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | Negative | NA | Negative |
| S02 | R020 | Negative | Negative | NA |
| S04 | R030 | Negative | Negative | NA |
| S07 | R040 | Negative | NA | Negative |
| S09 | R050 | Negative | Negative | NA |
| S10 | R060 | Negative | Negative | NA |
| S11 | R070 | Negative | Negative | NA |
| S15 | R080 | Negative | Negative | NA |

16.4.2.45 소변검사

| **SID** | **Microscopy WBC\_RID** | **Microscopy WBC\_Screening Visit** | **Microscopy WBC\_투여일(5d)** | **Microscopy WBC\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0-1 | NA | 1-3 |
| S02 | R020 | 0-1 | 0-1 | NA |
| S04 | R030 | 0-1 | 0-1 | NA |
| S07 | R040 | 1-3 | NA | 0-1 |
| S09 | R050 | 0-1 | 0-1 | NA |
| S10 | R060 | 1-3 | 0-1 | NA |
| S11 | R070 | 1-3 | 0-1 | NA |
| S15 | R080 | 0-1 | 1-3 | NA |

16.4.2.46 소변검사

| **SID** | **Microscopy RBC\_RID** | **Microscopy RBC\_Screening Visit** | **Microscopy RBC\_투여일(5d)** | **Microscopy RBC\_UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0-1 | NA | 0-1 |
| S02 | R020 | 0-1 | 0-1 | NA |
| S04 | R030 | 0-1 | 0-1 | NA |
| S07 | R040 | 0-1 | NA | 0-1 |
| S09 | R050 | 0-1 | 0-1 | NA |
| S10 | R060 | 0-1 | 0-1 | NA |
| S11 | R070 | 0-1 | 0-1 | NA |
| S15 | R080 | 1-3 | 4 - 9 | NA |

16.4.2.47 혈액응고검사

| **SID** | **RID** | **aPTT** | **PT(INR)** |
| --- | --- | --- | --- |
| S01 | R010 | 26.2 | 1.03 |
| S02 | R020 | 30.9 | 0.98 |
| S04 | R030 | 28.7 | 0.99 |
| S07 | R040 | 27.0 | 0.96 |
| S09 | R050 | 24.7 | 0.96 |
| S10 | R060 | 23.4 | 0.93 |
| S11 | R070 | 26.5 | 0.95 |
| S15 | R080 | 25.6 | 0.94 |

16.4.2.48 혈청검사

| **SID** | **RID** | **anti-HCV Ab** | **HBsAg** | **HIV Ag/Ab** | **Syphilis reagin test** |
| --- | --- | --- | --- | --- | --- |
| S01 | R010 | Negative | Negative | Negative | 0.2이하 |
| S02 | R020 | Negative | Negative | Negative | 0.2이하 |
| S04 | R030 | Negative | Negative | Negative | 0.2 이하 |
| S07 | R040 | Negative | Negative | Negative | 0.2 이하 |
| S09 | R050 | Negative | Negative | Negative | 0.2 이하 |
| S10 | R060 | Negative | Negative | Negative | 0.2 이하 |
| S11 | R070 | Negative | Negative | Negative | 0.2 이하 |
| S15 | R080 | Negative | Negative | Negative | 0.2 이하 |

### 병력

| **SID** | **RID** | **MHSTDTC** | **PT** | **SOC** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 2022-03-01 | COVID-19 | Infections and infestations |
| S02 | R020 | 2022-03-30 | COVID-19 | Infections and infestations |
| S04 | R030 | 2022-03-04 | COVID-19 | Infections and infestations |
| S09 | R050 | 2022-04-20 | COVID-19 | Infections and infestations |
| S15 | R080 | 2022-03-14 | COVID-19 | Infections and infestations |

### 시험대상자의 선정

| **SID** | **RID** | **IEYN** |
| --- | --- | --- |
| S01 | R010 | Yes |
| S02 | R020 | Yes |
| S03 | NA | No |
| S04 | R030 | Yes |
| S05 | NA | No |
| S06 | NA | No |
| S07 | R040 | Yes |
| S08 | NA | No |
| S09 | R050 | Yes |
| S10 | R060 | Yes |
| S11 | R070 | Yes |
| S12 | NA | Yes |
| S13 | NA | Yes |
| S14 | NA | No |
| S15 | R080 | Yes |
| S16 | NA | No |
| S17 | NA | Yes |
| S18 | NA | Yes |

