

| 検査項目<br>(単位) | ステップ  | 投与群               | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|--------------|-------|-------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|              |       | 対照薬               | スクリーニング | 2 | 6.50 | 0.00 | 6.5 | 6.50 | 6.50   | 6.50 | 6.5 |          |          |
|              |       |                   | Day-1   | 2 | 6.25 | 1.06 | 5.5 | 5.50 | 6.25   | 7.00 | 7.0 |          |          |
|              |       |                   | Day1    | 2 | 5.75 | 0.35 | 5.5 | 5.50 | 5.75   | 6.00 | 6.0 |          |          |
|              |       |                   | Day2    | 2 | 5.75 | 0.35 | 5.5 | 5.50 | 5.75   | 6.00 | 6.0 |          |          |
|              |       |                   | Day7    | 2 | 6.00 | 0.71 | 5.5 | 5.50 | 6.00   | 6.50 | 6.5 |          |          |
|              | ステップ4 | PYRNA<br>0.66g/kg | スクリーニング | 6 | 6.17 | 0.75 | 5.5 | 5.50 | 6.00   | 6.50 | 7.5 | 1.27     | 1.53     |
|              |       |                   | Day-1   | 6 | 7.17 | 0.41 | 6.5 | 7.00 | 7.25   | 7.50 | 7.5 | -0.86    | -0.30    |
|              |       |                   | Day1    | 6 | 6.42 | 0.58 | 6.0 | 6.00 | 6.25   | 6.50 | 7.5 | 1.59     | 2.55     |
|              |       |                   | Day2    | 6 | 7.08 | 0.92 | 6.0 | 6.00 | 7.25   | 8.00 | 8.0 | -0.36    | -2.10    |
|              |       |                   | Day7    | 6 | 5.92 | 0.38 | 5.5 | 5.50 | 6.00   | 6.00 | 6.5 | 0.31     | -0.10    |
|              |       | 対照薬               | スクリーニング | 2 | 6.25 | 0.35 | 6.0 | 6.00 | 6.25   | 6.50 | 6.5 |          |          |
|              |       |                   | Day-1   | 2 | 6.25 | 0.35 | 6.0 | 6.00 | 6.25   | 6.50 | 6.5 |          |          |
|              |       |                   | Day1    | 2 | 6.25 | 0.35 | 6.0 | 6.00 | 6.25   | 6.50 | 6.5 |          |          |
|              |       |                   | Day2    | 2 | 6.00 | 0.00 | 6.0 | 6.00 | 6.00   | 6.00 | 6.0 |          |          |
|              |       |                   | Day7    | 2 | 6.75 | 0.35 | 6.5 | 6.50 | 6.75   | 7.00 | 7.0 |          |          |

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表 12. 4. 2-2 臨床検査値の要約 (2) ; 食事の影響の評価パート

| 検査項目(単位)                              | 投与群                          | Day   | N    | Mean  | SD    | Min   | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------------------------------|------------------------------|-------|------|-------|-------|-------|-------|--------|-------|------|----------|----------|
| 赤血球数<br>( $\times 10^4/\mu\text{L}$ ) | スクリーニング                      |       | 6    | 516.0 | 37.2  | 455   | 488.0 | 531.0  | 541.0 | 550  | -1.0     | -0.2     |
|                                       | 空腹時投与<br>(PYRNA<br>0.17g/kg) | Day-1 | 6    | 486.8 | 37.6  | 436   | 458.0 | 487.5  | 510.0 | 542  | 0.1      | -0.3     |
|                                       |                              | Day1  | 6    | 479.2 | 46.1  | 405   | 452.0 | 489.0  | 504.0 | 536  | -0.7     | 0.3      |
|                                       |                              | Day2  | 6    | 470.7 | 32.7  | 408   | 464.0 | 483.0  | 487.0 | 499  | -1.8     | 3.6      |
|                                       |                              | Day7  | 3    | 469.7 | 43.9  | 435   | 435.0 | 455.0  | 519.0 | 519  | 1.3      |          |
|                                       |                              | Day-1 | 6    | 481.3 | 22.1  | 447   | 467.0 | 483.5  | 498.0 | 509  | -0.5     | -0.1     |
|                                       |                              | Day1  | 6    | 470.7 | 31.6  | 426   | 440.0 | 478.0  | 495.0 | 507  | -0.5     | -1.3     |
| Day2                                  | 6                            | 477.5 | 35.4 | 417   | 454.0 | 492.0 | 499.0 | 511    | -1.2  | 0.6  |          |          |
| Day7                                  | 3                            | 524.7 | 14.3 | 509   | 509.0 | 528.0 | 537.0 | 537    | -1.0  |      |          |          |
| 白血球数<br>( $\times 10^2/\mu\text{L}$ ) | スクリーニング                      |       | 6    | 44.0  | 9.5   | 32    | 37.0  | 44.0   | 48.0  | 59   | 0.5      | 0.1      |
|                                       | 空腹時投与<br>(PYRNA<br>0.17g/kg) | Day-1 | 6    | 57.7  | 8.3   | 47    | 52.0  | 58.0   | 65.0  | 66   | -0.2     | -2.6     |
|                                       |                              | Day1  | 6    | 50.0  | 7.3   | 42    | 45.0  | 47.5   | 59.0  | 59   | 0.6      | -1.7     |
|                                       |                              | Day2  | 6    | 47.0  | 7.1   | 33    | 47.0  | 49.5   | 51.0  | 52   | -2.1     | 4.8      |
|                                       |                              | Day7  | 3    | 53.3  | 1.5   | 52    | 52.0  | 53.0   | 55.0  | 55   | 0.9      |          |
|                                       |                              | Day-1 | 6    | 58.3  | 9.4   | 44    | 53.0  | 59.5   | 62.0  | 72   | -0.2     | 0.8      |
|                                       |                              | Day1  | 6    | 48.8  | 10.7  | 36    | 41.0  | 47.5   | 58.0  | 63   | 0.2      | -2.0     |
| Day2                                  | 6                            | 45.5  | 8.9  | 34    | 38.0  | 46.0  | 51.0  | 58     | 0.1   | -1.0 |          |          |
| Day7                                  | 3                            | 47.7  | 21.9 | 35    | 35.0  | 35.0  | 73.0  | 73     | 1.7   |      |          |          |
| ヘモグロビン量<br>(g/dL)                     | スクリーニング                      |       | 6    | 15.67 | 1.17  | 14.2  | 14.60 | 15.75  | 16.30 | 17.4 | 0.21     | -0.58    |
|                                       | 空腹時投与                        | Day-1 | 6    | 15.03 | 1.09  | 13.9  | 14.30 | 14.60  | 16.40 | 16.4 | 0.71     | -1.80    |

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| 検査項目(単位)                              | 投与群                 | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------------------------------|---------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 14.53 | 1.48 | 12.5 | 13.50 | 14.40  | 16.10 | 16.3 | -0.02    | -1.23    |
|                                       |                     | Day2    | 6 | 14.37 | 1.00 | 12.7 | 14.10 | 14.35  | 15.20 | 15.5 | -0.80    | 0.78     |
|                                       |                     | Day7    | 3 | 14.13 | 1.18 | 13.4 | 13.40 | 13.50  | 15.50 | 15.5 | 1.72     |          |
|                                       | 食後投与                | Day-1   | 6 | 14.78 | 0.93 | 14.0 | 14.10 | 14.35  | 15.80 | 16.1 | 0.82     | -1.73    |
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 14.25 | 1.03 | 13.2 | 13.20 | 14.10  | 15.30 | 15.6 | 0.35     | -1.82    |
|                                       |                     | Day2    | 6 | 14.50 | 1.09 | 12.9 | 13.70 | 14.55  | 15.40 | 15.9 | -0.26    | -0.64    |
|                                       |                     | Day7    | 3 | 15.93 | 1.07 | 15.0 | 15.00 | 15.70  | 17.10 | 17.1 | 0.94     |          |
| ヘマトクリット値<br>(%)                       |                     | スクリーニング | 6 | 46.32 | 2.99 | 42.3 | 43.90 | 46.50  | 48.10 | 50.6 | 0.07     | -0.66    |
|                                       | 空腹時投与               | Day-1   | 6 | 43.70 | 2.78 | 41.4 | 41.60 | 42.40  | 46.50 | 47.9 | 0.98     | -1.24    |
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 42.72 | 3.76 | 37.7 | 40.00 | 42.30  | 46.70 | 47.3 | 0.07     | -1.42    |
|                                       |                     | Day2    | 6 | 42.28 | 2.32 | 38.5 | 41.30 | 42.35  | 44.60 | 44.6 | -0.72    | 0.14     |
|                                       |                     | Day7    | 3 | 41.53 | 2.42 | 39.8 | 39.80 | 40.50  | 44.30 | 44.3 | 1.57     |          |
|                                       | 食後投与                | Day-1   | 6 | 43.20 | 2.29 | 41.2 | 41.50 | 42.15  | 45.90 | 46.3 | 0.85     | -1.81    |
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 41.95 | 2.57 | 39.2 | 39.70 | 41.35  | 44.90 | 45.2 | 0.47     | -1.89    |
|                                       |                     | Day2    | 6 | 42.88 | 2.72 | 39.4 | 40.60 | 42.65  | 45.90 | 46.1 | 0.10     | -1.60    |
|                                       |                     | Day7    | 3 | 46.10 | 3.00 | 43.1 | 43.10 | 46.10  | 49.10 | 49.1 | 0.00     |          |
| 血小板数<br>( $\times 10^4/\mu\text{L}$ ) |                     | スクリーニング | 6 | 24.23 | 4.13 | 17.4 | 21.40 | 25.45  | 27.40 | 28.3 | -1.01    | 0.11     |
|                                       | 空腹時投与               | Day-1   | 6 | 23.98 | 4.58 | 18.0 | 21.50 | 22.95  | 27.90 | 30.6 | 0.35     | -0.72    |
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 21.02 | 3.97 | 15.1 | 19.40 | 20.40  | 24.90 | 25.9 | -0.19    | -0.54    |
|                                       |                     | Day2    | 6 | 20.45 | 3.36 | 15.0 | 18.80 | 20.60  | 23.70 | 24.0 | -0.69    | 0.14     |
|                                       |                     | Day7    | 3 | 23.57 | 4.04 | 20.1 | 20.10 | 22.60  | 28.00 | 28.0 | 1.02     |          |
|                                       | 食後投与                | Day-1   | 6 | 24.47 | 4.87 | 16.9 | 21.00 | 25.30  | 28.10 | 30.2 | -0.61    | -0.40    |
|                                       | (PYRNA<br>0.17g/kg) | Day1    | 6 | 21.32 | 4.36 | 15.6 | 18.40 | 21.20  | 25.10 | 26.4 | -0.11    | -2.16    |

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| 検査項目(単位)           | 投与群                 | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|--------------------|---------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|                    | 0.17g/kg)           |         |   |       |       |      |       |        |       |      |          |          |
|                    |                     | Day2    | 6 | 21.88 | 3.90  | 16.1 | 18.30 | 23.05  | 25.40 | 25.4 | -0.72    | -1.35    |
|                    |                     | Day7    | 3 | 22.87 | 5.44  | 16.6 | 16.60 | 25.60  | 26.40 | 26.4 | -1.69    |          |
| 白血球分画(好中球)<br>(%)  |                     | スクリーニング | 6 | 55.70 | 9.30  | 41.4 | 50.80 | 56.80  | 58.90 | 69.5 | -0.14    | 1.13     |
|                    | 空腹時投与               | Day-1   | 6 | 54.52 | 8.66  | 43.3 | 49.40 | 52.55  | 62.40 | 66.9 | 0.38     | -0.79    |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 50.92 | 11.72 | 35.9 | 39.40 | 53.15  | 61.10 | 62.8 | -0.31    | -2.38    |
|                    |                     | Day2    | 6 | 57.07 | 10.34 | 42.7 | 46.10 | 60.85  | 64.40 | 67.5 | -0.67    | -1.73    |
|                    |                     | Day7    | 3 | 58.27 | 5.58  | 53.5 | 53.50 | 56.90  | 64.40 | 64.4 | 1.04     |          |
|                    | 食後投与                | Day-1   | 6 | 57.80 | 10.14 | 40.1 | 55.80 | 59.20  | 61.60 | 70.9 | -0.93    | 2.23     |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 49.12 | 9.69  | 34.7 | 40.60 | 51.45  | 56.10 | 60.4 | -0.59    | -0.92    |
|                    |                     | Day2    | 6 | 57.45 | 10.38 | 42.9 | 47.80 | 60.35  | 61.90 | 71.4 | -0.30    | -0.69    |
|                    |                     | Day7    | 3 | 61.57 | 6.31  | 55.8 | 55.80 | 60.60  | 68.30 | 68.3 | 0.67     |          |
| 白血球分画(好酸球)<br>(%)  |                     | スクリーニング | 6 | 4.17  | 2.79  | 1.1  | 1.40  | 4.25   | 6.30  | 7.7  | 0.07     | -2.37    |
|                    | 空腹時投与               | Day-1   | 6 | 2.83  | 1.69  | 0.7  | 1.90  | 2.75   | 3.10  | 5.8  | 0.96     | 2.15     |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 4.33  | 2.22  | 1.7  | 3.20  | 3.75   | 5.50  | 8.1  | 0.96     | 1.09     |
|                    |                     | Day2    | 6 | 3.47  | 1.78  | 1.8  | 2.30  | 2.70   | 5.00  | 6.3  | 1.02     | -0.59    |
|                    |                     | Day7    | 3 | 3.40  | 1.13  | 2.7  | 2.70  | 2.80   | 4.70  | 4.7  | 1.72     |          |
|                    | 食後投与                | Day-1   | 6 | 3.95  | 3.11  | 1.1  | 1.80  | 2.55   | 7.10  | 8.6  | 0.93     | -1.28    |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 5.22  | 2.68  | 1.9  | 3.40  | 4.65   | 7.70  | 9.0  | 0.41     | -1.13    |
|                    |                     | Day2    | 6 | 4.35  | 2.65  | 1.6  | 2.70  | 3.35   | 6.70  | 8.4  | 0.80     | -0.96    |
|                    |                     | Day7    | 3 | 1.97  | 1.53  | 0.8  | 0.80  | 1.40   | 3.70  | 3.7  | 1.44     |          |
| 白血球分画(好塩基球)<br>(%) |                     | スクリーニング | 6 | 0.73  | 0.29  | 0.2  | 0.60  | 0.85   | 0.90  | 1.0  | -1.48    | 1.94     |
|                    | 空腹時投与               | Day-1   | 6 | 0.67  | 0.27  | 0.3  | 0.60  | 0.60   | 0.80  | 1.1  | 0.54     | 1.28     |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.70  | 0.30  | 0.3  | 0.60  | 0.65   | 0.80  | 1.2  | 0.69     | 1.74     |

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| 検査項目(単位)    | 投与群                 | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|-------------|---------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|             | 0.17g/kg            |         |   |       |       |      |       |        |       |      |          |          |
|             |                     | Day2    | 6 | 0.58  | 0.27  | 0.4  | 0.40  | 0.50   | 0.60  | 1.1  | 1.79     | 3.38     |
|             |                     | Day7    | 3 | 0.57  | 0.06  | 0.5  | 0.50  | 0.60   | 0.60  | 0.6  | -1.73    |          |
|             | 食後投与                | Day-1   | 6 | 0.63  | 0.33  | 0.3  | 0.30  | 0.60   | 0.90  | 1.1  | 0.38     | -1.48    |
|             | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.70  | 0.28  | 0.4  | 0.50  | 0.65   | 0.90  | 1.1  | 0.43     | -1.57    |
|             |                     | Day2    | 6 | 0.53  | 0.22  | 0.2  | 0.40  | 0.55   | 0.70  | 0.8  | -0.46    | -0.30    |
|             |                     | Day7    | 3 | 0.60  | 0.30  | 0.3  | 0.30  | 0.60   | 0.90  | 0.9  | 0.00     |          |
| 白血球分画(リンパ球) |                     | スクリーニング | 6 | 34.43 | 7.59  | 25.3 | 27.00 | 34.90  | 38.80 | 45.7 | 0.24     | -0.66    |
| (%)         | 空腹時投与               | Day-1   | 6 | 36.28 | 7.20  | 27.3 | 27.70 | 38.10  | 42.50 | 44.0 | -0.52    | -1.83    |
|             | (PYRNA<br>0.17g/kg) | Day1    | 6 | 38.28 | 10.33 | 27.7 | 30.20 | 36.80  | 45.20 | 53.0 | 0.38     | -1.88    |
|             |                     | Day2    | 6 | 33.35 | 9.35  | 22.8 | 27.40 | 30.60  | 41.50 | 47.2 | 0.60     | -1.13    |
|             |                     | Day7    | 3 | 33.13 | 5.46  | 26.9 | 26.90 | 35.40  | 37.10 | 37.1 | -1.55    |          |
|             | 食後投与                | Day-1   | 6 | 32.22 | 7.24  | 22.8 | 28.00 | 31.65  | 34.80 | 44.4 | 0.72     | 1.45     |
|             | (PYRNA<br>0.17g/kg) | Day1    | 6 | 39.22 | 7.90  | 29.7 | 33.00 | 38.10  | 46.90 | 49.5 | 0.23     | -1.83    |
|             |                     | Day2    | 6 | 32.60 | 7.90  | 22.5 | 28.50 | 30.25  | 40.80 | 43.3 | 0.39     | -1.15    |
|             |                     | Day7    | 3 | 31.20 | 3.98  | 26.6 | 26.60 | 33.40  | 33.60 | 33.6 | -1.73    |          |
| 白血球分画(単球)   |                     | スクリーニング | 6 | 4.97  | 1.31  | 3.6  | 3.70  | 4.95   | 5.60  | 7.0  | 0.54     | -0.71    |
| (%)         | 空腹時投与               | Day-1   | 6 | 5.70  | 0.77  | 4.8  | 4.90  | 5.80   | 6.30  | 6.6  | -0.13    | -2.41    |
|             | (PYRNA<br>0.17g/kg) | Day1    | 6 | 5.77  | 0.73  | 4.9  | 5.00  | 5.80   | 6.40  | 6.7  | -0.03    | -1.63    |
|             |                     | Day2    | 6 | 5.53  | 0.56  | 4.5  | 5.50  | 5.65   | 5.70  | 6.2  | -1.36    | 3.22     |
|             |                     | Day7    | 3 | 4.63  | 0.59  | 4.2  | 4.20  | 4.40   | 5.30  | 5.3  | 1.51     |          |
|             | 食後投与                | Day-1   | 6 | 5.40  | 1.38  | 3.7  | 4.50  | 5.10   | 6.50  | 7.5  | 0.55     | -0.53    |
|             | (PYRNA<br>0.17g/kg) | Day1    | 6 | 5.75  | 1.67  | 4.3  | 4.30  | 5.25   | 6.90  | 8.5  | 0.98     | -0.12    |

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| 検査項目(単位) | 投与群                 | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|----------|---------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|          |                     | Day2    | 6 | 5.07 | 1.13 | 4.1 | 4.30 | 4.70   | 5.50 | 7.1 | 1.37     | 1.65     |
|          |                     | Day7    | 3 | 4.67 | 1.15 | 4.0 | 4.00 | 4.00   | 6.00 | 6.0 | 1.73     |          |
| 総蛋白      |                     | スクリーニング | 6 | 7.35 | 0.42 | 6.8 | 7.10 | 7.25   | 7.80 | 7.9 | 0.29     | -1.26    |
| (g/dL)   | 空腹時投与               | Day-1   | 6 | 7.17 | 0.33 | 6.8 | 6.90 | 7.15   | 7.30 | 7.7 | 0.68     | -0.22    |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 6.53 | 0.48 | 5.9 | 6.00 | 6.65   | 6.90 | 7.1 | -0.45    | -1.63    |
|          |                     | Day2    | 6 | 6.50 | 0.36 | 6.0 | 6.30 | 6.45   | 6.80 | 7.0 | 0.12     | -0.49    |
|          |                     | Day7    | 3 | 7.00 | 0.30 | 6.7 | 6.70 | 7.00   | 7.30 | 7.3 | 0.00     |          |
|          | 食後投与                | Day-1   | 6 | 7.02 | 0.43 | 6.4 | 6.90 | 6.95   | 7.20 | 7.7 | 0.34     | 1.47     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 6.42 | 0.19 | 6.2 | 6.20 | 6.45   | 6.50 | 6.7 | 0.15     | -0.85    |
|          |                     | Day2    | 6 | 6.55 | 0.48 | 5.8 | 6.30 | 6.60   | 6.80 | 7.2 | -0.40    | 0.59     |
|          |                     | Day7    | 3 | 7.53 | 0.60 | 6.9 | 6.90 | 7.60   | 8.10 | 8.1 | -0.49    |          |
| アルブミン    |                     | スクリーニング | 6 | 4.93 | 0.28 | 4.6 | 4.70 | 4.90   | 5.20 | 5.3 | 0.22     | -1.86    |
| (g/dL)   | 空腹時投与               | Day-1   | 6 | 4.90 | 0.32 | 4.5 | 4.60 | 4.95   | 5.00 | 5.4 | 0.32     | -0.01    |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 4.38 | 0.37 | 4.0 | 4.10 | 4.35   | 4.60 | 4.9 | 0.35     | -1.93    |
|          |                     | Day2    | 6 | 4.28 | 0.19 | 4.0 | 4.20 | 4.30   | 4.30 | 4.6 | 0.35     | 1.91     |
|          |                     | Day7    | 3 | 4.60 | 0.10 | 4.5 | 4.50 | 4.60   | 4.70 | 4.7 | 0.00     |          |
|          | 食後投与                | Day-1   | 6 | 4.72 | 0.31 | 4.3 | 4.50 | 4.75   | 4.80 | 5.2 | 0.33     | 0.69     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 4.33 | 0.21 | 4.1 | 4.20 | 4.30   | 4.40 | 4.7 | 1.17     | 1.97     |
|          |                     | Day2    | 6 | 4.35 | 0.33 | 4.0 | 4.10 | 4.30   | 4.50 | 4.9 | 0.93     | 0.56     |
|          |                     | Day7    | 3 | 5.17 | 0.35 | 4.8 | 4.80 | 5.20   | 5.50 | 5.5 | -0.42    |          |
| 総ビリルビン   |                     | スクリーニング | 6 | 0.82 | 0.17 | 0.5 | 0.80 | 0.85   | 0.90 | 1.0 | -1.44    | 2.72     |
| (mg/dL)  | 空腹時投与               | Day-1   | 6 | 0.80 | 0.26 | 0.5 | 0.60 | 0.80   | 1.00 | 1.1 | 0.00     | -2.83    |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.83 | 0.23 | 0.6 | 0.60 | 0.80   | 1.10 | 1.1 | 0.25     | -2.41    |

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| 検査項目(単位) | 投与群                 | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|----------|---------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|          |                     | Day2    | 6 | 0.85 | 0.16 | 0.7 | 0.70 | 0.80   | 1.00 | 1.1 | 0.81     | -1.03    |
|          |                     | Day7    | 3 | 0.67 | 0.06 | 0.6 | 0.60 | 0.70   | 0.70 | 0.7 | -1.73    |          |
|          | 食後投与                | Day-1   | 6 | 0.67 | 0.20 | 0.3 | 0.60 | 0.75   | 0.80 | 0.8 | -1.67    | 2.67     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.65 | 0.14 | 0.4 | 0.60 | 0.70   | 0.70 | 0.8 | -1.37    | 2.35     |
|          |                     | Day2    | 6 | 0.72 | 0.08 | 0.6 | 0.70 | 0.70   | 0.80 | 0.8 | -0.31    | -0.10    |
|          |                     | Day7    | 3 | 1.40 | 1.04 | 0.7 | 0.70 | 0.90   | 2.60 | 2.6 | 1.66     |          |
| AST      |                     | スクリーニング | 6 | 15.8 | 0.8  | 15  | 15.0 | 16.0   | 16.0 | 17  | 0.3      | -0.1     |
| (U/L)    | 空腹時投与               | Day-1   | 6 | 15.5 | 1.0  | 14  | 15.0 | 15.5   | 16.0 | 17  | 0.0      | -0.2     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 13.3 | 1.2  | 12  | 12.0 | 13.5   | 14.0 | 15  | 0.1      | -1.5     |
|          |                     | Day2    | 6 | 12.3 | 0.8  | 11  | 12.0 | 12.5   | 13.0 | 13  | -0.9     | -0.3     |
|          |                     | Day7    | 3 | 16.3 | 3.2  | 14  | 14.0 | 15.0   | 20.0 | 20  | 1.5      |          |
|          | 食後投与                | Day-1   | 6 | 15.0 | 1.1  | 14  | 14.0 | 15.0   | 16.0 | 16  | 0.0      | -3.3     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 13.0 | 0.6  | 12  | 13.0 | 13.0   | 13.0 | 14  | 0.0      | 2.5      |
|          |                     | Day2    | 6 | 13.2 | 0.8  | 12  | 13.0 | 13.0   | 14.0 | 14  | -0.3     | -0.1     |
|          |                     | Day7    | 3 | 20.3 | 8.4  | 15  | 15.0 | 16.0   | 30.0 | 30  | 1.7      |          |
| ALT      |                     | スクリーニング | 6 | 12.2 | 4.0  | 7   | 9.0  | 12.5   | 14.0 | 18  | 0.2      | -0.6     |
| (U/L)    | 空腹時投与               | Day-1   | 6 | 10.3 | 3.0  | 5   | 9.0  | 11.0   | 13.0 | 13  | -1.3     | 1.5      |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 9.7  | 2.3  | 6   | 8.0  | 10.0   | 12.0 | 12  | -0.7     | -0.4     |
|          |                     | Day2    | 6 | 9.2  | 2.3  | 5   | 8.0  | 10.0   | 11.0 | 11  | -1.5     | 1.7      |
|          |                     | Day7    | 3 | 10.0 | 3.5  | 6   | 6.0  | 12.0   | 12.0 | 12  | -1.7     |          |
|          | 食後投与                | Day-1   | 6 | 10.0 | 2.2  | 7   | 8.0  | 10.5   | 11.0 | 13  | -0.2     | -0.8     |
|          | (PYRNA<br>0.17g/kg) | Day1    | 6 | 8.7  | 2.3  | 5   | 7.0  | 9.5    | 10.0 | 11  | -1.0     | -0.1     |
|          |                     | Day2    | 6 | 9.5  | 2.1  | 6   | 8.0  | 10.5   | 11.0 | 11  | -1.2     | 0.2      |

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| 検査項目(単位)      | 投与群                 | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|---------------|---------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|               |                     | Day7    | 3 | 15.3  | 0.6  | 15  | 15.0  | 15.0   | 16.0  | 16  | 1.7      |          |
| ALP           |                     | スクリーニング | 6 | 202.7 | 58.6 | 145 | 151.0 | 192.0  | 262.0 | 274 | 0.2      | -2.6     |
| (U/L)         | 空腹時投与               | Day-1   | 6 | 198.3 | 52.5 | 148 | 150.0 | 185.5  | 258.0 | 263 | 0.4      | -2.3     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 178.3 | 48.5 | 130 | 135.0 | 172.0  | 214.0 | 247 | 0.4      | -1.9     |
|               |                     | Day2    | 6 | 173.7 | 42.2 | 136 | 136.0 | 163.5  | 215.0 | 228 | 0.3      | -2.5     |
|               |                     | Day7    | 3 | 175.0 | 47.8 | 138 | 138.0 | 158.0  | 229.0 | 229 | 1.4      |          |
|               | 食後投与                | Day-1   | 6 | 191.5 | 55.4 | 140 | 145.0 | 172.5  | 251.0 | 268 | 0.7      | -1.8     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 173.7 | 46.0 | 133 | 137.0 | 156.5  | 228.0 | 231 | 0.6      | -2.2     |
|               |                     | Day2    | 6 | 173.0 | 44.3 | 133 | 136.0 | 160.0  | 212.0 | 237 | 0.6      | -1.7     |
|               |                     | Day7    | 3 | 215.7 | 62.2 | 151 | 151.0 | 221.0  | 275.0 | 275 | -0.4     |          |
| LDH           |                     | スクリーニング | 6 | 143.8 | 14.8 | 127 | 135.0 | 138.5  | 159.0 | 165 | 0.7      | -1.3     |
| (U/L)         | 空腹時投与               | Day-1   | 6 | 140.7 | 15.3 | 126 | 128.0 | 137.5  | 154.0 | 161 | 0.3      | -2.4     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 114.8 | 14.0 | 96  | 104.0 | 115.5  | 122.0 | 136 | 0.2      | 0.0      |
|               |                     | Day2    | 6 | 104.0 | 11.2 | 93  | 95.0  | 100.0  | 117.0 | 119 | 0.7      | -1.8     |
|               |                     | Day7    | 3 | 125.0 | 16.7 | 110 | 110.0 | 122.0  | 143.0 | 143 | 0.8      |          |
|               | 食後投与                | Day-1   | 6 | 136.5 | 17.8 | 116 | 127.0 | 134.0  | 140.0 | 168 | 1.1      | 2.0      |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 110.2 | 8.9  | 99  | 106.0 | 107.0  | 120.0 | 122 | 0.5      | -1.3     |
|               |                     | Day2    | 6 | 108.3 | 10.8 | 96  | 99.0  | 107.0  | 117.0 | 124 | 0.4      | -1.2     |
|               |                     | Day7    | 3 | 144.0 | 18.2 | 123 | 123.0 | 153.0  | 156.0 | 156 | -1.7     |          |
| $\gamma$ -GTP |                     | スクリーニング | 6 | 24.3  | 10.7 | 16  | 17.0  | 18.5   | 36.0  | 40  | 1.0      | -1.5     |
| (U/L)         | 空腹時投与               | Day-1   | 6 | 20.8  | 8.2  | 13  | 14.0  | 18.0   | 29.0  | 33  | 0.8      | -1.3     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 20.0  | 9.4  | 12  | 14.0  | 15.0   | 30.0  | 34  | 1.0      | -1.4     |
|               |                     | Day2    | 6 | 18.3  | 8.1  | 11  | 12.0  | 15.0   | 27.0  | 30  | 0.8      | -1.6     |

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| 検査項目(単位)            | 投与群                 | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------------|---------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                     |                     | Day7    | 3 | 13.0  | 7.0  | 5    | 5.0   | 16.0   | 18.0  | 18   | -1.6     |          |
|                     | 食後投与                | Day-1   | 6 | 19.2  | 7.7  | 12   | 13.0  | 16.5   | 26.0  | 31   | 0.9      | -1.0     |
|                     | (PYRNA<br>0.17g/kg) | Day1    | 6 | 18.0  | 6.2  | 11   | 14.0  | 16.0   | 25.0  | 26   | 0.5      | -1.9     |
|                     |                     | Day2    | 6 | 18.3  | 6.9  | 12   | 14.0  | 15.0   | 25.0  | 29   | 1.0      | -1.0     |
|                     |                     | Day7    | 3 | 23.7  | 7.1  | 16   | 16.0  | 25.0   | 30.0  | 30   | -0.8     |          |
| BUN<br>(mg/dL)      |                     | スクリーニング | 6 | 11.50 | 4.24 | 4.9  | 11.20 | 11.45  | 11.70 | 18.3 | 0.11     | 2.48     |
|                     | 空腹時投与               | Day-1   | 6 | 12.22 | 3.96 | 5.4  | 9.70  | 13.65  | 15.00 | 15.9 | -1.24    | 0.76     |
|                     | (PYRNA<br>0.17g/kg) | Day1    | 6 | 13.02 | 3.26 | 8.3  | 9.60  | 14.40  | 15.20 | 16.2 | -0.82    | -1.48    |
|                     |                     | Day2    | 6 | 11.80 | 3.22 | 6.9  | 9.70  | 12.00  | 14.60 | 15.6 | -0.45    | -0.59    |
|                     |                     | Day7    | 3 | 10.03 | 3.10 | 6.5  | 6.50  | 11.30  | 12.30 | 12.3 | -1.53    |          |
|                     | 食後投与                | Day-1   | 6 | 12.47 | 4.00 | 6.5  | 9.50  | 12.90  | 15.70 | 17.3 | -0.42    | -0.76    |
|                     | (PYRNA<br>0.17g/kg) | Day1    | 6 | 13.00 | 2.89 | 8.6  | 10.70 | 13.70  | 14.80 | 16.5 | -0.59    | -0.54    |
|                     |                     | Day2    | 6 | 10.30 | 2.24 | 6.4  | 9.50  | 10.70  | 11.70 | 12.8 | -1.08    | 1.41     |
|                     |                     | Day7    | 3 | 13.97 | 4.80 | 10.9 | 10.90 | 11.50  | 19.50 | 19.5 | 1.70     |          |
| 総コレステロール<br>(mg/dL) |                     | スクリーニング | 6 | 167.5 | 31.8 | 118  | 153.0 | 166.5  | 195.0 | 206  | -0.4     | -0.2     |
|                     | 空腹時投与               | Day-1   | 6 | 161.7 | 27.6 | 120  | 147.0 | 160.0  | 188.0 | 195  | -0.3     | -0.5     |
|                     | (PYRNA<br>0.17g/kg) | Day1    | 6 | 157.2 | 32.1 | 107  | 145.0 | 153.5  | 189.0 | 195  | -0.4     | 0.0      |
|                     |                     | Day2    | 6 | 155.7 | 25.3 | 113  | 147.0 | 156.0  | 181.0 | 181  | -0.8     | 0.8      |
|                     |                     | Day7    | 3 | 141.7 | 23.8 | 116  | 116.0 | 146.0  | 163.0 | 163  | -0.8     |          |
|                     | 食後投与                | Day-1   | 6 | 156.7 | 16.5 | 134  | 144.0 | 157.5  | 172.0 | 175  | -0.2     | -1.8     |
|                     | (PYRNA<br>0.17g/kg) | Day1    | 6 | 150.2 | 13.0 | 128  | 142.0 | 154.0  | 161.0 | 162  | -1.1     | 0.6      |
|                     |                     | Day2    | 6 | 151.3 | 18.3 | 117  | 148.0 | 156.0  | 161.0 | 170  | -1.6     | 3.2      |
|                     |                     | Day7    | 3 | 158.7 | 11.0 | 146  | 146.0 | 164.0  | 166.0 | 166  | -1.7     |          |

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| 検査項目(単位)           | 投与群                 | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|--------------------|---------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
| トリグリセリド<br>(mg/dL) |                     | スクリーニング | 6 | 62.7  | 24.4  | 36   | 45.0  | 57.0   | 80.0  | 101  | 0.7      | -0.6     |
|                    | 空腹時投与               | Day-1   | 6 | 77.7  | 24.6  | 52   | 55.0  | 75.5   | 89.0  | 119  | 0.9      | 0.7      |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 59.8  | 12.0  | 50   | 52.0  | 56.5   | 61.0  | 83   | 1.9      | 4.0      |
|                    |                     | Day2    | 6 | 58.3  | 6.1   | 51   | 52.0  | 58.5   | 64.0  | 66   | 0.0      | -1.7     |
|                    |                     | Day7    | 3 | 52.7  | 15.9  | 42   | 42.0  | 45.0   | 71.0  | 71   | 1.7      |          |
|                    | 食後投与                | Day-1   | 6 | 92.0  | 32.2  | 51   | 70.0  | 92.0   | 101.0 | 146  | 0.7      | 1.3      |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 63.3  | 10.8  | 54   | 55.0  | 62.0   | 63.0  | 84   | 1.8      | 3.6      |
|                    |                     | Day2    | 6 | 75.2  | 9.4   | 60   | 72.0  | 75.5   | 81.0  | 87   | -0.6     | 0.5      |
|                    |                     | Day7    | 3 | 54.0  | 28.0  | 34   | 34.0  | 42.0   | 86.0  | 86   | 1.6      |          |
| 尿酸<br>(mg/dL)      |                     | スクリーニング | 6 | 5.22  | 1.29  | 3.6  | 4.20  | 5.25   | 5.70  | 7.3  | 0.54     | 0.48     |
|                    | 空腹時投与               | Day-1   | 6 | 5.30  | 1.32  | 3.6  | 4.20  | 5.20   | 6.60  | 7.0  | 0.11     | -1.41    |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 5.43  | 1.25  | 4.1  | 4.20  | 5.25   | 6.70  | 7.1  | 0.35     | -1.79    |
|                    |                     | Day2    | 6 | 5.02  | 1.17  | 3.9  | 3.90  | 4.70   | 6.30  | 6.6  | 0.60     | -1.75    |
|                    |                     | Day7    | 3 | 4.07  | 0.42  | 3.6  | 3.60  | 4.20   | 4.40  | 4.4  | -1.29    |          |
|                    | 食後投与                | Day-1   | 6 | 4.83  | 1.25  | 3.2  | 3.40  | 5.20   | 6.00  | 6.0  | -0.61    | -1.89    |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 5.03  | 1.08  | 3.7  | 3.90  | 5.10   | 6.10  | 6.3  | -0.14    | -1.76    |
|                    |                     | Day2    | 6 | 4.65  | 0.95  | 3.4  | 4.00  | 4.50   | 5.60  | 5.9  | 0.20     | -1.20    |
|                    |                     | Day7    | 3 | 6.23  | 1.33  | 4.7  | 4.70  | 6.90   | 7.10  | 7.1  | -1.69    |          |
| クレアチニン<br>(mg/dL)  |                     | スクリーニング | 6 | 0.743 | 0.086 | 0.66 | 0.680 | 0.715  | 0.820 | 0.87 | 0.660    | -1.473   |
|                    | 空腹時投与               | Day-1   | 6 | 0.770 | 0.087 | 0.65 | 0.690 | 0.785  | 0.820 | 0.89 | -0.170   | -0.708   |
|                    | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.693 | 0.082 | 0.59 | 0.620 | 0.700  | 0.750 | 0.80 | -0.020   | -1.863   |
|                    |                     | Day2    | 6 | 0.707 | 0.076 | 0.57 | 0.670 | 0.735  | 0.760 | 0.77 | -1.494   | 1.840    |
|                    |                     | Day7    | 3 | 0.680 | 0.106 | 0.60 | 0.600 | 0.640  | 0.800 | 0.80 | 1.458    |          |