### 신체 검사

| **SID** | **RID** | **Screening Visit** | **입원일(-1d)** | **투여일(1d)\_투여 전** | **투여일(1d)\_** **투여 후 4h** | **투여일(1d)\_** **투여 후 10h** | **투여일(2d)\_ 투여 전** | **투여일(2d)\_** **투여 후 4h** | **투여일(2d)\_** **투여 후 10h** | **투여일(3d)\_ 투여 전** | **투여일(3d)\_** **투여 후 4h** | **투여일(3d)\_** **투여 후 10h** | **투여일(4d)\_ 투여 전** | **투여일(4d)\_** **투여 후 4h** | **투여일(4d)\_** **투여 후 10h** | **투여일(5d)\_ 투여 전** | **투여일(5d)\_** **투여 후 4h** | **투여일(5d)\_** **투여 후 10h** | **UV1** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA | NA | NA | NA | NA | NA | Normal |
| S02 | R020 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |
| S03 | NA | Normal | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| S04 | R030 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |
| S07 | R040 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA | NA | NA | NA | Normal |
| S09 | R050 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |
| S10 | R060 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |
| S11 | R070 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |
| S15 | R080 | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | Normal | NA |

### 활력 징후

16.4.6.1 활력징후[SBP]

| **SID** | **RID** | **Screening Visit\_** | **입원일(-1d)\_** | **투여일(1d)\_투여 전** | **투여일(1d)\_투여 후 4 h** | **투여일(1d)\_투여 후 10 h** | **투여일(2d)\_투여 전** | **투여일(2d)\_투여 후 4 h** | **투여일(2d)\_투여 후 10 h** | **투여일(3d)\_투여 전** | **투여일(3d)\_투여 후 4 h** | **투여일(3d)\_투여 후 10 h** | **투여일(4d)\_투여 전** | **투여일(4d)\_투여 후 4 h** | **투여일(4d)\_투여 후 10 h** | **투여일(5d)\_투여 전** | **투여일(5d)\_투여 후 4 h** | **투여일(5d)\_투여 후 10 h** | **UV1\_** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 133 | 118 | 129 | 123 | 109 | 115 | 108 | 117 | 119 | 105 | 108 | NA | NA | NA | NA | NA | NA | 122 |
| S02 | R020 | 120 | 110 | 103 | 114 | 111 | 108 | 108 | 120 | 107 | 114 | 109 | 112 | 112 | 118 | 104 | 123 | 116 | NA |
| S04 | R030 | 119 | 114 | 107 | 107 | 102 | 109 | 109 | 104 | 106 | 103 | 119 | 105 | 101 | 112 | 116 | 108 | 114 | NA |
| S07 | R040 | 127 | 132 | 111 | 118 | 118 | 111 | 113 | 111 | 106 | 109 | 111 | 109 | 124 | NA | NA | NA | NA | 114 |
| S09 | R050 | 127 | 130 | 131 | 131 | 129 | 104 | 109 | 113 | 119 | 117 | 115 | 116 | 131 | 129 | 133 | 107 | 114 | NA |
| S10 | R060 | 130 | 120 | 118 | 111 | 122 | 114 | 111 | 123 | 110 | 109 | 104 | 109 | 111 | 113 | 100 | 110 | 119 | NA |
| S11 | R070 | 124 | 115 | 112 | 110 | 102 | 132 | 118 | 110 | 116 | 107 | 104 | 124 | 107 | 108 | 121 | 112 | 107 | NA |
| S15 | R080 | 131 | 125 | 109 | 130 | 115 | 117 | 116 | 117 | 113 | 101 | 120 | 108 | 110 | 109 | 112 | 122 | 119 | NA |
| N | 0 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 7 | 7 | 6 | 6 | 6 | 6 | 2 |
| Median | NA | 127 | 119 | 111.5 | 116 | 113 | 112.5 | 110 | 115 | 111.5 | 108 | 110 | 109 | 111 | 112.5 | 114 | 111 | 115 | 118 |
| Min | NA | 119 | 110 | 103 | 107 | 102 | 104 | 108 | 104 | 106 | 101 | 104 | 105 | 101 | 108 | 100 | 107 | 107 | 114 |
| Max | NA | 133 | 132 | 131 | 131 | 129 | 132 | 118 | 123 | 119 | 117 | 120 | 124 | 131 | 129 | 133 | 123 | 119 | 122 |
| Mean | NaN | 126.38 | 120.5 | 115 | 118 | 113.5 | 113.75 | 111.5 | 114.38 | 112 | 108.12 | 111.25 | 111.86 | 113.71 | 114.83 | 114.33 | 113.67 | 114.83 | 118 |
| SD | NA | 5.07 | 7.86 | 10.21 | 9.17 | 9.46 | 8.48 | 3.82 | 6.09 | 5.55 | 5.38 | 6.23 | 6.36 | 10.29 | 7.78 | 11.94 | 7.06 | 4.45 | 5.66 |
| CV | NA | 0.04 | 0.07 | 0.09 | 0.08 | 0.08 | 0.07 | 0.03 | 0.05 | 0.05 | 0.05 | 0.06 | 0.06 | 0.09 | 0.07 | 0.1 | 0.06 | 0.04 | 0.05 |