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| 検査項目(単位)      | 投与群                 | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------|---------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|               | 食後投与                | Day-1   | 6 | 0.768 | 0.080 | 0.69 | 0.700 | 0.745  | 0.840 | 0.89 | 0.790    | -0.987   |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 0.685 | 0.066 | 0.58 | 0.630 | 0.710  | 0.730 | 0.75 | -0.954   | -0.546   |
|               |                     | Day2    | 6 | 0.693 | 0.091 | 0.54 | 0.630 | 0.730  | 0.750 | 0.78 | -1.168   | 0.378    |
|               |                     | Day7    | 3 | 0.757 | 0.051 | 0.70 | 0.700 | 0.770  | 0.800 | 0.80 | -1.090   |          |
| CPK<br>(U/L)  | スクリーニング             | スクリーニング | 6 | 98.0  | 37.8  | 64   | 73.0  | 86.5   | 112.0 | 166  | 1.4      | 1.8      |
|               | 空腹時投与               | Day-1   | 6 | 113.0 | 46.0  | 73   | 77.0  | 102.5  | 130.0 | 193  | 1.2      | 1.0      |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 83.5  | 28.2  | 50   | 57.0  | 84.0   | 107.0 | 119  | 0.0      | -2.1     |
|               |                     | Day2    | 6 | 67.3  | 18.8  | 49   | 50.0  | 65.5   | 83.0  | 91   | 0.2      | -2.7     |
|               |                     | Day7    | 3 | 84.0  | 35.5  | 62   | 62.0  | 65.0   | 125.0 | 125  | 1.7      |          |
|               | 食後投与                | Day-1   | 6 | 112.8 | 40.5  | 74   | 77.0  | 109.5  | 146.0 | 161  | 0.1      | -3.0     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 79.0  | 24.4  | 55   | 57.0  | 78.0   | 98.0  | 108  | 0.1      | -3.0     |
|               |                     | Day2    | 6 | 67.0  | 16.6  | 49   | 52.0  | 68.0   | 81.0  | 84   | 0.0      | -3.1     |
|               |                     | Day7    | 3 | 108.0 | 29.6  | 88   | 88.0  | 94.0   | 142.0 | 142  | 1.7      |          |
| Na<br>(mEq/L) | スクリーニング             | スクリーニング | 6 | 139.5 | 1.5   | 138  | 138.0 | 139.5  | 140.0 | 142  | 0.8      | 0.3      |
|               | 空腹時投与               | Day-1   | 6 | 139.8 | 1.9   | 138  | 138.0 | 139.5  | 141.0 | 143  | 0.8      | -0.1     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 140.3 | 0.8   | 139  | 140.0 | 140.5  | 141.0 | 141  | -0.9     | -0.3     |
|               |                     | Day2    | 6 | 139.2 | 1.2   | 138  | 138.0 | 139.0  | 140.0 | 141  | 0.7      | -0.4     |
|               |                     | Day7    | 3 | 138.3 | 1.2   | 137  | 137.0 | 139.0  | 139.0 | 139  | -1.7     |          |
|               | 食後投与                | Day-1   | 6 | 139.8 | 1.2   | 139  | 139.0 | 139.5  | 140.0 | 142  | 1.6      | 2.6      |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 140.8 | 0.8   | 140  | 140.0 | 141.0  | 141.0 | 142  | 0.3      | -0.1     |
|               |                     | Day2    | 6 | 139.7 | 1.6   | 138  | 138.0 | 139.5  | 141.0 | 142  | 0.4      | -1.5     |
|               |                     | Day7    | 3 | 138.0 | 1.0   | 137  | 137.0 | 138.0  | 139.0 | 139  | 0.0      |          |
| K             | スクリーニング             | スクリーニング | 6 | 4.32  | 0.27  | 3.9  | 4.20  | 4.30   | 4.50  | 4.7  | -0.17    | 0.59     |

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| 検査項目(単位)      | 投与群                 | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|---------------|---------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
| (mEq/L)       | 空腹時投与               | Day-1   | 6 | 4.02  | 0.17 | 3.8 | 3.90  | 4.00   | 4.20  | 4.2 | -0.03    | -2.37    |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 3.87  | 0.23 | 3.5 | 3.80  | 3.90   | 3.90  | 4.2 | -0.33    | 2.05     |
|               |                     | Day2    | 6 | 3.93  | 0.24 | 3.7 | 3.80  | 3.90   | 3.90  | 4.4 | 1.83     | 4.06     |
|               |                     | Day7    | 3 | 4.00  | 0.26 | 3.8 | 3.80  | 3.90   | 4.30  | 4.3 | 1.46     |          |
|               | 食後投与                | Day-1   | 6 | 4.03  | 0.33 | 3.6 | 3.70  | 4.10   | 4.20  | 4.5 | -0.09    | -0.77    |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 3.92  | 0.24 | 3.7 | 3.70  | 3.85   | 4.10  | 4.3 | 0.88     | -0.50    |
|               |                     | Day2    | 6 | 4.05  | 0.34 | 3.8 | 3.80  | 3.95   | 4.10  | 4.7 | 1.85     | 3.64     |
|               |                     | Day7    | 3 | 3.90  | 0.26 | 3.6 | 3.60  | 4.00   | 4.10  | 4.1 | -1.46    |          |
| Cl<br>(mEq/L) | スクリーニング             | スクリーニング | 6 | 102.5 | 2.2  | 100 | 101.0 | 102.0  | 104.0 | 106 | 0.8      | 0.1      |
|               | 空腹時投与               | Day-1   | 6 | 103.5 | 2.9  | 100 | 101.0 | 103.5  | 105.0 | 108 | 0.5      | -0.1     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 107.0 | 1.3  | 105 | 106.0 | 107.5  | 108.0 | 108 | -0.9     | -0.8     |
|               |                     | Day2    | 6 | 105.5 | 1.0  | 104 | 105.0 | 105.5  | 106.0 | 107 | 0.0      | -0.2     |
|               |                     | Day7    | 3 | 103.3 | 2.1  | 101 | 101.0 | 104.0  | 105.0 | 105 | -1.3     |          |
|               | 食後投与                | Day-1   | 6 | 104.2 | 1.8  | 102 | 103.0 | 104.0  | 105.0 | 107 | 0.5      | -0.6     |
|               | (PYRNA<br>0.17g/kg) | Day1    | 6 | 107.7 | 0.5  | 107 | 107.0 | 108.0  | 108.0 | 108 | -1.0     | -1.9     |
|               |                     | Day2    | 6 | 105.2 | 1.7  | 103 | 104.0 | 105.0  | 106.0 | 108 | 0.7      | 0.8      |
|               |                     | Day7    | 3 | 101.3 | 2.3  | 100 | 100.0 | 100.0  | 104.0 | 104 | 1.7      |          |
| 血糖<br>(mg/dL) | スクリーニング             | スクリーニング | 6 | 87.3  | 4.0  | 82  | 83.0  | 88.5   | 90.0  | 92  | -0.5     | -1.5     |
|               | 空腹時投与               | Day1    | 6 | 85.5  | 3.4  | 82  | 84.0  | 84.5   | 86.0  | 92  | 1.6      | 3.4      |
|               | (PYRNA<br>0.17g/kg) | Day2    | 6 | 84.2  | 3.5  | 80  | 82.0  | 83.0   | 88.0  | 89  | 0.6      | -1.4     |
|               |                     | Day7    | 3 | 84.7  | 6.0  | 79  | 79.0  | 84.0   | 91.0  | 91  | 0.5      |          |
|               | 食後投与                | Day1    | 6 | 85.2  | 4.7  | 78  | 82.0  | 85.5   | 89.0  | 91  | -0.4     | -0.4     |
|               | (PYRNA<br>0.17g/kg) | Day2    | 6 | 85.8  | 3.5  | 81  | 83.0  | 86.0   | 88.0  | 91  | 0.1      | -0.3     |

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| 検査項目(単位)                     | 投与群                 | Day     | N | Mean   | SD    | Min   | Q1     | Median | Q3     | Max   | Skewness | Kurtosis |
|------------------------------|---------------------|---------|---|--------|-------|-------|--------|--------|--------|-------|----------|----------|
|                              | 0.17g/kg)           |         |   |        |       |       |        |        |        |       |          |          |
|                              |                     | Day7    | 3 | 82.3   | 13.3  | 67    | 67.0   | 89.0   | 91.0   | 91    | -1.7     |          |
| eGFR                         |                     | スクリーニング | 6 | 104.00 | 12.57 | 89.7  | 89.70  | 105.50 | 116.10 | 117.5 | -0.21    | -2.32    |
| (mL/min/1.73m <sup>2</sup> ) | 空腹時投与               | Day-1   | 6 | 100.07 | 12.40 | 84.7  | 92.00  | 97.80  | 108.70 | 119.4 | 0.57     | -0.16    |
|                              | (PYRNA<br>0.17g/kg) | Day1    | 6 | 112.13 | 11.92 | 103.2 | 103.40 | 105.70 | 125.80 | 129.0 | 0.96     | -1.69    |
|                              |                     | Day2    | 6 | 110.07 | 15.22 | 88.4  | 102.50 | 110.05 | 115.50 | 133.9 | 0.26     | 0.89     |
|                              |                     | Day7    | 3 | 117.17 | 12.19 | 103.4 | 103.40 | 121.50 | 126.60 | 126.6 | -1.40    |          |
|                              | 食後投与                | Day-1   | 6 | 100.55 | 14.45 | 74.4  | 93.20  | 106.45 | 110.90 | 111.9 | -1.52    | 1.80     |
|                              | (PYRNA<br>0.17g/kg) | Day1    | 6 | 113.50 | 13.24 | 93.8  | 105.50 | 113.35 | 123.60 | 131.4 | -0.18    | -0.14    |
|                              |                     | Day2    | 6 | 113.13 | 18.85 | 85.9  | 104.30 | 111.45 | 123.60 | 142.1 | 0.20     | 0.80     |
|                              |                     | Day7    | 3 | 99.33  | 12.68 | 87.2  | 87.20  | 98.30  | 112.50 | 112.5 | 0.36     |          |
| Ccr                          |                     | スクリーニング | 6 | 133.3  | 11.6  | 120   | 122.0  | 133.5  | 141.0  | 150   | 0.2      | -1.2     |
| (ml/min)                     | 空腹時投与               | Day-1   | 6 | 127.5  | 10.5  | 116   | 117.0  | 126.5  | 137.0  | 142   | 0.3      | -1.5     |
|                              | (PYRNA<br>0.17g/kg) | Day1    | 6 | 141.8  | 10.2  | 124   | 139.0  | 143.0  | 149.0  | 153   | -1.1     | 1.4      |
|                              |                     | Day2    | 6 | 139.5  | 18.1  | 119   | 125.0  | 136.5  | 152.0  | 168   | 0.7      | -0.3     |
|                              |                     | Day7    | 3 | 147.3  | 4.9   | 144   | 144.0  | 145.0  | 153.0  | 153   | 1.7      |          |
|                              | 食後投与                | Day-1   | 6 | 129.0  | 21.7  | 101   | 123.0  | 124.0  | 135.0  | 167   | 1.0      | 2.3      |
|                              | (PYRNA<br>0.17g/kg) | Day1    | 6 | 143.8  | 16.4  | 125   | 131.0  | 143.0  | 150.0  | 171   | 0.8      | 0.5      |
|                              |                     | Day2    | 6 | 143.2  | 20.3  | 116   | 123.0  | 146.0  | 161.0  | 167   | -0.3     | -1.5     |
|                              |                     | Day7    | 3 | 126.3  | 7.4   | 118   | 118.0  | 129.0  | 132.0  | 132   | -1.4     |          |
| pH                           |                     | スクリーニング | 6 | 6.42   | 0.38  | 6.0   | 6.00   | 6.50   | 6.50   | 7.0   | 0.31     | -0.10    |
|                              | 空腹時投与               | Day-1   | 6 | 6.33   | 0.82  | 5.5   | 5.50   | 6.25   | 7.00   | 7.5   | 0.38     | -1.48    |
|                              | (PYRNA<br>0.17g/kg) | Day1    | 6 | 6.08   | 0.20  | 6.0   | 6.00   | 6.00   | 6.00   | 6.5   | 2.45     | 6.00     |

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| 検査項目(単位) | 投与群                 | Day   | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|----------|---------------------|-------|---|------|------|-----|------|--------|------|-----|----------|----------|
|          |                     | Day2  | 6 | 6.58 | 0.20 | 6.5 | 6.50 | 6.50   | 6.50 | 7.0 | 2.45     | 6.00     |
|          |                     | Day7  | 3 | 6.17 | 0.76 | 5.5 | 5.50 | 6.00   | 7.00 | 7.0 | 0.94     |          |
|          | 食後投与                | Day-1 | 6 | 6.67 | 0.93 | 5.5 | 6.00 | 6.50   | 7.50 | 8.0 | 0.39     | -0.94    |
|          | (PYRNA<br>0.17g/kg) | Day1  | 6 | 6.33 | 0.41 | 6.0 | 6.00 | 6.25   | 6.50 | 7.0 | 0.86     | -0.30    |
|          |                     | Day2  | 6 | 6.92 | 0.74 | 6.0 | 6.50 | 6.75   | 7.50 | 8.0 | 0.42     | -0.86    |
|          |                     | Day7  | 3 | 6.00 | 0.00 | 6.0 | 6.00 | 6.00   | 6.00 | 6.0 |          |          |

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表 12. 4. 2-3 臨床検査値の要約(3) ; 反復投与パート

| 検査項目(単位)                              | ステップ  | 投与群                  | Day                  | N       | Mean  | SD    | Min  | Q1    | Median | Q3    | Max   | Skewness | Kurtosis |      |
|---------------------------------------|-------|----------------------|----------------------|---------|-------|-------|------|-------|--------|-------|-------|----------|----------|------|
| 赤血球数<br>( $\times 10^4/\mu\text{L}$ ) | ステップ1 | 対照薬                  | スクリーニング              | 3       | 487.7 | 19.1  | 466  | 466.0 | 495.0  | 502.0 | 502   | -1.5     |          |      |
|                                       |       |                      | Day-1                | 3       | 464.3 | 42.2  | 439  | 439.0 | 441.0  | 513.0 | 513   | 1.7      |          |      |
|                                       |       |                      | Day1                 | 3       | 455.0 | 40.7  | 417  | 417.0 | 450.0  | 498.0 | 498   | 0.5      |          |      |
|                                       |       |                      | Day8                 | 3       | 447.7 | 36.1  | 416  | 416.0 | 440.0  | 487.0 | 487   | 0.9      |          |      |
|                                       |       |                      | Day14                | 3       | 456.7 | 35.7  | 429  | 429.0 | 444.0  | 497.0 | 497   | 1.4      |          |      |
|                                       |       |                      | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 520.0 | 38.3 | 452   | 500.0  | 534.0 | 546.0 | 554      | -1.4     | 1.4  |
|                                       |       |                      |                      | Day-1   | 6     | 512.5 | 39.2 | 461   | 495.0  | 500.5 | 553.0 | 565      | 0.3      | -1.1 |
|                                       |       |                      |                      | Day1    | 6     | 499.2 | 25.1 | 457   | 488.0  | 501.5 | 521.0 | 526      | -0.9     | 0.7  |
|                                       |       |                      |                      | Day8    | 6     | 498.8 | 23.1 | 458   | 494.0  | 500.0 | 518.0 | 523      | -1.1     | 1.7  |
|                                       |       |                      |                      | Day14   | 6     | 507.8 | 32.5 | 457   | 493.0  | 505.5 | 542.0 | 544      | -0.4     | -0.1 |
|                                       |       |                      | PYRNA<br>1.0g/kg/day | スクリーニング | 6     | 489.3 | 32.7 | 443   | 463.0  | 494.0 | 507.0 | 535      | -0.1     | -0.4 |
|                                       |       |                      |                      | Day-1   | 6     | 491.5 | 22.3 | 457   | 485.0  | 491.5 | 498.0 | 526      | 0.0      | 1.8  |
|                                       |       |                      |                      | Day1    | 6     | 476.0 | 32.6 | 428   | 446.0  | 487.0 | 493.0 | 515      | -0.6     | -0.9 |
|                                       |       |                      |                      | Day8    | 6     | 464.2 | 35.1 | 414   | 438.0  | 466.0 | 495.0 | 506      | -0.3     | -1.3 |
| Day14                                 |       |                      |                      | 6       | 480.0 | 51.0  | 404  | 431.0 | 501.5  | 521.0 | 521   | -0.8     | -1.4     |      |
|                                       | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング              | 6       | 523.8 | 24.8  | 496  | 508.0 | 517.5  | 542.0 | 562   | 0.6      | -0.8     |      |
|                                       |       |                      | Day-1                | 6       | 493.7 | 11.4  | 482  | 486.0 | 489.0  | 507.0 | 509   | 0.7      | -1.7     |      |
|                                       |       |                      | Day1                 | 6       | 489.7 | 19.7  | 461  | 476.0 | 491.0  | 502.0 | 517   | -0.1     | -0.3     |      |
|                                       |       |                      | 中止時                  | 6       | 484.2 | 19.5  | 454  | 470.0 | 489.0  | 495.0 | 508   | -0.6     | -0.3     |      |
|                                       |       |                      | Day14                | 6       | 497.7 | 28.1  | 460  | 480.0 | 496.0  | 523.0 | 531   | -0.1     | -1.9     |      |
| 白血球数<br>( $\times 10^2/\mu\text{L}$ ) | ステップ1 | 対照薬                  | スクリーニング              | 3       | 75.3  | 18.0  | 57   | 57.0  | 76.0   | 93.0  | 93    | -0.2     |          |      |
|                                       |       |                      | Day-1                | 3       | 66.0  | 6.0   | 60   | 60.0  | 66.0   | 72.0  | 72    | 0.0      |          |      |
|                                       |       |                      | Day1                 | 3       | 57.3  | 13.7  | 45   | 45.0  | 55.0   | 72.0  | 72    | 0.7      |          |      |

| 検査項目(単位)         | ステップ  | 投与群                  | Day                  | N       | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |      |
|------------------|-------|----------------------|----------------------|---------|-------|------|------|-------|--------|-------|------|----------|----------|------|
|                  |       |                      | Day8                 | 3       | 59.0  | 18.2 | 47   | 47.0  | 50.0   | 80.0  | 80   | 1.7      |          |      |
|                  |       |                      | Day14                | 3       | 76.3  | 24.8 | 62   | 62.0  | 62.0   | 105.0 | 105  | 1.7      |          |      |
|                  |       |                      | スクリーニング              | 6       | 54.2  | 10.5 | 44   | 47.0  | 52.0   | 58.0  | 72   | 1.0      | 0.6      |      |
|                  |       |                      | Day-1                | 6       | 58.3  | 13.2 | 46   | 50.0  | 53.5   | 65.0  | 82   | 1.4      | 1.7      |      |
|                  |       |                      | Day1                 | 6       | 52.2  | 7.8  | 40   | 50.0  | 52.0   | 55.0  | 64   | -0.1     | 1.7      |      |
|                  |       |                      | PYRNA<br>0.5g/kg/day | Day8    | 6     | 51.0 | 10.8 | 42    | 45.0   | 47.5  | 52.0 | 72       | 1.9      | 4.0  |
|                  |       |                      |                      | Day14   | 6     | 58.3 | 8.3  | 49    | 52.0   | 58.0  | 60.0 | 73       | 1.1      | 1.8  |
|                  |       |                      |                      | スクリーニング | 6     | 57.2 | 12.6 | 39    | 53.0   | 56.5  | 60.0 | 78       | 0.4      | 2.0  |
|                  |       |                      |                      | Day-1   | 6     | 64.8 | 15.1 | 47    | 56.0   | 61.5  | 73.0 | 90       | 0.9      | 0.7  |
|                  |       |                      |                      | Day1    | 6     | 54.0 | 10.6 | 41    | 49.0   | 52.0  | 58.0 | 72       | 0.9      | 1.3  |
|                  |       |                      | PYRNA<br>1.0g/kg/day | Day8    | 6     | 54.7 | 12.2 | 43    | 44.0   | 53.0  | 62.0 | 73       | 0.5      | -1.4 |
|                  |       |                      |                      | Day14   | 6     | 58.3 | 13.8 | 44    | 46.0   | 56.5  | 68.0 | 79       | 0.5      | -1.2 |
|                  |       |                      |                      | スクリーニング | 6     | 61.0 | 10.0 | 51    | 53.0   | 58.0  | 72.0 | 74       | 0.5      | -2.1 |
|                  |       |                      |                      | Day-1   | 6     | 67.2 | 9.3  | 53    | 61.0   | 68.0  | 76.0 | 77       | -0.5     | -0.9 |
| Day1             |       |                      |                      | 6       | 59.2  | 11.0 | 47   | 47.0  | 59.0   | 71.0  | 72   | 0.0      | -2.0     |      |
|                  |       | PYRNA<br>2.0g/kg/day | 中止時                  | 6       | 68.2  | 10.6 | 58   | 59.0  | 67.5   | 70.0  | 87   | 1.2      | 1.8      |      |
|                  |       |                      | Day14                | 6       | 62.8  | 16.2 | 44   | 50.0  | 62.0   | 69.0  | 90   | 0.8      | 0.9      |      |
|                  |       |                      | スクリーニング              | 3       | 15.17 | 0.38 | 14.9 | 14.90 | 15.00  | 15.60 | 15.6 | 1.60     |          |      |
|                  |       |                      | Day-1                | 3       | 14.53 | 1.10 | 13.8 | 13.80 | 14.00  | 15.80 | 15.8 | 1.67     |          |      |
|                  |       |                      | Day1                 | 3       | 14.23 | 0.95 | 13.3 | 13.30 | 14.20  | 15.20 | 15.2 | 0.16     |          |      |
| ヘモグロビン<br>(g/dL) | ステップ1 | 対照薬                  | Day8                 | 3       | 13.93 | 0.87 | 13.2 | 13.20 | 13.70  | 14.90 | 14.9 | 1.12     |          |      |
|                  |       |                      | Day14                | 3       | 14.40 | 0.70 | 13.9 | 13.90 | 14.10  | 15.20 | 15.2 | 1.57     |          |      |
|                  |       |                      | スクリーニング              | 6       | 15.53 | 1.21 | 13.4 | 15.20 | 15.65  | 16.60 | 16.7 | -1.17    | 1.57     |      |