16.4.6.2 활력징후[DBP]

| **SID** | **RID** | **Screening Visit\_** | **입원일(-1d)\_** | **투여일(1d)\_투여 전** | **투여일(1d)\_투여 후 4 h** | **투여일(1d)\_투여 후 10 h** | **투여일(2d)\_투여 전** | **투여일(2d)\_투여 후 4 h** | **투여일(2d)\_투여 후 10 h** | **투여일(3d)\_투여 전** | **투여일(3d)\_투여 후 4 h** | **투여일(3d)\_투여 후 10 h** | **투여일(4d)\_투여 전** | **투여일(4d)\_투여 후 4 h** | **투여일(4d)\_투여 후 10 h** | **투여일(5d)\_투여 전** | **투여일(5d)\_투여 후 4 h** | **투여일(5d)\_투여 후 10 h** | **UV1\_** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 82 | 65 | 72 | 63 | 64 | 73 | 65 | 74 | 73 | 68 | 62 | NA | NA | NA | NA | NA | NA | 65 |
| S02 | R020 | 71 | 65 | 69 | 73 | 70 | 56 | 72 | 73 | 65 | 75 | 70 | 69 | 69 | 74 | 68 | 80 | 72 | NA |
| S04 | R030 | 81 | 76 | 67 | 73 | 65 | 65 | 72 | 81 | 70 | 64 | 70 | 70 | 68 | 73 | 73 | 76 | 76 | NA |
| S07 | R040 | 84 | 89 | 71 | 77 | 77 | 66 | 65 | 74 | 75 | 64 | 69 | 64 | 75 | NA | NA | NA | NA | 69 |
| S09 | R050 | 83 | 76 | 90 | 78 | 73 | 64 | 70 | 65 | 80 | 69 | 69 | 76 | 78 | 80 | 79 | 66 | 64 | NA |
| S10 | R060 | 84 | 82 | 74 | 71 | 78 | 71 | 70 | 72 | 75 | 69 | 64 | 64 | 72 | 76 | 69 | 68 | 70 | NA |
| S11 | R070 | 74 | 67 | 65 | 64 | 54 | 66 | 61 | 66 | 67 | 64 | 64 | 71 | 62 | 60 | 76 | 61 | 67 | NA |
| S15 | R080 | 78 | 68 | 65 | 69 | 65 | 66 | 65 | 67 | 78 | 58 | 60 | 66 | 67 | 63 | 72 | 65 | 70 | NA |
| N | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 7 | 7 | 6 | 6 | 6 | 6 | 2 |
| Median | - | 81.5 | 72 | 70 | 72 | 67.5 | 66 | 67.5 | 72.5 | 74 | 66 | 66.5 | 69 | 69 | 73.5 | 72.5 | 67 | 70 | 67 |
| Min | - | 71 | 65 | 65 | 63 | 54 | 56 | 61 | 65 | 65 | 58 | 60 | 64 | 62 | 60 | 68 | 61 | 64 | 65 |
| Max | - | 84 | 89 | 90 | 78 | 78 | 73 | 72 | 81 | 80 | 75 | 70 | 76 | 78 | 80 | 79 | 80 | 76 | 69 |
| Mean | - | 79.62 | 73.5 | 71.62 | 71 | 68.25 | 65.88 | 67.5 | 71.5 | 72.88 | 66.38 | 66 | 68.57 | 70.14 | 71 | 72.83 | 69.33 | 69.83 | 67 |
| SD | - | 4.87 | 8.8 | 8.11 | 5.48 | 7.92 | 5.06 | 4.04 | 5.32 | 5.22 | 5.04 | 3.96 | 4.31 | 5.34 | 7.8 | 4.17 | 7.2 | 4.12 | 2.83 |
| CV | - | 0.06 | 0.12 | 0.11 | 0.08 | 0.12 | 0.08 | 0.06 | 0.07 | 0.07 | 0.08 | 0.06 | 0.06 | 0.08 | 0.11 | 0.06 | 0.1 | 0.06 | 0.04 |

16.4.6.3 활력징후[PULSE]

| **SID** | **RID** | **Screening Visit\_** | **입원일(-1d)\_** | **투여일(1d)\_투여 전** | **투여일(1d)\_투여 후 4 h** | **투여일(1d)\_투여 후 10 h** | **투여일(2d)\_투여 전** | **투여일(2d)\_투여 후 4 h** | **투여일(2d)\_투여 후 10 h** | **투여일(3d)\_투여 전** | **투여일(3d)\_투여 후 4 h** | **투여일(3d)\_투여 후 10 h** | **투여일(4d)\_투여 전** | **투여일(4d)\_투여 후 4 h** | **투여일(4d)\_투여 후 10 h** | **투여일(5d)\_투여 전** | **투여일(5d)\_투여 후 4 h** | **투여일(5d)\_투여 후 10 h** | **UV1\_** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 83 | 92 | 62 | 69 | 67 | 73 | 61 | 61 | 68 | 62 | 59 | NA | NA | NA | NA | NA | NA | 82 |
| S02 | R020 | 69 | 76 | 74 | 72 | 74 | 78 | 76 | 68 | 72 | 84 | 68 | 69 | 75 | 69 | 60 | 68 | 75 | NA |
| S04 | R030 | 66 | 68 | 59 | 58 | 67 | 59 | 59 | 71 | 57 | 64 | 60 | 64 | 66 | 61 | 64 | 65 | 68 | NA |
| S07 | R040 | 98 | 100 | 74 | 82 | 85 | 77 | 84 | 85 | 79 | 83 | 75 | 95 | 95 | NA | NA | NA | NA | 94 |
| S09 | R050 | 87 | 86 | 69 | 63 | 69 | 77 | 69 | 70 | 65 | 63 | 72 | 67 | 70 | 76 | 60 | 63 | 71 | NA |
| S10 | R060 | 96 | 100 | 98 | 80 | 87 | 84 | 80 | 87 | 88 | 95 | 71 | 65 | 98 | 89 | 90 | 90 | 81 | NA |
| S11 | R070 | 64 | 73 | 55 | 55 | 58 | 53 | 55 | 53 | 52 | 57 | 53 | 52 | 56 | 54 | 54 | 56 | 56 | NA |
| S15 | R080 | 94 | 84 | 75 | 58 | 60 | 67 | 65 | 59 | 74 | 84 | 77 | 82 | 77 | 74 | 84 | 75 | 86 | NA |
| N | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 7 | 7 | 6 | 6 | 6 | 6 | 2 |
| Median | - | 85 | 85 | 71.5 | 66 | 68 | 75 | 67 | 69 | 70 | 73.5 | 69.5 | 67 | 75 | 71.5 | 62 | 66.5 | 73 | 88 |
| Min | - | 64 | 68 | 55 | 55 | 58 | 53 | 55 | 53 | 52 | 57 | 53 | 52 | 56 | 54 | 54 | 56 | 56 | 82 |
| Max | - | 98 | 100 | 98 | 82 | 87 | 84 | 84 | 87 | 88 | 95 | 77 | 95 | 98 | 89 | 90 | 90 | 86 | 94 |
| Mean | - | 82.12 | 84.88 | 70.75 | 67.12 | 70.88 | 71 | 68.62 | 69.25 | 69.38 | 74 | 66.88 | 70.57 | 76.71 | 70.5 | 68.67 | 69.5 | 72.83 | 88 |
| SD | - | 13.99 | 12.04 | 13.35 | 10.32 | 10.6 | 10.54 | 10.49 | 11.99 | 11.61 | 14.02 | 8.58 | 13.91 | 15.16 | 12.24 | 14.68 | 11.81 | 10.53 | 8.49 |
| CV | - | 0.17 | 0.14 | 0.19 | 0.15 | 0.15 | 0.15 | 0.15 | 0.17 | 0.17 | 0.19 | 0.13 | 0.2 | 0.2 | 0.17 | 0.21 | 0.17 | 0.14 | 0.1 |