| 検査項目(単位)        | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|-----------------|-------|----------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                 |       |                      | Day-1   | 6 | 15.40 | 1.10 | 14.0 | 14.50 | 15.35  | 16.30 | 16.9 | 0.13     | -1.40    |
|                 |       |                      | Day1    | 6 | 15.03 | 0.82 | 13.9 | 14.20 | 15.30  | 15.50 | 16.0 | -0.51    | -1.43    |
|                 |       |                      | Day8    | 6 | 14.98 | 0.70 | 13.7 | 14.90 | 15.05  | 15.60 | 15.6 | -1.46    | 2.66     |
|                 |       |                      | Day14   | 6 | 15.32 | 0.99 | 13.9 | 14.70 | 15.35  | 15.90 | 16.7 | -0.06    | -0.40    |
|                 |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 14.67 | 0.73 | 13.6 | 14.30 | 14.65  | 15.00 | 15.8 | 0.18     | 1.03     |
|                 |       |                      | Day-1   | 6 | 14.87 | 0.51 | 14.4 | 14.50 | 14.75  | 15.00 | 15.8 | 1.44     | 2.17     |
|                 |       |                      | Day1    | 6 | 14.33 | 0.54 | 13.9 | 13.90 | 14.20  | 14.50 | 15.3 | 1.36     | 1.68     |
|                 |       |                      | Day8    | 6 | 13.92 | 0.88 | 12.7 | 13.20 | 14.00  | 14.40 | 15.2 | 0.03     | -0.27    |
|                 |       |                      | Day14   | 6 | 14.53 | 1.19 | 12.5 | 14.10 | 14.75  | 15.40 | 15.7 | -1.03    | 0.60     |
|                 | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 15.75 | 0.87 | 14.9 | 15.20 | 15.50  | 16.10 | 17.3 | 1.33     | 1.74     |
|                 |       |                      | Day-1   | 6 | 14.85 | 0.51 | 14.3 | 14.60 | 14.75  | 14.90 | 15.8 | 1.53     | 3.25     |
|                 |       |                      | Day1    | 6 | 14.83 | 0.60 | 13.8 | 14.70 | 14.85  | 15.30 | 15.5 | -0.99    | 1.29     |
|                 |       |                      | 中止時     | 6 | 14.58 | 0.76 | 13.5 | 14.10 | 14.55  | 15.40 | 15.4 | -0.21    | -1.29    |
|                 |       |                      | Day14   | 6 | 15.02 | 1.02 | 13.8 | 14.30 | 14.75  | 16.20 | 16.3 | 0.43     | -1.67    |
| ヘマトクリット値<br>(%) | ステップ1 | 対照薬                  | スクリーニング | 3 | 45.10 | 1.11 | 43.9 | 43.90 | 45.30  | 46.10 | 46.1 | -0.78    |          |
|                 |       |                      | Day-1   | 3 | 43.03 | 2.27 | 41.3 | 41.30 | 42.20  | 45.60 | 45.6 | 1.43     |          |
|                 |       |                      | Day1    | 3 | 41.60 | 2.61 | 38.9 | 38.90 | 41.80  | 44.10 | 44.1 | -0.34    |          |
|                 |       |                      | Day8    | 3 | 40.60 | 2.05 | 38.6 | 38.60 | 40.50  | 42.70 | 42.7 | 0.22     |          |
|                 |       |                      | Day14   | 3 | 41.97 | 1.53 | 40.8 | 40.80 | 41.40  | 43.70 | 43.7 | 1.44     |          |
|                 |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 45.93 | 3.28 | 40.4 | 44.80 | 46.15  | 48.10 | 50.0 | -0.80    | 1.26     |
|                 |       |                      | Day-1   | 6 | 45.95 | 2.72 | 41.8 | 44.30 | 46.30  | 47.70 | 49.3 | -0.45    | -0.54    |
|                 |       |                      | Day1    | 6 | 44.27 | 1.90 | 41.5 | 42.50 | 44.85  | 45.80 | 46.1 | -0.66    | -1.53    |
|                 |       |                      | Day8    | 6 | 43.95 | 1.67 | 40.8 | 43.90 | 44.15  | 45.20 | 45.5 | -1.63    | 3.26     |
|                 |       |                      | Day14   | 6 | 44.63 | 2.39 | 40.8 | 43.50 | 44.70  | 47.00 | 47.1 | -0.64    | -0.14    |

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| 検査項目(単位)                              | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------------------------------|-------|----------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                                       |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 43.70 | 2.40 | 39.4 | 42.60 | 44.55  | 44.90 | 46.2 | -1.35    | 1.86     |
|                                       |       |                      | Day-1   | 6 | 44.23 | 1.03 | 43.2 | 43.20 | 44.20  | 44.70 | 45.9 | 0.69     | -0.01    |
|                                       |       |                      | Day1    | 6 | 42.08 | 1.97 | 38.7 | 41.30 | 42.45  | 43.30 | 44.3 | -1.02    | 1.17     |
|                                       |       |                      | Day8    | 6 | 40.88 | 2.94 | 36.0 | 38.60 | 42.25  | 42.90 | 43.3 | -1.16    | -0.09    |
|                                       |       |                      | Day14   | 6 | 42.63 | 3.84 | 35.6 | 41.60 | 43.70  | 45.60 | 45.6 | -1.50    | 2.22     |
|                                       | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 46.60 | 2.47 | 43.7 | 45.50 | 46.20  | 47.00 | 51.0 | 1.16     | 2.22     |
|                                       |       |                      | Day-1   | 6 | 43.38 | 1.27 | 42.2 | 42.60 | 43.10  | 43.50 | 45.8 | 1.72     | 3.47     |
|                                       |       |                      | Day1    | 6 | 43.13 | 1.94 | 39.5 | 42.60 | 43.75  | 44.50 | 44.7 | -1.68    | 2.88     |
|                                       |       |                      | 中止時     | 6 | 43.02 | 1.96 | 39.3 | 42.40 | 43.85  | 44.30 | 44.4 | -1.82    | 3.18     |
|                                       |       |                      | Day14   | 6 | 44.20 | 2.73 | 40.2 | 43.00 | 43.75  | 46.80 | 47.7 | -0.09    | -0.52    |
| 血小板数<br>( $\times 10^4/\mu\text{L}$ ) | ステップ1 | 対照薬                  | スクリーニング | 3 | 23.40 | 5.38 | 17.7 | 17.70 | 24.10  | 28.40 | 28.4 | -0.58    |          |
|                                       |       |                      | Day-1   | 3 | 22.67 | 2.75 | 20.0 | 20.00 | 22.50  | 25.50 | 25.5 | 0.27     |          |
|                                       |       |                      | Day1    | 3 | 21.13 | 2.86 | 18.4 | 18.40 | 20.90  | 24.10 | 24.1 | 0.37     |          |
|                                       |       |                      | Day8    | 3 | 22.43 | 1.34 | 20.9 | 20.90 | 23.00  | 23.40 | 23.4 | -1.56    |          |
|                                       |       |                      | Day14   | 3 | 23.53 | 1.02 | 22.8 | 22.80 | 23.10  | 24.70 | 24.7 | 1.57     |          |
|                                       |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 25.33 | 4.44 | 18.6 | 21.90 | 26.25  | 28.90 | 30.1 | -0.61    | -1.01    |
|                                       |       |                      | Day-1   | 6 | 26.58 | 4.28 | 20.6 | 22.00 | 28.40  | 28.60 | 31.5 | -0.65    | -1.36    |
|                                       |       |                      | Day1    | 6 | 24.78 | 4.13 | 18.8 | 20.70 | 26.00  | 28.00 | 29.2 | -0.68    | -1.32    |
|                                       |       |                      | Day8    | 6 | 23.93 | 4.76 | 18.0 | 19.60 | 23.80  | 28.00 | 30.4 | 0.13     | -1.30    |
|                                       |       |                      | Day14   | 6 | 26.23 | 4.30 | 19.8 | 22.90 | 26.85  | 30.30 | 30.7 | -0.53    | -1.09    |
|                                       |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 23.28 | 5.96 | 12.0 | 23.10 | 24.10  | 27.80 | 28.6 | -1.69    | 3.43     |
|                                       |       |                      | Day-1   | 6 | 23.45 | 5.70 | 12.8 | 22.20 | 24.90  | 26.80 | 29.1 | -1.59    | 3.03     |
|                                       |       |                      | Day1    | 6 | 21.38 | 5.31 | 11.8 | 20.00 | 22.20  | 25.50 | 26.6 | -1.34    | 2.11     |

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| 検査項目(単位)          | ステップ  | 投与群                  | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|-------------------|-------|----------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|                   |       |                      | Day8    | 6 | 20.30 | 5.10  | 10.8 | 19.70 | 21.15  | 23.90 | 25.1 | -1.57    | 2.94     |
|                   |       |                      | Day14   | 6 | 23.68 | 5.68  | 13.4 | 23.90 | 24.25  | 25.40 | 30.9 | -1.15    | 3.08     |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 25.53 | 3.54  | 21.5 | 23.00 | 25.40  | 26.10 | 31.8 | 1.12     | 2.03     |
|                   |       |                      | Day-1   | 6 | 25.12 | 3.20  | 22.2 | 23.40 | 24.05  | 25.80 | 31.2 | 1.77     | 3.45     |
|                   |       |                      | Day1    | 6 | 22.80 | 3.09  | 20.0 | 20.60 | 21.85  | 24.10 | 28.4 | 1.45     | 1.98     |
|                   |       |                      | 中止時     | 6 | 22.78 | 3.09  | 19.5 | 20.50 | 22.20  | 24.50 | 27.8 | 0.80     | -0.12    |
|                   |       |                      | Day14   | 6 | 25.52 | 3.52  | 21.9 | 23.00 | 25.05  | 26.20 | 31.9 | 1.35     | 2.30     |
| 白血球分画(好中球<br>(%)) | ステップ1 | 対照薬                  | スクリーニング | 3 | 55.57 | 13.12 | 43.6 | 43.60 | 53.50  | 69.60 | 69.6 | 0.69     |          |
|                   |       |                      | Day-1   | 3 | 55.23 | 2.23  | 52.7 | 52.70 | 56.10  | 56.90 | 56.9 | -1.48    |          |
|                   |       |                      | Day1    | 3 | 45.77 | 7.78  | 38.4 | 38.40 | 45.00  | 53.90 | 53.9 | 0.44     |          |
|                   |       |                      | Day8    | 3 | 55.60 | 5.41  | 50.0 | 50.00 | 56.00  | 60.80 | 60.8 | -0.33    |          |
|                   |       |                      | Day14   | 3 | 54.73 | 6.47  | 50.9 | 50.90 | 51.10  | 62.20 | 62.2 | 1.73     |          |
|                   |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 58.15 | 6.56  | 49.7 | 50.90 | 59.35  | 64.70 | 64.9 | -0.42    | -1.80    |
|                   |       |                      | Day-1   | 6 | 55.53 | 7.26  | 44.0 | 52.70 | 56.30  | 57.60 | 66.3 | -0.23    | 1.61     |
|                   |       |                      | Day1    | 6 | 49.58 | 6.34  | 41.8 | 44.00 | 49.35  | 53.90 | 59.1 | 0.35     | -0.54    |
|                   |       |                      | Day8    | 6 | 63.33 | 4.55  | 57.4 | 59.60 | 63.05  | 67.50 | 69.4 | 0.11     | -1.20    |
|                   |       |                      | Day14   | 6 | 52.40 | 5.66  | 45.1 | 46.40 | 53.40  | 56.70 | 59.4 | -0.29    | -1.54    |
|                   |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 53.17 | 5.15  | 48.2 | 48.30 | 52.05  | 57.60 | 60.8 | 0.61     | -1.27    |
|                   |       |                      | Day-1   | 6 | 54.92 | 5.52  | 48.5 | 49.70 | 55.05  | 59.90 | 61.3 | -0.03    | -2.58    |
|                   |       |                      | Day1    | 6 | 53.10 | 2.11  | 49.3 | 52.50 | 53.45  | 54.90 | 55.0 | -1.33    | 1.93     |
|                   |       |                      | Day8    | 6 | 61.70 | 5.58  | 53.3 | 57.60 | 62.25  | 67.20 | 67.6 | -0.49    | -0.91    |
|                   |       |                      | Day14   | 6 | 55.50 | 5.12  | 47.2 | 51.90 | 56.65  | 60.20 | 60.4 | -0.88    | -0.13    |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 54.97 | 10.15 | 38.8 | 50.30 | 54.80  | 65.00 | 66.1 | -0.56    | -0.03    |

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| 検査項目(単位)          | ステップ  | 投与群                  | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|-------------------|-------|----------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|                   |       |                      | Day-1   | 6 | 56.17 | 7.33  | 48.2 | 49.50 | 55.95  | 59.90 | 67.5 | 0.53     | -0.72    |
|                   |       |                      | Day1    | 6 | 48.33 | 8.99  | 36.2 | 42.40 | 48.50  | 55.50 | 58.9 | -0.17    | -1.99    |
|                   |       |                      | 中止時     | 6 | 57.50 | 10.94 | 39.9 | 52.00 | 58.65  | 67.80 | 68.0 | -0.74    | -0.32    |
|                   |       |                      | Day14   | 6 | 52.48 | 7.71  | 42.2 | 46.30 | 53.25  | 57.60 | 62.3 | -0.11    | -1.67    |
| 白血球分画(好酸球<br>(%)) | ステップ1 | 対照薬                  | スクリーニング | 3 | 2.90  | 0.85  | 2.1  | 2.10  | 2.80   | 3.80  | 3.8  | 0.52     |          |
|                   |       |                      | Day-1   | 3 | 4.07  | 2.40  | 1.7  | 1.70  | 4.00   | 6.50  | 6.5  | 0.12     |          |
|                   |       |                      | Day1    | 3 | 5.27  | 0.90  | 4.7  | 4.70  | 4.80   | 6.30  | 6.3  | 1.71     |          |
|                   |       |                      | Day8    | 3 | 4.13  | 1.46  | 2.6  | 2.60  | 4.30   | 5.50  | 5.5  | -0.51    |          |
|                   |       |                      | Day14   | 3 | 3.90  | 1.48  | 2.9  | 2.90  | 3.20   | 5.60  | 5.6  | 1.65     |          |
|                   |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 3.05  | 2.46  | 0.7  | 0.90  | 2.85   | 3.50  | 7.5  | 1.31     | 2.23     |
|                   |       |                      | Day-1   | 6 | 3.05  | 2.64  | 0.4  | 0.90  | 2.70   | 3.90  | 7.7  | 1.18     | 1.57     |
|                   |       |                      | Day1    | 6 | 4.02  | 2.63  | 1.3  | 1.60  | 3.95   | 4.70  | 8.6  | 1.02     | 1.45     |
|                   |       |                      | Day8    | 6 | 2.40  | 1.26  | 0.4  | 1.70  | 2.60   | 3.50  | 3.6  | -0.72    | -0.64    |
|                   |       |                      | Day14   | 6 | 2.97  | 1.99  | 0.8  | 0.90  | 3.05   | 4.10  | 5.9  | 0.30     | -1.01    |
|                   |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 4.30  | 2.37  | 1.3  | 2.40  | 4.30   | 6.70  | 6.8  | -0.10    | -2.41    |
|                   |       |                      | Day-1   | 6 | 4.63  | 4.21  | 1.5  | 2.10  | 3.20   | 4.90  | 12.9 | 2.05     | 4.45     |
|                   |       |                      | Day1    | 6 | 4.80  | 3.49  | 2.0  | 2.20  | 4.00   | 5.20  | 11.4 | 1.72     | 3.25     |
|                   |       |                      | Day8    | 6 | 3.75  | 1.77  | 1.6  | 2.60  | 3.45   | 4.80  | 6.6  | 0.68     | 0.26     |
|                   |       |                      | Day14   | 6 | 4.07  | 1.54  | 2.3  | 2.90  | 3.80   | 5.20  | 6.4  | 0.54     | -0.87    |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 4.37  | 3.12  | 1.3  | 2.90  | 3.20   | 5.50  | 10.1 | 1.53     | 2.49     |
|                   |       |                      | Day-1   | 6 | 4.22  | 1.97  | 1.5  | 3.20  | 4.05   | 5.30  | 7.2  | 0.25     | 0.11     |
|                   |       |                      | Day1    | 6 | 5.38  | 2.45  | 2.3  | 4.60  | 4.80   | 6.10  | 9.7  | 1.03     | 2.26     |
|                   |       |                      | 中止時     | 6 | 3.37  | 1.38  | 1.2  | 2.90  | 3.35   | 4.00  | 5.4  | -0.18    | 1.26     |
|                   |       |                      | Day14   | 6 | 4.22  | 1.53  | 1.6  | 3.60  | 4.35   | 5.60  | 5.8  | -0.96    | 1.00     |

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| 検査項目(単位)           | ステップ  | 投与群   | Day                  | N       | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |       |
|--------------------|-------|-------|----------------------|---------|-------|-------|------|-------|--------|-------|------|----------|----------|-------|
| 白血球分画(好塩基球)<br>(%) | ステップ1 | 対照薬   | スクリーニング              | 3       | 0.83  | 0.29  | 0.5  | 0.50  | 1.00   | 1.00  | 1.0  | -1.73    |          |       |
|                    |       |       | Day-1                | 3       | 0.83  | 0.40  | 0.4  | 0.40  | 0.90   | 1.20  | 1.2  | -0.72    |          |       |
|                    |       |       | Day1                 | 3       | 0.80  | 0.46  | 0.4  | 0.40  | 0.70   | 1.30  | 1.3  | 0.94     |          |       |
|                    |       |       | Day8                 | 3       | 0.90  | 0.10  | 0.8  | 0.80  | 0.90   | 1.00  | 1.0  | 0.00     |          |       |
|                    |       |       | Day14                | 3       | 0.83  | 0.21  | 0.6  | 0.60  | 0.90   | 1.00  | 1.0  | -1.29    |          |       |
|                    |       |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 0.53  | 0.28 | 0.2   | 0.20   | 0.60  | 0.70 | 0.9      | -0.27    | -1.32 |
|                    |       |       |                      | Day-1   | 6     | 0.55  | 0.27 | 0.2   | 0.30   | 0.55  | 0.80 | 0.9      | 0.00     | -1.54 |
|                    |       |       |                      | Day1    | 6     | 0.43  | 0.21 | 0.2   | 0.30   | 0.40  | 0.50 | 0.8      | 1.17     | 1.97  |
|                    |       |       |                      | Day8    | 6     | 0.42  | 0.27 | 0.2   | 0.20   | 0.30  | 0.70 | 0.8      | 0.73     | -1.78 |
|                    |       |       |                      | Day14   | 6     | 0.50  | 0.26 | 0.2   | 0.30   | 0.45  | 0.70 | 0.9      | 0.61     | -0.65 |
|                    |       |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6     | 0.82  | 0.55 | 0.2   | 0.50   | 0.70  | 1.00 | 1.8      | 1.21     | 1.94  |
|                    |       |       |                      | Day-1   | 6     | 0.63  | 0.44 | 0.3   | 0.40   | 0.50  | 0.60 | 1.5      | 2.15     | 4.92  |
|                    |       |       |                      | Day1    | 6     | 0.57  | 0.49 | 0.2   | 0.20   | 0.40  | 0.70 | 1.5      | 1.78     | 3.22  |
|                    |       |       |                      | Day8    | 6     | 0.55  | 0.23 | 0.2   | 0.50   | 0.50  | 0.70 | 0.9      | 0.07     | 0.82  |
|                    |       |       |                      | Day14   | 6     | 0.68  | 0.31 | 0.3   | 0.50   | 0.65  | 0.80 | 1.2      | 0.80     | 1.27  |
|                    |       | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6     | 0.80  | 0.82 | 0.2   | 0.30   | 0.55  | 0.80 | 2.4      | 2.03     | 4.37  |
| Day-1              |       |       |                      | 6       | 0.87  | 0.91  | 0.2  | 0.30  | 0.50   | 1.10  | 2.6  | 1.86     | 3.45     |       |
| Day1               |       |       |                      | 6       | 0.65  | 0.63  | 0.2  | 0.30  | 0.45   | 0.60  | 1.9  | 2.18     | 4.97     |       |
| 中止時                |       |       |                      | 6       | 0.48  | 0.44  | 0.2  | 0.20  | 0.25   | 0.70  | 1.3  | 1.64     | 2.13     |       |
| Day14              |       |       |                      | 6       | 0.55  | 0.41  | 0.2  | 0.20  | 0.40   | 0.90  | 1.2  | 0.92     | -0.81    |       |
| 白血球分画(リンパ球)<br>(%) | ステップ1 | 対照薬   | スクリーニング              | 3       | 35.90 | 13.19 | 21.4 | 21.40 | 39.10  | 47.20 | 47.2 | -1.03    |          |       |
|                    |       |       | Day-1                | 3       | 35.00 | 1.54  | 33.3 | 33.30 | 35.40  | 36.30 | 36.3 | -1.09    |          |       |
|                    |       |       | Day1                 | 3       | 42.23 | 8.79  | 32.8 | 32.80 | 43.70  | 50.20 | 50.2 | -0.73    |          |       |
|                    |       |       | Day8                 | 3       | 33.97 | 5.23  | 28.3 | 28.30 | 35.00  | 38.60 | 38.6 | -0.85    |          |       |