16.4.6.4 활력징후[BODY TEMPERATURE]

| **SID** | **RID** | **Screening Visit\_** | **입원일(-1d)\_** | **투여일(1d)\_투여 전** | **투여일(1d)\_투여 후 4 h** | **투여일(1d)\_투여 후 10 h** | **투여일(2d)\_투여 전** | **투여일(2d)\_투여 후 4 h** | **투여일(2d)\_투여 후 10 h** | **투여일(3d)\_투여 전** | **투여일(3d)\_투여 후 4 h** | **투여일(3d)\_투여 후 10 h** | **투여일(4d)\_투여 전** | **투여일(4d)\_투여 후 4 h** | **투여일(4d)\_투여 후 10 h** | **투여일(5d)\_투여 전** | **투여일(5d)\_투여 후 4 h** | **투여일(5d)\_투여 후 10 h** | **UV1\_** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 36.9 | 36.9 | 36.1 | 36.7 | 36.7 | 36.5 | 36.2 | 37 | 36.5 | 36.9 | 36.7 | NA | NA | NA | NA | NA | NA | 36.8 |
| S02 | R020 | 36.1 | 36.6 | 36.6 | 36.9 | 36.9 | 36.4 | 36.8 | 37.1 | 36.4 | 37 | 36.8 | 36.8 | 36.4 | 36.6 | 36.3 | 36.9 | 37 | NA |
| S04 | R030 | 36.1 | 37 | 36.3 | 36.8 | 36.6 | 36.2 | 36.1 | 36.8 | 36.7 | 36.7 | 36.9 | 36.8 | 36.8 | 36 | 36.3 | 36.9 | 37 | NA |
| S07 | R040 | 36.3 | 37.2 | 36.9 | 36.6 | 36.7 | 36.5 | 37.2 | 37.2 | 37.2 | 37 | 36.8 | 36.4 | 36.9 | NA | NA | NA | NA | 36.9 |
| S09 | R050 | 36.6 | 37 | 36.4 | 36.5 | 36.1 | 36.1 | 36.1 | 36.5 | 36.1 | 36.4 | 36.3 | 36.6 | 36.7 | 36.1 | 36.7 | 36.5 | 36 | NA |
| S10 | R060 | 36.3 | 36.6 | 36.8 | 36.5 | 36.1 | 36.5 | 36.9 | 36.7 | 36.4 | 36.5 | 36.7 | 36.4 | 36.7 | 37.1 | 36.8 | 36.6 | 36.7 | NA |
| S11 | R070 | 37.1 | 36.8 | 36.6 | 36.9 | 36.6 | 36.9 | 36.4 | 36.7 | 37.2 | 36.3 | 36.7 | 36.8 | 36.9 | 36.5 | 36.5 | 36.8 | 36.8 | NA |
| S15 | R080 | 36.5 | 36.9 | 36 | 37.2 | 36.9 | 36.8 | 36.9 | 36.4 | 36.8 | 37 | 37.2 | 36.6 | 36.9 | 37.1 | 36.1 | 37.2 | 36.7 | NA |
| N | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 7 | 7 | 6 | 6 | 6 | 6 | 2 |
| Median | - | 36.4 | 36.9 | 36.5 | 36.75 | 36.65 | 36.5 | 36.6 | 36.75 | 36.6 | 36.8 | 36.75 | 36.6 | 36.8 | 36.55 | 36.4 | 36.85 | 36.75 | 36.85 |
| Min | - | 36.1 | 36.6 | 36 | 36.5 | 36.1 | 36.1 | 36.1 | 36.4 | 36.1 | 36.3 | 36.3 | 36.4 | 36.4 | 36 | 36.1 | 36.5 | 36 | 36.8 |
| Max | - | 37.1 | 37.2 | 36.9 | 37.2 | 36.9 | 36.9 | 37.2 | 37.2 | 37.2 | 37 | 37.2 | 36.8 | 36.9 | 37.1 | 36.8 | 37.2 | 37 | 36.9 |
| Mean | - | 36.49 | 36.88 | 36.46 | 36.76 | 36.58 | 36.49 | 36.58 | 36.8 | 36.66 | 36.73 | 36.76 | 36.63 | 36.76 | 36.57 | 36.45 | 36.82 | 36.7 | 36.85 |
| SD | - | 0.36 | 0.21 | 0.32 | 0.24 | 0.32 | 0.27 | 0.43 | 0.28 | 0.39 | 0.29 | 0.25 | 0.18 | 0.18 | 0.47 | 0.27 | 0.25 | 0.37 | 0.07 |
| CV | - | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0 | 0 | 0.01 | 0.01 | 0.01 | 0.01 | 0 |

### 12-Lead 심전도

16.4.7.1 12-Lead 심전도[Ventricular rate]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 58 | NA | 73 |
| S02 | R020 | 59 | 57 | NA |
| S04 | R030 | 58 | 61 | NA |
| S07 | R040 | 70 | NA | 86 |
| S09 | R050 | 72 | 61 | NA |
| S10 | R060 | 77 | 66 | NA |
| S11 | R070 | 56 | 50 | NA |
| S15 | R080 | 66 | 64 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 62.5 | 61 | 79.5 |
| Min | - | 56 | 50 | 73 |
| Max | - | 77 | 66 | 86 |
| Mean | - | 64.5 | 59.83 | 79.5 |
| SD | - | 7.86 | 5.71 | 9.19 |
| CV | - | 0.12 | 0.1 | 0.12 |

16.4.7.2 12-Lead 심전도[PR Interval]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 160 | NA | 152 |
| S02 | R020 | 180 | 184 | NA |
| S04 | R030 | 176 | 176 | NA |
| S07 | R040 | 152 | NA | 148 |
| S09 | R050 | 148 | 156 | NA |
| S10 | R060 | 168 | 140 | NA |
| S11 | R070 | 128 | 140 | NA |
| S15 | R080 | 148 | 148 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 156 | 152 | 150 |
| Min | - | 128 | 140 | 148 |
| Max | - | 180 | 184 | 152 |
| Mean | - | 157.5 | 157.33 | 150 |
| SD | - | 17.1 | 18.7 | 2.83 |
| CV | - | 0.11 | 0.12 | 0.02 |

16.4.7.3 12-Lead 심전도[QRSD Interval]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 82 | NA | 86 |
| S02 | R020 | 82 | 80 | NA |
| S04 | R030 | 92 | 92 | NA |
| S07 | R040 | 102 | NA | 92 |
| S09 | R050 | 100 | 98 | NA |
| S10 | R060 | 98 | 118 | NA |
| S11 | R070 | 94 | 90 | NA |
| S15 | R080 | 86 | 86 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 93 | 91 | 89 |
| Min | - | 82 | 80 | 86 |
| Max | - | 102 | 118 | 92 |
| Mean | - | 92 | 94 | 89 |
| SD | - | 7.93 | 13.21 | 4.24 |
| CV | - | 0.09 | 0.14 | 0.05 |

16.4.7.4 12-Lead 심전도[QT Interval]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 416 | NA | 388 |
| S02 | R020 | 376 | 388 | NA |
| S04 | R030 | 404 | 380 | NA |
| S07 | R040 | 392 | NA | 364 |
| S09 | R050 | 372 | 408 | NA |
| S10 | R060 | 368 | 396 | NA |
| S11 | R070 | 408 | 404 | NA |
| S15 | R080 | 412 | 396 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 398 | 396 | 376 |
| Min | - | 368 | 380 | 364 |
| Max | - | 416 | 408 | 388 |
| Mean | - | 393.5 | 395.33 | 376 |
| SD | - | 19.24 | 10.25 | 16.97 |
| CV | - | 0.05 | 0.03 | 0.05 |