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| 検査項目(単位)         | ステップ  | 投与群                  | Day     | N     | Mean  | SD    | Min   | Q1    | Median | Q3    | Max   | Skewness | Kurtosis |       |
|------------------|-------|----------------------|---------|-------|-------|-------|-------|-------|--------|-------|-------|----------|----------|-------|
|                  |       |                      | Day14   | 3     | 35.70 | 5.59  | 29.3  | 29.30 | 38.20  | 39.60 | 39.6  | -1.61    |          |       |
|                  |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 31.57 | 5.56  | 23.6  | 26.20 | 33.25  | 34.70 | 38.4  | -0.52    | -1.02    |       |
|                  |       |                      | Day-1   | 6     | 33.90 | 6.25  | 25.6  | 30.00 | 32.90  | 39.20 | 42.8  | 0.27     | -0.70    |       |
|                  |       |                      | Day1    | 6     | 39.77 | 7.06  | 26.3  | 38.60 | 42.00  | 43.30 | 46.4  | -1.78    | 3.62     |       |
|                  |       |                      | Day8    | 6     | 27.65 | 4.62  | 21.4  | 23.30 | 28.30  | 31.40 | 33.2  | -0.29    | -1.56    |       |
|                  |       |                      | Day14   | 6     | 36.82 | 5.78  | 27.1  | 32.90 | 38.85  | 40.90 | 42.3  | -1.11    | 0.29     |       |
|                  |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6     | 35.73 | 5.03  | 30.2  | 30.90 | 36.15  | 36.90 | 44.1  | 0.72     | 0.76     |       |
|                  |       |                      | Day-1   | 6     | 33.17 | 4.94  | 28.2  | 29.20 | 32.00  | 37.80 | 39.8  | 0.39     | -2.19    |       |
|                  |       |                      | Day1    | 6     | 35.25 | 3.14  | 30.7  | 34.00 | 34.55  | 38.70 | 39.0  | -0.03    | -0.69    |       |
|                  |       |                      | Day8    | 6     | 28.13 | 5.96  | 20.2  | 24.10 | 28.30  | 30.20 | 37.7  | 0.45     | 0.76     |       |
|                  |       |                      | Day14   | 6     | 34.03 | 4.93  | 29.4  | 29.40 | 32.80  | 38.60 | 41.2  | 0.62     | -1.47    |       |
|                  | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6     | 33.68 | 8.73  | 26.2  | 27.00 | 30.80  | 38.20 | 49.1  | 1.33     | 1.28     |       |
|                  |       |                      |         | Day-1 | 6     | 32.68 | 7.37  | 23.1  | 28.20  | 31.25 | 38.80 | 43.5     | 0.39     | -0.56 |
|                  |       |                      |         | Day1  | 6     | 39.18 | 9.16  | 29.6  | 31.20  | 37.55 | 45.50 | 53.7     | 0.73     | -0.41 |
|                  |       |                      |         | 中止時   | 6     | 32.68 | 10.22 | 23.9  | 24.30  | 29.30 | 39.90 | 49.4     | 0.98     | -0.25 |
|                  |       |                      |         | Day14 | 6     | 36.25 | 7.30  | 27.5  | 31.00  | 35.00 | 42.30 | 46.7     | 0.38     | -1.30 |
| 白血球分画(単球)<br>(%) | ステップ1 | 対照薬                  | スクリーニング | 3     | 4.80  | 0.46  | 4.3   | 4.30  | 4.90   | 5.20  | 5.2   | -0.94    |          |       |
|                  |       |                      | Day-1   | 3     | 4.87  | 1.24  | 4.1   | 4.10  | 4.20   | 6.30  | 6.3   | 1.72     |          |       |
|                  |       |                      | Day1    | 3     | 5.93  | 0.55  | 5.3   | 5.30  | 6.20   | 6.30  | 6.3   | -1.67    |          |       |
|                  |       |                      | Day8    | 3     | 5.40  | 0.30  | 5.1   | 5.10  | 5.40   | 5.70  | 5.7   | 0.00     |          |       |
|                  |       |                      | Day14   | 3     | 4.83  | 0.42  | 4.5   | 4.50  | 4.70   | 5.30  | 5.3   | 1.29     |          |       |
|                  |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 6.70  | 1.69  | 3.6   | 6.50  | 7.00   | 7.50  | 8.6   | -1.38    | 2.87     |       |
|                  |       |                      | Day-1   | 6     | 6.97  | 2.14  | 3.7   | 6.50  | 6.95   | 7.30  | 10.4  | 0.17     | 2.27     |       |

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| 検査項目(単位)      | ステップ  | 投与群                  | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max  | Skewness | Kurtosis |
|---------------|-------|----------------------|---------|---|------|------|-----|------|--------|------|------|----------|----------|
|               |       |                      | Day1    | 6 | 6.20 | 2.13 | 3.2 | 5.60 | 6.00   | 6.60 | 9.8  | 0.60     | 2.18     |
|               |       |                      | Day8    | 6 | 6.20 | 1.84 | 3.9 | 4.80 | 6.25   | 7.90 | 8.1  | -0.13    | -2.68    |
|               |       |                      | Day14   | 6 | 7.32 | 2.44 | 3.4 | 6.40 | 7.25   | 9.60 | 10.0 | -0.62    | 0.00     |
|               |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 5.98 | 2.60 | 3.5 | 4.60 | 4.75   | 8.00 | 10.3 | 1.14     | 0.02     |
|               |       |                      | Day-1   | 6 | 6.65 | 1.42 | 5.3 | 5.50 | 6.45   | 7.10 | 9.1  | 1.10     | 0.96     |
|               |       |                      | Day1    | 6 | 6.28 | 1.34 | 5.2 | 5.40 | 5.70   | 7.00 | 8.7  | 1.50     | 1.65     |
|               |       |                      | Day8    | 6 | 5.87 | 1.41 | 4.7 | 4.90 | 5.15   | 7.30 | 8.0  | 1.01     | -1.25    |
|               |       |                      | Day14   | 6 | 5.72 | 1.16 | 4.4 | 4.50 | 5.90   | 6.10 | 7.5  | 0.33     | -0.24    |
|               | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 6.18 | 1.72 | 4.5 | 4.90 | 5.65   | 7.30 | 9.1  | 1.11     | 0.49     |
|               |       |                      | Day-1   | 6 | 6.07 | 0.90 | 4.7 | 5.60 | 6.05   | 6.70 | 7.3  | -0.22    | 0.15     |
|               |       |                      | Day1    | 6 | 6.45 | 0.85 | 5.3 | 5.80 | 6.55   | 6.70 | 7.8  | 0.33     | 0.63     |
|               |       |                      | 中止時     | 6 | 5.97 | 0.76 | 5.0 | 5.00 | 6.35   | 6.50 | 6.6  | -0.89    | -1.87    |
|               |       |                      | Day14   | 6 | 6.50 | 1.19 | 5.5 | 5.80 | 6.00   | 7.00 | 8.7  | 1.63     | 2.43     |
| 総蛋白<br>(g/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 7.50 | 0.44 | 7.0 | 7.00 | 7.70   | 7.80 | 7.8  | -1.63    |          |
|               |       |                      | Day-1   | 3 | 7.30 | 0.10 | 7.2 | 7.20 | 7.30   | 7.40 | 7.4  | 0.00     |          |
|               |       |                      | Day1    | 3 | 6.77 | 0.06 | 6.7 | 6.70 | 6.80   | 6.80 | 6.8  | -1.73    |          |
|               |       |                      | Day8    | 3 | 6.93 | 0.06 | 6.9 | 6.90 | 6.90   | 7.00 | 7.0  | 1.73     |          |
|               |       |                      | Day14   | 3 | 7.13 | 0.06 | 7.1 | 7.10 | 7.10   | 7.20 | 7.2  | 1.73     |          |
|               |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 7.13 | 0.25 | 6.8 | 7.00 | 7.10   | 7.30 | 7.5  | 0.24     | -0.57    |
|               |       |                      | Day-1   | 6 | 7.15 | 0.27 | 6.8 | 6.90 | 7.20   | 7.30 | 7.5  | -0.14    | -1.40    |
|               |       |                      | Day1    | 6 | 6.62 | 0.33 | 6.3 | 6.30 | 6.60   | 6.70 | 7.2  | 1.12     | 1.66     |
|               |       |                      | Day8    | 6 | 7.08 | 0.34 | 6.7 | 6.90 | 7.05   | 7.10 | 7.7  | 1.34     | 2.82     |
|               |       |                      | Day14   | 6 | 7.25 | 0.23 | 7.0 | 7.00 | 7.25   | 7.50 | 7.5  | 0.00     | -2.04    |
|               |       | PYRNA                | スクリーニング | 6 | 7.43 | 0.33 | 7.1 | 7.10 | 7.40   | 7.70 | 7.9  | 0.38     | -1.48    |

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| 検査項目(単位)        | ステップ  | 投与群                  | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|-----------------|-------|----------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|                 |       | 1.0g/kg/day          |         |   |      |      |     |      |        |      |     |          |          |
|                 |       |                      | Day-1   | 6 | 7.47 | 0.41 | 7.0 | 7.10 | 7.50   | 7.80 | 7.9 | -0.06    | -2.96    |
|                 |       |                      | Day1    | 6 | 6.82 | 0.34 | 6.4 | 6.60 | 6.75   | 7.10 | 7.3 | 0.32     | -1.42    |
|                 |       |                      | Day8    | 6 | 6.98 | 0.37 | 6.4 | 6.90 | 6.95   | 7.20 | 7.5 | -0.32    | 1.17     |
|                 |       |                      | Day14   | 6 | 7.35 | 0.30 | 6.9 | 7.20 | 7.35   | 7.50 | 7.8 | 0.00     | 0.77     |
|                 | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 7.55 | 0.21 | 7.3 | 7.40 | 7.50   | 7.80 | 7.8 | 0.40     | -1.62    |
|                 |       |                      | Day-1   | 6 | 7.43 | 0.23 | 7.0 | 7.40 | 7.50   | 7.60 | 7.6 | -1.88    | 3.80     |
|                 |       |                      | Day1    | 6 | 6.95 | 0.49 | 6.4 | 6.50 | 6.90   | 7.30 | 7.7 | 0.51     | -0.74    |
|                 |       |                      | 中止時     | 6 | 6.93 | 0.42 | 6.5 | 6.60 | 6.80   | 7.40 | 7.5 | 0.61     | -1.84    |
|                 |       |                      | Day14   | 6 | 7.37 | 0.25 | 7.1 | 7.10 | 7.35   | 7.60 | 7.7 | 0.22     | -1.71    |
| アルブミン<br>(g/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 4.90 | 0.10 | 4.8 | 4.80 | 4.90   | 5.00 | 5.0 | 0.00     |          |
|                 |       |                      | Day-1   | 3 | 4.87 | 0.29 | 4.7 | 4.70 | 4.70   | 5.20 | 5.2 | 1.73     |          |
|                 |       |                      | Day1    | 3 | 4.27 | 0.23 | 4.0 | 4.00 | 4.40   | 4.40 | 4.4 | -1.73    |          |
|                 |       |                      | Day8    | 3 | 4.53 | 0.25 | 4.3 | 4.30 | 4.50   | 4.80 | 4.8 | 0.59     |          |
|                 |       |                      | Day14   | 3 | 4.60 | 0.10 | 4.5 | 4.50 | 4.60   | 4.70 | 4.7 | 0.00     |          |
|                 |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 4.70 | 0.25 | 4.4 | 4.50 | 4.70   | 4.80 | 5.1 | 0.56     | -0.17    |
|                 |       |                      | Day-1   | 6 | 4.73 | 0.31 | 4.3 | 4.60 | 4.70   | 4.90 | 5.2 | 0.21     | 0.32     |
|                 |       |                      | Day1    | 6 | 4.08 | 0.23 | 3.7 | 4.00 | 4.10   | 4.20 | 4.4 | -0.57    | 1.50     |
|                 |       |                      | Day8    | 6 | 4.52 | 0.20 | 4.2 | 4.40 | 4.55   | 4.60 | 4.8 | -0.33    | 0.52     |
|                 |       |                      | Day14   | 6 | 4.80 | 0.26 | 4.5 | 4.60 | 4.75   | 5.00 | 5.2 | 0.61     | -0.65    |
|                 |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 4.87 | 0.31 | 4.4 | 4.70 | 4.85   | 5.20 | 5.2 | -0.33    | -0.55    |
|                 |       |                      | Day-1   | 6 | 5.03 | 0.34 | 4.4 | 4.90 | 5.15   | 5.30 | 5.3 | -1.57    | 2.31     |
|                 |       |                      | Day1    | 6 | 4.30 | 0.31 | 3.7 | 4.30 | 4.40   | 4.40 | 4.6 | -1.88    | 4.23     |
|                 |       |                      | Day8    | 6 | 4.37 | 0.22 | 4.1 | 4.20 | 4.35   | 4.50 | 4.7 | 0.46     | -0.30    |

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| 検査項目(単位)          | ステップ  | 投与群                  | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|-------------------|-------|----------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|                   |       |                      | Day14   | 6 | 4.85 | 0.25 | 4.4 | 4.80 | 4.90   | 5.00 | 5.1 | -1.31    | 1.85     |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 4.88 | 0.19 | 4.7 | 4.70 | 4.85   | 5.00 | 5.2 | 0.84     | -0.06    |
|                   |       |                      | Day-1   | 6 | 5.00 | 0.17 | 4.8 | 4.90 | 4.95   | 5.20 | 5.2 | 0.38     | -1.79    |
|                   |       |                      | Day1    | 6 | 4.53 | 0.24 | 4.2 | 4.40 | 4.50   | 4.70 | 4.9 | 0.30     | 0.16     |
|                   |       |                      | 中止時     | 6 | 4.42 | 0.15 | 4.3 | 4.30 | 4.40   | 4.40 | 4.7 | 1.84     | 3.91     |
|                   |       |                      | Day14   | 6 | 4.80 | 0.27 | 4.4 | 4.70 | 4.75   | 5.10 | 5.1 | -0.19    | -0.58    |
| 総ビリルビン<br>(mg/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 0.77 | 0.32 | 0.4 | 0.40 | 0.90   | 1.00 | 1.0 | -1.55    |          |
|                   |       |                      | Day-1   | 3 | 0.73 | 0.25 | 0.5 | 0.50 | 0.70   | 1.00 | 1.0 | 0.59     |          |
|                   |       |                      | Day1    | 3 | 0.93 | 0.32 | 0.7 | 0.70 | 0.80   | 1.30 | 1.3 | 1.55     |          |
|                   |       |                      | Day8    | 3 | 0.77 | 0.12 | 0.7 | 0.70 | 0.70   | 0.90 | 0.9 | 1.73     |          |
|                   |       |                      | Day14   | 3 | 0.57 | 0.15 | 0.4 | 0.40 | 0.60   | 0.70 | 0.7 | -0.94    |          |
|                   |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 0.75 | 0.31 | 0.4 | 0.50 | 0.70   | 1.00 | 1.2 | 0.46     | -1.26    |
|                   |       |                      | Day-1   | 6 | 0.78 | 0.25 | 0.5 | 0.60 | 0.75   | 0.90 | 1.2 | 0.87     | 0.74     |
|                   |       |                      | Day1    | 6 | 0.87 | 0.41 | 0.4 | 0.60 | 0.85   | 0.90 | 1.6 | 1.21     | 2.36     |
|                   |       |                      | Day8    | 6 | 0.82 | 0.13 | 0.7 | 0.70 | 0.80   | 0.90 | 1.0 | 0.33     | -2.25    |
|                   |       |                      | Day14   | 6 | 0.70 | 0.32 | 0.2 | 0.60 | 0.65   | 1.00 | 1.1 | -0.32    | -0.01    |
|                   |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 0.73 | 0.22 | 0.4 | 0.60 | 0.75   | 0.90 | 1.0 | -0.46    | -0.30    |
|                   |       |                      | Day-1   | 6 | 0.77 | 0.29 | 0.3 | 0.60 | 0.80   | 1.00 | 1.1 | -0.64    | -0.30    |
|                   |       |                      | Day1    | 6 | 0.92 | 0.19 | 0.6 | 0.80 | 0.95   | 1.10 | 1.1 | -0.84    | -0.06    |
|                   |       |                      | Day8    | 6 | 0.68 | 0.13 | 0.6 | 0.60 | 0.60   | 0.80 | 0.9 | 1.21     | -0.46    |
|                   |       |                      | Day14   | 6 | 0.55 | 0.30 | 0.3 | 0.30 | 0.50   | 0.60 | 1.1 | 1.44     | 2.19     |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 0.80 | 0.20 | 0.5 | 0.60 | 0.90   | 0.90 | 1.0 | -0.90    | -1.18    |
|                   |       |                      | Day-1   | 6 | 0.58 | 0.08 | 0.5 | 0.50 | 0.60   | 0.60 | 0.7 | 0.31     | -0.10    |

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| 検査項目(単位)     | ステップ  | 投与群                  | Day     | N | Mean | SD   | Min | Q1   | Median | Q3   | Max | Skewness | Kurtosis |
|--------------|-------|----------------------|---------|---|------|------|-----|------|--------|------|-----|----------|----------|
|              |       |                      | Day1    | 6 | 0.77 | 0.19 | 0.5 | 0.60 | 0.80   | 0.90 | 1.0 | -0.39    | -0.94    |
|              |       |                      | 中止時     | 6 | 0.87 | 0.20 | 0.6 | 0.70 | 0.90   | 1.00 | 1.1 | -0.25    | -1.83    |
|              |       |                      | Day14   | 6 | 0.80 | 0.33 | 0.3 | 0.60 | 0.85   | 0.90 | 1.3 | -0.05    | 0.83     |
| AST<br>(U/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 16.7 | 3.8  | 14  | 14.0 | 15.0   | 21.0 | 21  | 1.6      |          |
|              |       |                      | Day-1   | 3 | 16.3 | 2.9  | 13  | 13.0 | 18.0   | 18.0 | 18  | -1.7     |          |
|              |       |                      | Day1    | 3 | 15.0 | 2.6  | 12  | 12.0 | 16.0   | 17.0 | 17  | -1.5     |          |
|              |       |                      | Day8    | 3 | 13.0 | 2.6  | 11  | 11.0 | 12.0   | 16.0 | 16  | 1.5      |          |
|              |       |                      | Day14   | 3 | 14.7 | 2.5  | 12  | 12.0 | 15.0   | 17.0 | 17  | -0.6     |          |
|              |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 17.5 | 4.9  | 9   | 15.0 | 18.5   | 22.0 | 22  | -1.1     | 1.0      |
|              |       |                      | Day-1   | 6 | 17.8 | 3.9  | 11  | 16.0 | 19.0   | 20.0 | 22  | -1.2     | 1.3      |
|              |       |                      | Day1    | 6 | 16.7 | 4.0  | 10  | 14.0 | 18.0   | 19.0 | 21  | -1.0     | 0.2      |
|              |       |                      | Day8    | 6 | 20.3 | 5.4  | 11  | 17.0 | 22.0   | 25.0 | 25  | -1.2     | 0.7      |
|              |       |                      | Day14   | 6 | 19.5 | 6.8  | 11  | 16.0 | 18.0   | 23.0 | 31  | 0.8      | 1.1      |
|              |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 16.0 | 2.6  | 12  | 14.0 | 16.5   | 18.0 | 19  | -0.6     | -0.6     |
|              |       |                      | Day-1   | 6 | 16.3 | 3.7  | 13  | 14.0 | 15.5   | 17.0 | 23  | 1.4      | 2.1      |
|              |       |                      | Day1    | 6 | 15.5 | 3.1  | 11  | 14.0 | 15.5   | 17.0 | 20  | 0.0      | -0.2     |
|              |       |                      | Day8    | 6 | 20.8 | 8.5  | 13  | 15.0 | 18.5   | 24.0 | 36  | 1.3      | 1.7      |
|              |       |                      | Day14   | 6 | 16.8 | 4.5  | 14  | 15.0 | 15.0   | 16.0 | 26  | 2.3      | 5.6      |
|              | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 16.8 | 2.2  | 15  | 15.0 | 16.5   | 17.0 | 21  | 1.6      | 3.0      |
|              |       |                      | Day-1   | 6 | 16.8 | 3.2  | 14  | 15.0 | 16.0   | 17.0 | 23  | 1.9      | 4.1      |
|              |       |                      | Day1    | 6 | 18.0 | 6.1  | 14  | 14.0 | 16.0   | 18.0 | 30  | 2.1      | 4.5      |
|              |       |                      | 中止時     | 6 | 17.8 | 4.4  | 14  | 15.0 | 16.5   | 19.0 | 26  | 1.7      | 3.0      |
|              |       |                      | Day14   | 6 | 19.2 | 8.8  | 14  | 15.0 | 16.0   | 17.0 | 37  | 2.4      | 5.7      |
| ALT          | ステップ1 | 対照薬                  | スクリーニング | 3 | 15.0 | 3.5  | 13  | 13.0 | 13.0   | 19.0 | 19  | 1.7      |          |

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| 検査項目(単位) | ステップ  | 投与群                  | Day     | N     | Mean  | SD   | Min   | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|----------|-------|----------------------|---------|-------|-------|------|-------|-------|--------|-------|------|----------|----------|
| (U/L)    |       |                      | Day-1   | 3     | 15.3  | 5.8  | 12    | 12.0  | 12.0   | 22.0  | 22   | 1.7      |          |
|          |       |                      | Day1    | 3     | 14.3  | 6.7  | 10    | 10.0  | 11.0   | 22.0  | 22   | 1.7      |          |
|          |       |                      | Day8    | 3     | 13.0  | 2.6  | 10    | 10.0  | 14.0   | 15.0  | 15   | -1.5     |          |
|          |       |                      | Day14   | 3     | 12.7  | 2.1  | 11    | 11.0  | 12.0   | 15.0  | 15   | 1.3      |          |
|          |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 17.8  | 10.1 | 6     | 11.0  | 16.5   | 22.0  | 35   | 0.9      | 1.2      |
|          |       |                      | Day-1   | 6     | 19.2  | 12.5 | 7     | 13.0  | 15.5   | 21.0  | 43   | 1.7      | 3.6      |
|          |       |                      | Day1    | 6     | 17.7  | 11.6 | 6     | 11.0  | 14.5   | 21.0  | 39   | 1.5      | 2.7      |
|          |       |                      | Day8    | 6     | 30.5  | 17.2 | 9     | 20.0  | 30.0   | 34.0  | 60   | 0.9      | 1.5      |
|          |       |                      | Day14   | 6     | 26.2  | 20.9 | 8     | 15.0  | 21.5   | 24.0  | 67   | 2.0      | 4.5      |
|          |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6     | 14.5  | 4.3  | 11    | 11.0  | 12.5   | 20.0  | 20   | 0.8      | -1.9     |
|          |       |                      | Day-1   | 6     | 15.5  | 5.9  | 9     | 12.0  | 13.5   | 20.0  | 25   | 0.9      | -0.1     |
|          |       |                      | Day1    | 6     | 13.8  | 4.7  | 9     | 10.0  | 12.5   | 18.0  | 21   | 0.8      | -1.0     |
|          |       |                      | Day8    | 6     | 30.7  | 16.6 | 15    | 16.0  | 25.5   | 47.0  | 55   | 0.7      | -1.4     |
|          |       |                      | Day14   | 6     | 22.2  | 13.1 | 11    | 16.0  | 18.5   | 21.0  | 48   | 2.1      | 4.7      |
|          | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6     | 15.7  | 3.9  | 12    | 12.0  | 15.0   | 18.0  | 22   | 0.8      | -0.1     |
|          |       |                      | Day-1   | 6     | 15.5  | 5.0  | 12    | 13.0  | 13.0   | 17.0  | 25   | 1.9      | 3.4      |
|          |       |                      | Day1    | 6     | 15.5  | 6.9  | 11    | 12.0  | 12.0   | 17.0  | 29   | 2.0      | 4.0      |
|          |       |                      | 中止時     | 6     | 15.7  | 6.9  | 11    | 12.0  | 12.5   | 17.0  | 29   | 2.0      | 4.0      |
|          |       |                      | Day14   | 6     | 17.5  | 10.4 | 10    | 11.0  | 14.5   | 17.0  | 38   | 2.1      | 4.6      |
| ALP      | ステップ1 | 対照薬                  | スクリーニング | 3     | 222.3 | 18.0 | 205   | 205.0 | 221.0  | 241.0 | 241  | 0.3      |          |
| (U/L)    |       |                      | Day-1   | 3     | 222.0 | 11.8 | 209   | 209.0 | 225.0  | 232.0 | 232  | -1.1     |          |
| Day1     |       |                      | 3       | 204.3 | 15.5  | 187  | 187.0 | 209.0 | 217.0  | 217   | -1.2 |          |          |
| Day8     |       |                      | 3       | 198.0 | 7.8   | 189  | 189.0 | 202.0 | 203.0  | 203   | -1.7 |          |          |
| Day14    |       |                      | 3       | 218.7 | 16.8  | 208  | 208.0 | 210.0 | 238.0  | 238   | 1.7  |          |          |

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| 検査項目(単位) | ステップ  | 投与群                  | Day     | N     | Mean  | SD   | Min   | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|----------|-------|----------------------|---------|-------|-------|------|-------|-------|--------|-------|------|----------|----------|
|          |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 169.0 | 35.4 | 136   | 140.0 | 157.5  | 202.0 | 221  | 0.7      | -1.5     |
|          |       |                      | Day-1   | 6     | 188.0 | 58.1 | 129   | 137.0 | 182.0  | 235.0 | 263  | 0.2      | -2.6     |
|          |       |                      | Day1    | 6     | 159.7 | 38.2 | 127   | 129.0 | 144.5  | 203.0 | 210  | 0.6      | -2.1     |
|          |       |                      | Day8    | 6     | 165.8 | 40.7 | 128   | 134.0 | 150.0  | 212.0 | 221  | 0.7      | -1.8     |
|          |       |                      | Day14   | 6     | 183.2 | 50.8 | 136   | 149.0 | 159.5  | 242.0 | 253  | 0.8      | -1.7     |
|          |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6     | 191.7 | 35.4 | 143   | 152.0 | 205.5  | 218.0 | 226  | -0.8     | -1.7     |
|          |       |                      | Day-1   | 6     | 203.2 | 37.6 | 146   | 173.0 | 212.5  | 235.0 | 240  | -0.7     | -1.1     |
|          |       |                      | Day1    | 6     | 184.2 | 30.3 | 138   | 158.0 | 195.0  | 209.0 | 210  | -0.8     | -1.2     |
|          |       |                      | Day8    | 6     | 178.5 | 34.7 | 130   | 146.0 | 183.5  | 210.0 | 218  | -0.4     | -1.4     |
|          |       |                      | Day14   | 6     | 217.5 | 62.0 | 141   | 165.0 | 211.5  | 287.0 | 289  | 0.1      | -1.9     |
|          | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6     | 200.3 | 44.3 | 138   | 180.0 | 191.0  | 241.0 | 261  | 0.1      | -0.5     |
|          |       |                      | Day-1   | 6     | 190.3 | 42.1 | 142   | 169.0 | 177.5  | 214.0 | 262  | 1.0      | 1.0      |
|          |       |                      | Day1    | 6     | 176.2 | 30.0 | 140   | 158.0 | 167.0  | 210.0 | 215  | 0.5      | -1.6     |
|          |       |                      | 中止時     | 6     | 173.0 | 32.5 | 123   | 163.0 | 167.0  | 207.0 | 211  | -0.3     | -0.2     |
|          |       |                      | Day14   | 6     | 184.3 | 37.9 | 146   | 161.0 | 168.5  | 219.0 | 243  | 0.9      | -0.9     |
| LDH      | ステップ1 | 対照薬                  | スクリーニング | 3     | 147.7 | 13.9 | 136   | 136.0 | 144.0  | 163.0 | 163  | 1.1      |          |
| (U/L)    |       |                      | Day-1   | 3     | 152.7 | 15.0 | 137   | 137.0 | 154.0  | 167.0 | 167  | -0.4     |          |
| Day1     |       |                      | 3       | 128.7 | 6.7   | 121  | 121.0 | 132.0 | 133.0  | 133   | -1.7 |          |          |
| Day8     |       |                      | 3       | 114.7 | 4.2   | 110  | 110.0 | 116.0 | 118.0  | 118   | -1.3 |          |          |
| Day14    |       |                      | 3       | 143.0 | 15.9  | 125  | 125.0 | 149.0 | 155.0  | 155   | -1.5 |          |          |
|          |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6     | 156.2 | 34.6 | 113   | 119.0 | 163.0  | 175.0 | 204  | -0.1     | -1.0     |
|          |       |                      | Day-1   | 6     | 156.2 | 30.8 | 114   | 120.0 | 171.5  | 175.0 | 185  | -0.9     | -1.7     |
|          |       |                      | Day1    | 6     | 131.7 | 25.5 | 100   | 101.0 | 140.0  | 147.0 | 162  | -0.5     | -1.6     |

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| 検査項目(単位)       | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|----------------|-------|----------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|                |       |                      | Day8    | 6 | 128.7 | 23.1 | 100 | 102.0 | 133.0  | 152.0 | 152 | -0.4     | -1.9     |
|                |       |                      | Day14   | 6 | 152.7 | 24.8 | 121 | 122.0 | 163.0  | 169.0 | 178 | -0.7     | -1.8     |
|                |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 148.5 | 14.7 | 135 | 137.0 | 146.5  | 150.0 | 176 | 1.6      | 3.1      |
|                |       |                      | Day-1   | 6 | 154.0 | 10.8 | 142 | 145.0 | 152.0  | 163.0 | 170 | 0.5      | -1.2     |
|                |       |                      | Day1    | 6 | 131.3 | 10.3 | 119 | 124.0 | 130.5  | 140.0 | 144 | 0.1      | -2.4     |
|                |       |                      | Day8    | 6 | 130.2 | 13.6 | 106 | 123.0 | 135.5  | 139.0 | 142 | -1.4     | 1.4      |
|                |       |                      | Day14   | 6 | 147.3 | 9.9  | 132 | 140.0 | 149.5  | 156.0 | 157 | -0.7     | -0.9     |
|                | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 144.7 | 16.8 | 126 | 134.0 | 139.5  | 157.0 | 172 | 0.9      | 0.0      |
|                |       |                      | Day-1   | 6 | 150.5 | 19.2 | 130 | 135.0 | 148.5  | 157.0 | 184 | 1.1      | 1.4      |
|                |       |                      | Day1    | 6 | 138.3 | 18.2 | 118 | 130.0 | 134.5  | 141.0 | 172 | 1.5      | 3.1      |
|                |       |                      | 中止時     | 6 | 135.3 | 17.3 | 116 | 120.0 | 133.5  | 146.0 | 163 | 0.7      | -0.1     |
|                |       |                      | Day14   | 6 | 152.7 | 26.3 | 132 | 139.0 | 145.5  | 149.0 | 205 | 2.2      | 5.0      |
| γ-GTP<br>(U/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 19.3  | 5.1  | 15  | 15.0  | 18.0   | 25.0  | 25  | 1.1      |          |
|                |       |                      | Day-1   | 3 | 23.0  | 13.0 | 15  | 15.0  | 16.0   | 38.0  | 38  | 1.7      |          |
|                |       |                      | Day1    | 3 | 22.7  | 10.7 | 16  | 16.0  | 17.0   | 35.0  | 35  | 1.7      |          |
|                |       |                      | Day8    | 3 | 20.7  | 10.0 | 13  | 13.0  | 17.0   | 32.0  | 32  | 1.4      |          |
|                |       |                      | Day14   | 3 | 20.0  | 10.4 | 13  | 13.0  | 15.0   | 32.0  | 32  | 1.7      |          |
|                |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 23.3  | 21.0 | 10  | 11.0  | 15.5   | 23.0  | 65  | 2.2      | 4.9      |
|                |       |                      | Day-1   | 6 | 25.0  | 18.4 | 14  | 16.0  | 18.0   | 22.0  | 62  | 2.3      | 5.5      |
|                |       |                      | Day1    | 6 | 21.8  | 15.6 | 12  | 13.0  | 16.5   | 20.0  | 53  | 2.2      | 5.2      |
|                |       |                      | Day8    | 6 | 23.3  | 15.5 | 14  | 15.0  | 16.5   | 24.0  | 54  | 2.2      | 4.8      |
|                |       |                      | Day14   | 6 | 25.8  | 22.4 | 14  | 14.0  | 17.0   | 22.0  | 71  | 2.3      | 5.6      |
|                |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 14.2  | 5.6  | 9   | 10.0  | 12.5   | 17.0  | 24  | 1.3      | 1.4      |

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| 検査項目(単位)       | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|----------------|-------|----------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                |       |                      | Day-1   | 6 | 15.8  | 4.2  | 12   | 14.0  | 14.5   | 16.0  | 24   | 1.9      | 4.1      |
|                |       |                      | Day1    | 6 | 15.0  | 3.7  | 12   | 12.0  | 14.5   | 15.0  | 22   | 1.7      | 3.5      |
|                |       |                      | Day8    | 6 | 15.5  | 4.5  | 11   | 13.0  | 15.0   | 15.0  | 24   | 1.7      | 3.8      |
|                |       |                      | Day14   | 6 | 16.8  | 3.5  | 13   | 15.0  | 16.0   | 18.0  | 23   | 1.2      | 1.7      |
|                | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 31.5  | 26.3 | 16   | 17.0  | 18.5   | 36.0  | 83   | 2.1      | 4.2      |
|                |       |                      | Day-1   | 6 | 30.5  | 26.3 | 12   | 13.0  | 18.0   | 43.0  | 79   | 1.6      | 2.2      |
|                |       |                      | Day1    | 6 | 30.3  | 24.1 | 13   | 16.0  | 18.5   | 41.0  | 75   | 1.7      | 2.4      |
|                |       |                      | 中止時     | 6 | 30.8  | 25.3 | 14   | 17.0  | 18.0   | 39.0  | 79   | 1.9      | 3.3      |
|                |       |                      | Day14   | 6 | 32.0  | 26.1 | 15   | 15.0  | 17.5   | 49.0  | 78   | 1.5      | 1.0      |
| BUN<br>(mg/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 10.57 | 0.25 | 10.3 | 10.30 | 10.60  | 10.80 | 10.8 | -0.59    |          |
|                |       |                      | Day-1   | 3 | 12.30 | 2.17 | 9.8  | 9.80  | 13.40  | 13.70 | 13.7 | -1.69    |          |
|                |       |                      | Day1    | 3 | 13.60 | 4.70 | 8.9  | 8.90  | 13.60  | 18.30 | 18.3 | 0.00     |          |
|                |       |                      | Day8    | 3 | 9.80  | 2.72 | 6.8  | 6.80  | 10.50  | 12.10 | 12.1 | -1.08    |          |
|                |       |                      | Day14   | 3 | 12.47 | 3.10 | 10.2 | 10.20 | 11.20  | 16.00 | 16.0 | 1.53     |          |
|                |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 12.57 | 2.40 | 9.9  | 10.10 | 12.70  | 14.00 | 16.0 | 0.22     | -1.31    |
|                |       |                      | Day-1   | 6 | 12.75 | 2.15 | 10.3 | 10.60 | 12.85  | 14.60 | 15.3 | -0.03    | -2.51    |
|                |       |                      | Day1    | 6 | 13.38 | 2.41 | 10.3 | 10.70 | 13.90  | 15.20 | 16.3 | -0.38    | -1.57    |
|                |       |                      | Day8    | 6 | 11.88 | 1.69 | 9.2  | 10.80 | 12.20  | 12.90 | 14.0 | -0.61    | 0.15     |
|                |       |                      | Day14   | 6 | 12.93 | 2.99 | 8.9  | 11.70 | 12.75  | 13.50 | 18.0 | 0.70     | 1.87     |
|                |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 11.13 | 2.54 | 9.0  | 9.30  | 10.10  | 12.90 | 15.4 | 1.13     | 0.14     |
|                |       |                      | Day-1   | 6 | 10.65 | 0.94 | 9.7  | 9.70  | 10.60  | 11.20 | 12.1 | 0.54     | -0.67    |
|                |       |                      | Day1    | 6 | 12.55 | 1.74 | 11.0 | 11.20 | 12.05  | 13.70 | 15.3 | 0.79     | -0.74    |
|                |       |                      | Day8    | 6 | 10.80 | 1.17 | 9.2  | 9.90  | 10.90  | 11.70 | 12.2 | -0.21    | -1.81    |
|                |       |                      | Day14   | 6 | 11.65 | 2.52 | 8.4  | 10.30 | 11.10  | 13.60 | 15.4 | 0.40     | -0.56    |