16.4.7.5 12-Lead 심전도[QTc Interval]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 409 | NA | 428 |
| S02 | R020 | 373 | 378 | NA |
| S04 | R030 | 397 | 383 | NA |
| S07 | R040 | 423 | NA | 436 |
| S09 | R050 | 408 | 411 | NA |
| S10 | R060 | 417 | 415 | NA |
| S11 | R070 | 394 | 369 | NA |
| S15 | R080 | 432 | 409 | NA |
| N | 8 | 8 | 6 | 2 |
| Median | - | 408.5 | 396 | 432 |
| Min | - | 373 | 369 | 428 |
| Max | - | 432 | 415 | 436 |
| Mean | - | 406.62 | 394.17 | 432 |
| SD | - | 18.55 | 19.78 | 5.66 |
| CV | - | 0.05 | 0.05 | 0.01 |

16.4.7.6 12-Lead 심전도[Over all]

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 비정상/NCS | NA | 비정상/NCS |
| S02 | R020 | 비정상/NCS | 비정상/NCS | NA |
| S04 | R030 | 비정상/NCS | 정상 | NA |
| S07 | R040 | 정상 | NA | 정상 |
| S09 | R050 | 정상 | 정상 | NA |
| S10 | R060 | 정상 | 비정상/NCS | NA |
| S11 | R070 | 비정상/NCS | 비정상/NCS | NA |
| S15 | R080 | 정상 | 정상 | NA |

### 안과검사

16.4.8.1 시력검사(OD)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0.67 | NA | 0.67 |
| S02 | R020 | 1.54 | 1.18 | NA |
| S04 | R030 | 1.54 | 1.54 | NA |
| S07 | R040 | 1.54 | NA | 1.54 |
| S09 | R050 | 1.00 | 1 | NA |
| S10 | R060 | 0.80 | 0.8 | NA |
| S11 | R070 | 1.54 | 1.33 | NA |
| S15 | R080 | 1.54 | 1.54 | NA |

16.4.8.2 시력검사(OS)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 0.80 | NA | 0.8 |
| S02 | R020 | 2.00 | 1.54 | NA |
| S04 | R030 | 1.54 | 1.54 | NA |
| S07 | R040 | 1.54 | NA | 1.54 |
| S09 | R050 | 0.80 | 0.8 | NA |
| S10 | R060 | 1.54 | 1.54 | NA |
| S11 | R070 | 1.54 | 1.54 | NA |
| S15 | R080 | 1.33 | 1.33 | NA |

16.4.8.3 안압검사(OD)

| **SID** | **RID** | **Screening Visit\_1회** | **Screening Visit\_2회** | **Screening Visit\_평균** | **Screening Visit\_3회** | **투여일(5d)\_1회** | **투여일(5d)\_2회** | **투여일(5d)\_평균** | **투여일(5d)\_3회** | **투여일(5d)\_중앙값** | **UV1\_1회** | **UV1\_2회** | **UV1\_평균** | **UV1\_3회** | **UV1\_중앙값** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 16 | 17 | 16.5 | NA | NA | NA | NA | NA | NA | 17 | 16 | 16.5 | NA | NA |
| S02 | R020 | 16 | 15 | 15.5 | NA | 14 | 14 | 14 | NA | NA | NA | NA | NA | NA | NA |
| S04 | R030 | 16 | 17 | 16.5 | NA | 14 | 14 | 14 | NA | NA | NA | NA | NA | NA | NA |
| S07 | R040 | 11 | 12 | 11.5 | NA | NA | NA | NA | NA | NA | 12 | 12 | 12 | NA | NA |
| S09 | R050 | 18 | 18 | 18.0 | NA | 19 | 19 | 19 | NA | NA | NA | NA | NA | NA | NA |
| S10 | R060 | 16 | 17 | 16.5 | NA | 14 | 16 | 15 | NA | NA | NA | NA | NA | NA | NA |
| S11 | R070 | 17 | 16 | 16.5 | NA | 16 | 18 | 17 | NA | NA | NA | NA | NA | NA | NA |
| S15 | R080 | 11 | 13 | 12.0 | NA | 13 | 12 | 12.5 | NA | NA | NA | NA | NA | NA | NA |