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| 検査項目(単位)            | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|---------------------|-------|----------------------|---------|---|-------|------|------|-------|--------|-------|------|----------|----------|
|                     | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 11.37 | 2.31 | 8.3  | 10.20 | 10.75  | 14.00 | 14.2 | 0.24     | -1.22    |
|                     |       |                      | Day-1   | 6 | 12.50 | 2.84 | 9.3  | 10.30 | 12.35  | 13.40 | 17.3 | 0.88     | 0.83     |
|                     |       |                      | Day1    | 6 | 13.62 | 3.26 | 10.9 | 10.90 | 12.95  | 14.80 | 19.2 | 1.09     | 0.64     |
|                     |       |                      | 中止時     | 6 | 10.85 | 2.38 | 7.6  | 8.80  | 11.20  | 12.40 | 13.9 | -0.20    | -1.37    |
|                     |       |                      | Day14   | 6 | 13.63 | 2.37 | 11.0 | 11.60 | 13.30  | 15.50 | 17.1 | 0.45     | -1.29    |
| 総コレステロール<br>(mg/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 181.7 | 25.0 | 157  | 157.0 | 181.0  | 207.0 | 207  | 0.1      |          |
|                     |       |                      | Day-1   | 3 | 172.7 | 25.8 | 144  | 144.0 | 180.0  | 194.0 | 194  | -1.2     |          |
|                     |       |                      | Day1    | 3 | 165.3 | 22.5 | 146  | 146.0 | 160.0  | 190.0 | 190  | 1.0      |          |
|                     |       |                      | Day8    | 3 | 154.0 | 15.1 | 140  | 140.0 | 152.0  | 170.0 | 170  | 0.6      |          |
|                     |       |                      | Day14   | 3 | 167.0 | 20.0 | 147  | 147.0 | 167.0  | 187.0 | 187  | 0.0      |          |
|                     |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 162.8 | 26.0 | 139  | 145.0 | 153.5  | 179.0 | 207  | 1.1      | 0.4      |
|                     |       |                      | Day-1   | 6 | 163.7 | 25.4 | 128  | 147.0 | 162.5  | 183.0 | 199  | 0.0      | -0.6     |
|                     |       |                      | Day1    | 6 | 155.5 | 24.5 | 129  | 134.0 | 154.0  | 166.0 | 196  | 0.8      | 0.4      |
|                     |       |                      | Day8    | 6 | 156.2 | 18.3 | 145  | 146.0 | 150.5  | 152.0 | 193  | 2.3      | 5.5      |
|                     |       |                      | Day14   | 6 | 158.3 | 20.6 | 134  | 139.0 | 158.0  | 171.0 | 190  | 0.4      | -0.4     |
|                     |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 170.8 | 23.7 | 144  | 155.0 | 166.5  | 181.0 | 212  | 1.1      | 1.4      |
|                     |       |                      | Day-1   | 6 | 169.0 | 27.2 | 141  | 150.0 | 162.5  | 185.0 | 213  | 0.8      | -0.2     |
|                     |       |                      | Day1    | 6 | 158.8 | 30.2 | 129  | 131.0 | 156.5  | 171.0 | 209  | 0.9      | 0.3      |
|                     |       |                      | Day8    | 6 | 141.2 | 22.6 | 118  | 125.0 | 136.5  | 154.0 | 177  | 0.7      | -0.6     |
|                     |       |                      | Day14   | 6 | 162.3 | 18.2 | 144  | 149.0 | 155.5  | 185.0 | 185  | 0.7      | -1.9     |
|                     | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 178.3 | 16.3 | 158  | 162.0 | 179.0  | 193.0 | 199  | -0.1     | -1.5     |
|                     |       |                      | Day-1   | 6 | 167.5 | 17.2 | 144  | 155.0 | 167.5  | 181.0 | 190  | -0.1     | -1.3     |
|                     |       |                      | Day1    | 6 | 163.2 | 17.4 | 133  | 155.0 | 168.5  | 170.0 | 184  | -1.0     | 1.6      |

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| 検査項目(単位)           | ステップ  | 投与群                  | Day     | N | Mean  | SD    | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|--------------------|-------|----------------------|---------|---|-------|-------|-----|-------|--------|-------|-----|----------|----------|
|                    |       |                      | 中止時     | 6 | 161.0 | 15.4  | 135 | 155.0 | 162.5  | 173.0 | 178 | -0.9     | 0.7      |
|                    |       |                      | Day14   | 6 | 161.7 | 11.5  | 144 | 153.0 | 164.0  | 170.0 | 175 | -0.6     | -0.7     |
| トリグリセリド<br>(mg/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 86.3  | 24.2  | 59  | 59.0  | 95.0   | 105.0 | 105 | -1.4     |          |
|                    |       |                      | Day-1   | 3 | 66.0  | 23.5  | 43  | 43.0  | 65.0   | 90.0  | 90  | 0.2      |          |
|                    |       |                      | Day1    | 3 | 91.0  | 49.4  | 62  | 62.0  | 63.0   | 148.0 | 148 | 1.7      |          |
|                    |       |                      | Day8    | 3 | 93.3  | 34.6  | 69  | 69.0  | 78.0   | 133.0 | 133 | 1.6      |          |
|                    |       |                      | Day14   | 3 | 108.7 | 42.9  | 61  | 61.0  | 121.0  | 144.0 | 144 | -1.2     |          |
|                    |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 83.8  | 41.3  | 27  | 67.0  | 78.0   | 101.0 | 152 | 0.6      | 1.5      |
|                    |       |                      | Day-1   | 6 | 130.5 | 98.6  | 39  | 42.0  | 124.5  | 143.0 | 310 | 1.4      | 2.4      |
|                    |       |                      | Day1    | 6 | 116.3 | 104.1 | 51  | 52.0  | 77.5   | 117.0 | 323 | 2.2      | 4.9      |
|                    |       |                      | Day8    | 6 | 86.2  | 38.6  | 59  | 61.0  | 71.0   | 95.0  | 160 | 1.9      | 3.5      |
|                    |       |                      | Day14   | 6 | 139.2 | 120.1 | 62  | 82.0  | 100.0  | 109.0 | 382 | 2.3      | 5.6      |
|                    |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 70.7  | 19.9  | 48  | 48.0  | 73.5   | 90.0  | 91  | -0.2     | -2.4     |
|                    |       |                      | Day-1   | 6 | 83.3  | 31.2  | 60  | 67.0  | 68.0   | 95.0  | 142 | 1.8      | 2.9      |
|                    |       |                      | Day1    | 6 | 79.8  | 29.3  | 35  | 65.0  | 81.5   | 98.0  | 118 | -0.4     | -0.2     |
|                    |       |                      | Day8    | 6 | 72.2  | 11.9  | 53  | 70.0  | 72.0   | 76.0  | 90  | -0.2     | 2.1      |
|                    |       |                      | Day14   | 6 | 78.8  | 28.9  | 48  | 53.0  | 75.0   | 105.0 | 117 | 0.3      | -2.2     |
|                    | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 73.7  | 27.1  | 38  | 50.0  | 76.0   | 92.0  | 110 | -0.1     | -1.3     |
|                    |       |                      | Day-1   | 6 | 105.0 | 50.4  | 53  | 61.0  | 93.0   | 158.0 | 172 | 0.5      | -1.9     |
|                    |       |                      | Day1    | 6 | 93.8  | 55.9  | 52  | 59.0  | 74.0   | 103.0 | 201 | 1.9      | 3.6      |
|                    |       |                      | 中止時     | 6 | 93.2  | 32.9  | 68  | 73.0  | 83.0   | 96.0  | 156 | 1.8      | 3.5      |
|                    |       |                      | Day14   | 6 | 89.5  | 58.4  | 42  | 63.0  | 70.5   | 86.0  | 205 | 2.1      | 4.8      |
| 尿酸<br>(mg/dL)      | ステップ1 | 対照薬                  | スクリーニング | 3 | 6.33  | 0.15  | 6.2 | 6.20  | 6.30   | 6.50  | 6.5 | 0.94     |          |
|                    |       |                      | Day-1   | 3 | 6.00  | 1.05  | 5.0 | 5.00  | 5.90   | 7.10  | 7.1 | 0.42     |          |

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| 検査項目(単位)          | ステップ  | 投与群                  | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|-------------------|-------|----------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|                   |       |                      | Day1    | 3 | 6.50  | 0.89  | 5.8  | 5.80  | 6.20   | 7.50  | 7.5  | 1.35     |          |
|                   |       |                      | Day8    | 3 | 6.43  | 0.51  | 6.0  | 6.00  | 6.30   | 7.00  | 7.0  | 1.09     |          |
|                   |       |                      | Day14   | 3 | 6.63  | 0.78  | 6.0  | 6.00  | 6.40   | 7.50  | 7.5  | 1.23     |          |
|                   |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 4.48  | 0.69  | 3.6  | 3.70  | 4.65   | 5.10  | 5.2  | -0.52    | -1.82    |
|                   |       |                      | Day-1   | 6 | 4.40  | 0.40  | 3.8  | 4.10  | 4.45   | 4.80  | 4.8  | -0.49    | -1.29    |
|                   |       |                      | Day1    | 6 | 4.70  | 0.51  | 4.0  | 4.40  | 4.65   | 5.10  | 5.4  | 0.07     | -0.74    |
|                   |       |                      | Day8    | 6 | 3.95  | 0.48  | 3.1  | 3.80  | 4.05   | 4.20  | 4.5  | -1.11    | 1.63     |
|                   |       |                      | Day14   | 6 | 4.32  | 0.75  | 3.4  | 3.70  | 4.20   | 5.20  | 5.2  | 0.26     | -1.72    |
|                   |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 5.92  | 1.53  | 3.1  | 5.30  | 6.50   | 6.90  | 7.2  | -1.61    | 2.42     |
|                   |       |                      | Day-1   | 6 | 5.95  | 1.06  | 4.2  | 5.40  | 6.10   | 6.70  | 7.2  | -0.78    | 0.55     |
|                   |       |                      | Day1    | 6 | 6.42  | 1.04  | 4.7  | 5.90  | 6.65   | 7.10  | 7.5  | -0.89    | 0.17     |
|                   |       |                      | Day8    | 6 | 4.82  | 0.84  | 3.4  | 4.30  | 5.10   | 5.20  | 5.8  | -0.97    | 0.79     |
|                   |       |                      | Day14   | 6 | 5.88  | 0.97  | 4.6  | 5.20  | 5.90   | 6.80  | 6.9  | -0.19    | -2.33    |
|                   | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 5.55  | 0.69  | 4.6  | 5.20  | 5.40   | 6.30  | 6.4  | 0.11     | -1.06    |
|                   |       |                      | Day-1   | 6 | 5.55  | 0.56  | 4.8  | 5.00  | 5.65   | 5.90  | 6.3  | -0.20    | -1.03    |
|                   |       |                      | Day1    | 6 | 5.88  | 0.80  | 4.8  | 5.20  | 6.00   | 6.30  | 7.0  | -0.06    | -0.69    |
|                   |       |                      | 中止時     | 6 | 5.00  | 0.88  | 3.8  | 4.20  | 5.15   | 5.50  | 6.2  | -0.16    | -0.81    |
|                   |       |                      | Day14   | 6 | 5.88  | 0.74  | 4.8  | 5.40  | 5.90   | 6.40  | 6.9  | -0.14    | -0.20    |
| クレアチニン<br>(mg/dL) | ステップ1 | 対照薬                  | スクリーニング | 3 | 0.677 | 0.061 | 0.61 | 0.610 | 0.690  | 0.730 | 0.73 | -0.935   |          |
|                   |       |                      | Day-1   | 3 | 0.690 | 0.125 | 0.55 | 0.550 | 0.730  | 0.790 | 0.79 | -1.293   |          |
|                   |       |                      | Day1    | 3 | 0.683 | 0.130 | 0.55 | 0.550 | 0.690  | 0.810 | 0.81 | -0.230   |          |
|                   |       |                      | Day8    | 3 | 0.690 | 0.101 | 0.58 | 0.580 | 0.710  | 0.780 | 0.78 | -0.852   |          |
|                   |       |                      | Day14   | 3 | 0.767 | 0.182 | 0.57 | 0.570 | 0.800  | 0.930 | 0.93 | -0.795   |          |
|                   |       | PYRNA                | スクリーニング | 6 | 0.747 | 0.068 | 0.64 | 0.710 | 0.755  | 0.780 | 0.84 | -0.382   | 0.574    |

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| 検査項目(単位)     | ステップ  | 投与群                  | Day     | N | Mean  | SD    | Min  | Q1    | Median | Q3    | Max  | Skewness | Kurtosis |
|--------------|-------|----------------------|---------|---|-------|-------|------|-------|--------|-------|------|----------|----------|
|              |       | 0.5g/kg/day          |         |   |       |       |      |       |        |       |      |          |          |
|              |       |                      | Day-1   | 6 | 0.740 | 0.046 | 0.67 | 0.730 | 0.735  | 0.760 | 0.81 | 0.019    | 1.549    |
|              |       |                      | Day1    | 6 | 0.713 | 0.084 | 0.62 | 0.660 | 0.690  | 0.770 | 0.85 | 0.853    | 0.011    |
|              |       |                      | Day8    | 6 | 0.692 | 0.080 | 0.61 | 0.610 | 0.690  | 0.750 | 0.80 | 0.217    | -2.006   |
|              |       |                      | Day14   | 6 | 0.758 | 0.077 | 0.68 | 0.700 | 0.735  | 0.830 | 0.87 | 0.642    | -1.488   |
|              |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 0.728 | 0.079 | 0.63 | 0.660 | 0.735  | 0.770 | 0.84 | 0.150    | -1.224   |
|              |       |                      | Day-1   | 6 | 0.733 | 0.100 | 0.62 | 0.640 | 0.740  | 0.760 | 0.90 | 0.708    | 0.748    |
|              |       |                      | Day1    | 6 | 0.697 | 0.094 | 0.59 | 0.590 | 0.710  | 0.750 | 0.83 | 0.039    | -0.961   |
|              |       |                      | Day8    | 6 | 0.643 | 0.066 | 0.57 | 0.570 | 0.645  | 0.700 | 0.73 | 0.047    | -1.549   |
|              |       |                      | Day14   | 6 | 0.742 | 0.038 | 0.69 | 0.720 | 0.735  | 0.780 | 0.79 | 0.110    | -1.025   |
|              | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 0.745 | 0.049 | 0.69 | 0.710 | 0.740  | 0.760 | 0.83 | 1.040    | 1.465    |
|              |       |                      | Day-1   | 6 | 0.737 | 0.049 | 0.69 | 0.690 | 0.735  | 0.770 | 0.80 | 0.194    | -2.582   |
|              |       |                      | Day1    | 6 | 0.715 | 0.047 | 0.67 | 0.670 | 0.710  | 0.760 | 0.77 | 0.141    | -2.843   |
|              |       |                      | 中止時     | 6 | 0.708 | 0.056 | 0.62 | 0.690 | 0.705  | 0.740 | 0.79 | -0.200   | 1.137    |
|              |       |                      | Day14   | 6 | 0.770 | 0.040 | 0.72 | 0.730 | 0.780  | 0.780 | 0.83 | 0.141    | -0.289   |
| CPK<br>(U/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 106.3 | 52.3  | 51   | 51.0  | 113.0  | 155.0 | 155  | -0.6     |          |
|              |       |                      | Day-1   | 3 | 109.7 | 32.7  | 73   | 73.0  | 120.0  | 136.0 | 136  | -1.3     |          |
|              |       |                      | Day1    | 3 | 88.0  | 20.9  | 64   | 64.0  | 98.0   | 102.0 | 102  | -1.7     |          |
|              |       |                      | Day8    | 3 | 60.3  | 11.9  | 47   | 47.0  | 64.0   | 70.0  | 70   | -1.3     |          |
|              |       |                      | Day14   | 3 | 90.3  | 35.9  | 50   | 50.0  | 102.0  | 119.0 | 119  | -1.3     |          |
|              |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 111.2 | 60.4  | 62   | 64.0  | 101.5  | 111.0 | 227  | 1.8      | 3.8      |
|              |       |                      | Day-1   | 6 | 102.3 | 30.9  | 68   | 77.0  | 97.0   | 127.0 | 148  | 0.5      | -1.2     |
|              |       |                      | Day1    | 6 | 79.5  | 23.8  | 54   | 64.0  | 72.5   | 96.0  | 118  | 0.9      | -0.2     |
|              |       |                      | Day8    | 6 | 66.2  | 15.5  | 46   | 54.0  | 65.0   | 81.0  | 86   | 0.1      | -1.5     |

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| 検査項目(単位)      | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|---------------|-------|----------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|               |       |                      | Day14   | 6 | 99.7  | 30.3 | 62  | 78.0  | 98.5   | 111.0 | 150 | 0.7      | 1.0      |
|               |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 78.0  | 17.2 | 58  | 60.0  | 79.5   | 90.0  | 101 | 0.0      | -1.7     |
|               |       |                      | Day-1   | 6 | 80.7  | 18.0 | 58  | 68.0  | 79.0   | 96.0  | 104 | 0.1      | -1.9     |
|               |       |                      | Day1    | 6 | 66.2  | 13.9 | 52  | 53.0  | 65.5   | 76.0  | 85  | 0.2      | -2.2     |
|               |       |                      | Day8    | 6 | 53.3  | 11.3 | 43  | 47.0  | 50.5   | 54.0  | 75  | 1.8      | 3.8      |
|               |       |                      | Day14   | 6 | 90.0  | 33.2 | 54  | 73.0  | 83.5   | 95.0  | 151 | 1.4      | 2.8      |
|               | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 102.3 | 26.0 | 74  | 84.0  | 96.0   | 121.0 | 143 | 0.7      | -0.6     |
|               |       |                      | Day-1   | 6 | 98.7  | 24.0 | 72  | 76.0  | 96.5   | 117.0 | 134 | 0.4      | -1.1     |
|               |       |                      | Day1    | 6 | 84.5  | 26.1 | 62  | 64.0  | 75.5   | 100.0 | 130 | 1.3      | 1.0      |
|               |       |                      | 中止時     | 6 | 81.7  | 20.3 | 54  | 70.0  | 80.5   | 97.0  | 108 | -0.1     | -1.4     |
|               |       |                      | Day14   | 6 | 107.2 | 32.8 | 64  | 90.0  | 100.0  | 132.0 | 157 | 0.4      | -0.1     |
| Na<br>(mEq/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 137.3 | 2.1  | 135 | 135.0 | 138.0  | 139.0 | 139 | -1.3     |          |
|               |       |                      | Day-1   | 3 | 137.0 | 1.0  | 136 | 136.0 | 137.0  | 138.0 | 138 | 0.0      |          |
|               |       |                      | Day1    | 3 | 136.7 | 0.6  | 136 | 136.0 | 137.0  | 137.0 | 137 | -1.7     |          |
|               |       |                      | Day8    | 3 | 139.7 | 0.6  | 139 | 139.0 | 140.0  | 140.0 | 140 | -1.7     |          |
|               |       |                      | Day14   | 3 | 138.0 | 2.0  | 136 | 136.0 | 138.0  | 140.0 | 140 | 0.0      |          |
|               |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 139.0 | 1.9  | 136 | 138.0 | 139.0  | 141.0 | 141 | -0.5     | -0.1     |
|               |       |                      | Day-1   | 6 | 137.7 | 2.0  | 135 | 136.0 | 138.0  | 139.0 | 140 | -0.3     | -1.8     |
|               |       |                      | Day1    | 6 | 137.0 | 1.3  | 136 | 136.0 | 136.5  | 138.0 | 139 | 0.9      | -0.8     |
|               |       |                      | Day8    | 6 | 139.7 | 1.4  | 138 | 138.0 | 140.0  | 141.0 | 141 | -0.5     | -1.9     |
|               |       |                      | Day14   | 6 | 139.5 | 1.0  | 138 | 139.0 | 139.5  | 140.0 | 141 | 0.0      | -0.2     |
|               |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 139.7 | 0.5  | 139 | 139.0 | 140.0  | 140.0 | 140 | -1.0     | -1.9     |
|               |       |                      | Day-1   | 6 | 137.5 | 1.0  | 136 | 137.0 | 137.5  | 138.0 | 139 | 0.0      | -0.2     |

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| 検査項目(単位)     | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|--------------|-------|----------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|              |       |                      | Day1    | 6 | 136.8 | 2.3  | 133 | 136.0 | 137.0  | 139.0 | 139 | -0.9     | 0.1      |
|              |       |                      | Day8    | 6 | 140.0 | 1.1  | 138 | 140.0 | 140.0  | 141.0 | 141 | -1.4     | 2.5      |
|              |       |                      | Day14   | 6 | 138.7 | 1.9  | 137 | 137.0 | 138.5  | 139.0 | 142 | 1.3      | 1.9      |
|              | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 139.7 | 0.8  | 139 | 139.0 | 139.5  | 140.0 | 141 | 0.9      | -0.3     |
|              |       |                      | Day-1   | 6 | 138.5 | 1.0  | 137 | 138.0 | 138.5  | 139.0 | 140 | 0.0      | -0.2     |
|              |       |                      | Day1    | 6 | 139.7 | 2.0  | 138 | 138.0 | 139.0  | 141.0 | 143 | 1.2      | 0.4      |
|              |       |                      | 中止時     | 6 | 141.2 | 0.8  | 140 | 141.0 | 141.0  | 142.0 | 142 | -0.3     | -0.1     |
|              |       |                      | Day14   | 6 | 138.8 | 1.5  | 137 | 138.0 | 138.5  | 140.0 | 141 | 0.4      | -0.9     |
| K<br>(mEq/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 4.37  | 0.50 | 3.9 | 3.90  | 4.30   | 4.90  | 4.9 | 0.59     |          |
|              |       |                      | Day-1   | 3 | 4.23  | 0.12 | 4.1 | 4.10  | 4.30   | 4.30  | 4.3 | -1.73    |          |
|              |       |                      | Day1    | 3 | 3.90  | 0.17 | 3.8 | 3.80  | 3.80   | 4.10  | 4.1 | 1.73     |          |
|              |       |                      | Day8    | 3 | 3.87  | 0.35 | 3.5 | 3.50  | 3.90   | 4.20  | 4.2 | -0.42    |          |
|              |       |                      | Day14   | 3 | 4.03  | 0.15 | 3.9 | 3.90  | 4.00   | 4.20  | 4.2 | 0.94     |          |
|              |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 4.20  | 0.34 | 3.8 | 3.80  | 4.25   | 4.50  | 4.6 | -0.27    | -1.83    |
|              |       |                      | Day-1   | 6 | 4.13  | 0.23 | 3.8 | 3.90  | 4.25   | 4.30  | 4.3 | -0.94    | -1.44    |
|              |       |                      | Day1    | 6 | 3.92  | 0.19 | 3.7 | 3.80  | 3.85   | 4.10  | 4.2 | 0.64     | -1.24    |
|              |       |                      | Day8    | 6 | 4.03  | 0.27 | 3.7 | 3.80  | 4.00   | 4.30  | 4.4 | 0.27     | -1.42    |
|              |       |                      | Day14   | 6 | 4.13  | 0.26 | 3.7 | 4.10  | 4.15   | 4.20  | 4.5 | -0.55    | 2.16     |
|              |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 4.05  | 0.33 | 3.6 | 3.90  | 4.00   | 4.20  | 4.6 | 0.61     | 1.34     |
|              |       |                      | Day-1   | 6 | 3.97  | 0.25 | 3.5 | 3.90  | 4.05   | 4.10  | 4.2 | -1.61    | 2.85     |
|              |       |                      | Day1    | 6 | 3.90  | 0.18 | 3.6 | 3.80  | 3.95   | 4.00  | 4.1 | -0.94    | 0.59     |
|              |       |                      | Day8    | 6 | 3.90  | 0.13 | 3.7 | 3.80  | 3.95   | 4.00  | 4.0 | -0.89    | -0.78    |
|              |       |                      | Day14   | 6 | 4.02  | 0.38 | 3.5 | 3.80  | 3.95   | 4.40  | 4.5 | 0.11     | -1.02    |
|              | ステップ2 | PYRNA                | スクリーニング | 6 | 4.18  | 0.37 | 3.9 | 3.90  | 4.00   | 4.60  | 4.7 | 0.83     | -1.79    |

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| 検査項目(単位)      | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|---------------|-------|----------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|               |       | 2.0g/kg/day          |         |   |       |      |     |       |        |       |     |          |          |
|               |       |                      | Day-1   | 6 | 4.27  | 0.22 | 3.9 | 4.20  | 4.30   | 4.40  | 4.5 | -0.97    | 0.73     |
|               |       |                      | Day1    | 6 | 4.12  | 0.33 | 3.7 | 3.90  | 4.05   | 4.40  | 4.6 | 0.43     | -0.81    |
|               |       |                      | 中止時     | 6 | 3.75  | 0.27 | 3.4 | 3.60  | 3.75   | 3.80  | 4.2 | 0.71     | 1.60     |
|               |       |                      | Day14   | 6 | 4.05  | 0.24 | 3.8 | 3.80  | 4.05   | 4.30  | 4.3 | 0.00     | -2.90    |
| Cl<br>(mEq/L) | ステップ1 | 対照薬                  | スクリーニング | 3 | 101.7 | 2.5  | 99  | 99.0  | 102.0  | 104.0 | 104 | -0.6     |          |
|               |       |                      | Day-1   | 3 | 103.3 | 1.5  | 102 | 102.0 | 103.0  | 105.0 | 105 | 0.9      |          |
|               |       |                      | Day1    | 3 | 104.7 | 1.2  | 104 | 104.0 | 104.0  | 106.0 | 106 | 1.7      |          |
|               |       |                      | Day8    | 3 | 105.0 | 1.0  | 104 | 104.0 | 105.0  | 106.0 | 106 | 0.0      |          |
|               |       |                      | Day14   | 3 | 104.0 | 1.0  | 103 | 103.0 | 104.0  | 105.0 | 105 | 0.0      |          |
|               |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 102.3 | 1.8  | 99  | 102.0 | 103.0  | 103.0 | 104 | -1.8     | 3.6      |
|               |       |                      | Day-1   | 6 | 102.8 | 2.3  | 99  | 102.0 | 103.0  | 105.0 | 105 | -0.9     | 0.1      |
|               |       |                      | Day1    | 6 | 104.3 | 1.5  | 103 | 103.0 | 104.0  | 105.0 | 107 | 1.3      | 1.5      |
|               |       |                      | Day8    | 6 | 102.7 | 2.3  | 99  | 101.0 | 103.5  | 104.0 | 105 | -1.0     | -0.1     |
|               |       |                      | Day14   | 6 | 103.8 | 1.9  | 102 | 102.0 | 103.5  | 105.0 | 107 | 0.8      | -0.1     |
|               |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 102.5 | 2.0  | 100 | 102.0 | 102.0  | 103.0 | 106 | 1.1      | 2.5      |
|               |       |                      | Day-1   | 6 | 102.5 | 1.6  | 100 | 102.0 | 102.5  | 103.0 | 105 | 0.0      | 1.3      |
|               |       |                      | Day1    | 6 | 104.5 | 1.6  | 102 | 103.0 | 105.0  | 106.0 | 106 | -0.8     | -1.0     |
|               |       |                      | Day8    | 6 | 103.8 | 1.9  | 102 | 102.0 | 103.5  | 105.0 | 107 | 0.8      | -0.1     |
|               |       |                      | Day14   | 6 | 102.8 | 1.6  | 101 | 101.0 | 103.0  | 104.0 | 105 | 0.0      | -1.3     |
|               | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 102.2 | 0.4  | 102 | 102.0 | 102.0  | 102.0 | 103 | 2.4      | 6.0      |
|               |       |                      | Day-1   | 6 | 102.8 | 0.8  | 102 | 102.0 | 103.0  | 103.0 | 104 | 0.3      | -0.1     |
|               |       |                      | Day1    | 6 | 106.0 | 3.0  | 104 | 104.0 | 105.0  | 106.0 | 112 | 2.1      | 4.7      |
|               |       |                      | 中止時     | 6 | 103.0 | 1.1  | 101 | 103.0 | 103.0  | 104.0 | 104 | -1.4     | 2.5      |

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| 検査項目(単位)                             | ステップ  | 投与群                  | Day     | N | Mean   | SD    | Min   | Q1     | Median | Q3     | Max   | Skewness | Kurtosis |
|--------------------------------------|-------|----------------------|---------|---|--------|-------|-------|--------|--------|--------|-------|----------|----------|
|                                      |       |                      | Day14   | 6 | 102.7  | 2.2   | 99    | 101.0  | 104.0  | 104.0  | 104   | -1.3     | 0.2      |
| 血糖<br>(mg/dL)                        | ステップ1 | 対照薬                  | スクリーニング | 3 | 84.0   | 3.0   | 81    | 81.0   | 84.0   | 87.0   | 87    | 0.0      |          |
|                                      |       |                      | Day1    | 3 | 83.7   | 0.6   | 83    | 83.0   | 84.0   | 84.0   | 84    | -1.7     |          |
|                                      |       |                      | Day8    | 3 | 79.3   | 5.0   | 74    | 74.0   | 80.0   | 84.0   | 84    | -0.6     |          |
|                                      |       |                      | Day14   | 3 | 84.7   | 3.5   | 81    | 81.0   | 85.0   | 88.0   | 88    | -0.4     |          |
|                                      |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 83.5   | 7.5   | 74    | 79.0   | 82.5   | 87.0   | 96    | 0.7      | 1.1      |
|                                      |       |                      | Day1    | 6 | 83.0   | 6.9   | 70    | 82.0   | 84.5   | 88.0   | 89    | -1.7     | 3.0      |
|                                      |       |                      | Day8    | 6 | 76.5   | 7.3   | 64    | 72.0   | 78.5   | 83.0   | 83    | -1.1     | 0.6      |
|                                      |       |                      | Day14   | 6 | 87.5   | 7.4   | 75    | 83.0   | 89.5   | 93.0   | 95    | -1.0     | 0.4      |
|                                      |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 82.8   | 3.8   | 78    | 79.0   | 83.5   | 86.0   | 87    | -0.3     | -2.1     |
|                                      |       |                      | Day1    | 6 | 83.3   | 4.9   | 75    | 80.0   | 85.5   | 86.0   | 88    | -1.2     | 0.5      |
|                                      |       |                      | Day8    | 6 | 81.7   | 3.1   | 77    | 80.0   | 82.0   | 83.0   | 86    | -0.2     | 0.3      |
|                                      |       |                      | Day14   | 6 | 90.2   | 2.8   | 88    | 88.0   | 89.0   | 92.0   | 95    | 1.3      | 0.8      |
|                                      | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 85.8   | 3.2   | 80    | 85.0   | 86.5   | 88.0   | 89    | -1.4     | 2.4      |
|                                      |       |                      | Day1    | 6 | 80.8   | 4.5   | 74    | 80.0   | 80.5   | 82.0   | 88    | 0.2      | 2.0      |
|                                      |       |                      | 中止時     | 6 | 103.7  | 31.9  | 77    | 84.0   | 86.5   | 135.0  | 153   | 1.0      | -1.1     |
|                                      |       |                      | Day14   | 6 | 87.5   | 5.8   | 79    | 82.0   | 89.5   | 92.0   | 93    | -0.8     | -1.4     |
| eGFR<br>(mL/min/1.73m <sup>2</sup> ) | ステップ1 | 対照薬                  | スクリーニング | 3 | 115.60 | 15.76 | 106.3 | 106.30 | 106.70 | 133.80 | 133.8 | 1.73     |          |
|                                      |       |                      | Day-1   | 3 | 116.07 | 30.16 | 92.0  | 92.00  | 106.30 | 149.90 | 149.9 | 1.30     |          |
|                                      |       |                      | Day1    | 3 | 117.53 | 30.39 | 89.6  | 89.60  | 113.10 | 149.90 | 149.9 | 0.64     |          |
|                                      |       |                      | Day8    | 3 | 114.57 | 23.35 | 98.9  | 98.90  | 103.40 | 141.40 | 141.4 | 1.66     |          |
|                                      |       |                      | Day14   | 3 | 105.50 | 33.74 | 81.6  | 81.60  | 90.80  | 144.10 | 144.1 | 1.59     |          |
|                                      |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 105.18 | 11.93 | 96.7  | 96.90  | 101.55 | 105.90 | 128.5 | 2.02     | 4.33     |

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| 検査項目(単位)        | ステップ  | 投与群                  | Day     | N | Mean   | SD    | Min   | Q1     | Median | Q3     | Max   | Skewness | Kurtosis |
|-----------------|-------|----------------------|---------|---|--------|-------|-------|--------|--------|--------|-------|----------|----------|
|                 |       |                      | Day-1   | 6 | 105.82 | 9.36  | 95.9  | 98.70  | 105.05 | 107.90 | 122.3 | 1.14     | 1.60     |
|                 |       |                      | Day1    | 6 | 110.82 | 11.88 | 91.0  | 106.30 | 111.55 | 120.00 | 124.5 | -0.80    | 0.68     |
|                 |       |                      | Day8    | 6 | 114.72 | 13.93 | 97.2  | 107.50 | 110.70 | 126.70 | 135.5 | 0.53     | -0.58    |
|                 |       |                      | Day14   | 6 | 103.48 | 11.37 | 88.7  | 94.40  | 103.50 | 114.70 | 116.1 | -0.11    | -2.17    |
|                 |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 104.20 | 14.31 | 84.6  | 100.10 | 100.85 | 111.10 | 127.7 | 0.58     | 1.35     |
|                 |       |                      | Day-1   | 6 | 104.07 | 16.65 | 78.5  | 99.50  | 103.00 | 110.50 | 129.9 | 0.05     | 1.72     |
|                 |       |                      | Day1    | 6 | 110.02 | 17.47 | 85.7  | 103.20 | 106.65 | 120.70 | 137.2 | 0.36     | 0.61     |
|                 |       |                      | Day8    | 6 | 119.17 | 15.01 | 98.7  | 111.30 | 118.55 | 125.40 | 142.5 | 0.33     | 0.36     |
|                 |       |                      | Day14   | 6 | 101.23 | 8.59  | 92.5  | 97.10  | 97.35  | 107.50 | 115.6 | 1.11     | 0.26     |
|                 | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 104.28 | 5.97  | 95.5  | 100.70 | 104.75 | 106.70 | 113.3 | 0.03     | 0.80     |
|                 |       |                      | Day-1   | 6 | 105.63 | 7.00  | 99.2  | 99.50  | 104.05 | 110.10 | 116.9 | 0.83     | -0.43    |
|                 |       |                      | Day1    | 6 | 109.13 | 7.45  | 102.8 | 103.60 | 106.05 | 115.50 | 120.8 | 0.92     | -0.89    |
|                 |       |                      | 中止時     | 6 | 110.42 | 7.88  | 98.6  | 103.60 | 112.60 | 115.10 | 120.0 | -0.59    | -0.68    |
|                 |       |                      | Day14   | 6 | 100.48 | 4.20  | 93.4  | 97.80  | 102.10 | 102.30 | 105.2 | -1.03    | 0.70     |
| Cer<br>(ml/min) | ステップ1 | 対照薬                  | スクリーニング | 3 | 165.3  | 61.2  | 130   | 130.0  | 130.0  | 236.0  | 236   | 1.7      |          |
|                 |       |                      | Day-1   | 3 | 167.3  | 80.6  | 113   | 113.0  | 129.0  | 260.0  | 260   | 1.7      |          |
|                 |       |                      | Day1    | 3 | 168.7  | 80.2  | 110   | 110.0  | 136.0  | 260.0  | 260   | 1.5      |          |
|                 |       |                      | Day8    | 3 | 163.3  | 71.8  | 117   | 117.0  | 127.0  | 246.0  | 246   | 1.7      |          |
|                 |       |                      | Day14   | 3 | 155.7  | 84.6  | 100   | 100.0  | 114.0  | 253.0  | 253   | 1.7      |          |
|                 |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 133.5  | 14.8  | 122   | 123.0  | 129.5  | 135.0  | 162   | 1.9      | 3.9      |
|                 |       |                      | Day-1   | 6 | 129.8  | 8.0   | 118   | 123.0  | 132.0  | 136.0  | 138   | -0.6     | -1.4     |
|                 |       |                      | Day1    | 6 | 136.0  | 17.8  | 117   | 122.0  | 131.0  | 153.0  | 162   | 0.7      | -1.3     |
|                 |       |                      | Day8    | 6 | 138.7  | 14.5  | 123   | 131.0  | 135.0  | 143.0  | 165   | 1.4      | 2.5      |
|                 |       |                      | Day14   | 6 | 126.2  | 15.4  | 112   | 113.0  | 120.5  | 144.0  | 147   | 0.8      | -1.8     |

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| 検査項目(単位) | ステップ  | 投与群                  | Day     | N | Mean  | SD   | Min | Q1    | Median | Q3    | Max | Skewness | Kurtosis |
|----------|-------|----------------------|---------|---|-------|------|-----|-------|--------|-------|-----|----------|----------|
|          |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 131.8 | 21.2 | 119 | 120.0 | 124.5  | 129.0 | 174 | 2.2      | 5.0      |
|          |       |                      | Day-1   | 6 | 131.3 | 24.3 | 111 | 114.0 | 122.0  | 144.0 | 175 | 1.5      | 1.6      |
|          |       |                      | Day1    | 6 | 138.5 | 26.4 | 119 | 120.0 | 125.5  | 157.0 | 184 | 1.3      | 0.6      |
|          |       |                      | Day8    | 6 | 149.7 | 21.0 | 131 | 135.0 | 142.5  | 160.0 | 187 | 1.4      | 1.4      |
|          |       |                      | Day14   | 6 | 129.5 | 16.3 | 109 | 119.0 | 128.0  | 136.0 | 157 | 0.8      | 1.3      |
|          | ステップ2 | PYRNA<br>2.0g/kg/day | スクリーニング | 6 | 133.7 | 13.4 | 114 | 120.0 | 139.0  | 144.0 | 146 | -0.8     | -1.4     |
|          |       |                      | Day-1   | 6 | 135.0 | 12.9 | 118 | 119.0 | 141.5  | 145.0 | 145 | -0.9     | -1.9     |
|          |       |                      | Day1    | 6 | 139.3 | 13.5 | 121 | 123.0 | 146.5  | 149.0 | 150 | -0.9     | -1.8     |
|          |       |                      | 中止時     | 6 | 139.2 | 14.1 | 116 | 133.0 | 140.5  | 147.0 | 158 | -0.6     | 1.1      |
|          |       |                      | Day14   | 6 | 129.5 | 12.4 | 110 | 122.0 | 131.5  | 138.0 | 144 | -0.6     | -0.3     |
| pH       | ステップ1 | 対照薬                  | スクリーニング | 3 | 6.67  | 0.58 | 6.0 | 6.00  | 7.00   | 7.00  | 7.0 | -1.73    |          |
|          |       |                      | Day-1   | 3 | 5.83  | 0.29 | 5.5 | 5.50  | 6.00   | 6.00  | 6.0 | -1.73    |          |
|          |       |                      | Day1    | 3 | 5.83  | 0.29 | 5.5 | 5.50  | 6.00   | 6.00  | 6.0 | -1.73    |          |
|          |       |                      | Day8    | 3 | 6.17  | 0.29 | 6.0 | 6.00  | 6.00   | 6.50  | 6.5 | 1.73     |          |
|          |       |                      | Day14   | 3 | 5.83  | 0.29 | 5.5 | 5.50  | 6.00   | 6.00  | 6.0 | -1.73    |          |
|          |       | PYRNA<br>0.5g/kg/day | スクリーニング | 6 | 6.50  | 0.63 | 5.5 | 6.00  | 6.75   | 7.00  | 7.0 | -0.89    | -0.78    |
|          |       |                      | Day-1   | 6 | 6.33  | 0.82 | 5.5 | 5.50  | 6.25   | 7.00  | 7.5 | 0.38     | -1.48    |
|          |       |                      | Day1    | 6 | 6.17  | 0.61 | 5.5 | 5.50  | 6.25   | 6.50  | 7.0 | 0.08     | -1.55    |
|          |       |                      | Day8    | 6 | 8.17  | 0.41 | 7.5 | 8.00  | 8.25   | 8.50  | 8.5 | -0.86    | -0.30    |
|          |       |                      | Day14   | 6 | 5.92  | 0.20 | 5.5 | 6.00  | 6.00   | 6.00  | 6.0 | -2.45    | 6.00     |
|          |       | PYRNA<br>1.0g/kg/day | スクリーニング | 6 | 6.33  | 0.75 | 5.5 | 6.00  | 6.00   | 7.00  | 7.5 | 0.84     | -0.65    |
|          |       |                      | Day-1   | 6 | 6.00  | 0.63 | 5.5 | 5.50  | 5.75   | 6.50  | 7.0 | 0.89     | -0.78    |

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