16.4.8.4 안압검사(OS)

| **SID** | **RID** | **Screening Visit\_1회** | **Screening Visit\_2회** | **Screening Visit\_평균** | **Screening Visit\_3회** | **Screening Visit\_중앙값** | **투여일(5d)\_1회** | **투여일(5d)\_2회** | **투여일(5d)\_평균** | **투여일(5d)\_3회** | **투여일(5d)\_중앙값** | **UV1\_1회** | **UV1\_2회** | **UV1\_평균** | **UV1\_3회** | **UV1\_중앙값** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S01 | R010 | 20 | 17 | NA | 19 | 19 | NA | NA | NA | NA | NA | 19 | 18 | 18.5 | NA | NA |
| S02 | R020 | 17 | 15 | 16 | NA | NA | 15 | 15 | 15 | NA | NA | NA | NA | NA | NA | NA |
| S04 | R030 | 17 | 17 | 17 | NA | NA | 15 | 15 | 15 | NA | NA | NA | NA | NA | NA | NA |
| S07 | R040 | 12 | 12 | 12 | NA | NA | NA | NA | NA | NA | NA | 13 | 12 | 12.5 | NA | NA |
| S09 | R050 | 19 | 18 | 18.5 | NA | NA | 19 | 19 | 19 | NA | NA | NA | NA | NA | NA | NA |
| S10 | R060 | 16 | 15 | 15.5 | NA | NA | 17 | 15 | 16 | NA | NA | NA | NA | NA | NA | NA |
| S11 | R070 | 16 | 15 | 15.5 | NA | NA | 17 | 16 | 16.5 | NA | NA | NA | NA | NA | NA | NA |
| S15 | R080 | 11 | 11 | 11 | NA | NA | 11 | 10 | 10.5 | NA | NA | NA | NA | NA | NA | NA |

16.4.8.5 눈물막 파괴 시간(OD)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 11 | NA | NA |
| S02 | R020 | 11 | NA | NA |
| S04 | R030 | 13 | NA | NA |
| S07 | R040 | 14 | NA | NA |
| S09 | R050 | 11 | NA | NA |
| S10 | R060 | 12 | NA | NA |
| S11 | R070 | 11 | NA | NA |
| S15 | R080 | 15 | NA | NA |

16.4.8.6 눈물막 파괴 시간(OS)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 11 | NA | NA |
| S02 | R020 | 12 | NA | NA |
| S04 | R030 | 14 | NA | NA |
| S07 | R040 | 14 | NA | NA |
| S09 | R050 | 11 | NA | NA |
| S10 | R060 | 14 | NA | NA |
| S11 | R070 | 12 | NA | NA |
| S15 | R080 | 16 | NA | NA |

16.4.8.7 쉬르머 검사(OD)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 8 | NA | NA |
| S02 | R020 | 21 | NA | NA |
| S04 | R030 | 16 | NA | NA |
| S07 | R040 | 6 | NA | NA |
| S09 | R050 | 29 | NA | NA |
| S10 | R060 | 19 | NA | NA |
| S11 | R070 | 30 | NA | NA |
| S15 | R080 | 30 | NA | NA |

16.4.8.8 쉬르머 검사(OS)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | 22 | NA | NA |
| S02 | R020 | 30 | NA | NA |
| S04 | R030 | 16 | NA | NA |
| S07 | R040 | 9 | NA | NA |
| S09 | R050 | 11 | NA | NA |
| S10 | R060 | 16 | NA | NA |
| S11 | R070 | 19 | NA | NA |
| S15 | R080 | 28 | NA | NA |

16.4.8.9 세극동 검사(OD)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | grade Ⅰ | NA | grade 0 |
| S02 | R020 | grade Ⅰ | grade 0 | NA |
| S04 | R030 | grade 0 | grade 0 | NA |
| S07 | R040 | grade 0 | NA | grade 0 |
| S09 | R050 | grade Ⅰ | grade 0 | NA |
| S10 | R060 | grade 0 | grade 0 | NA |
| S11 | R070 | grade Ⅰ | grade 0 | NA |
| S15 | R080 | grade 0 | grade 0 | NA |

16.4.8.10 세극동 검사(OS)

| **SID** | **RID** | **Screening Visit** | **투여일(5d)** | **UV1** |
| --- | --- | --- | --- | --- |
| S01 | R010 | grade Ⅰ | NA | grade 0 |
| S02 | R020 | grade 0 | grade 0 | NA |
| S04 | R030 | grade 0 | grade 0 | NA |
| S07 | R040 | grade 0 | NA | grade 0 |
| S09 | R050 | grade Ⅰ | grade Ⅰ | NA |
| S10 | R060 | grade 0 | grade Ⅰ | NA |
| S11 | R070 | grade Ⅰ | grade Ⅰ | NA |
| S15 | R080 | grade 0 | grade 0 | NA |