|  |  |  |
| --- | --- | --- |
| 3% COAT | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 1.000 | 0.150 | 0.001 |
| 2.000 | 0.350 | 0.011 |
| 2.500 | 0.460 | 0.045 |
| 3.000 | 0.580 | 0.156 |
| 4.000 | 0.880 | 0.314 |
| 5.000 | 0.970 | 0.741 |
| 6.000 | 1.000 | 0.874 |

|  |  |  |
| --- | --- | --- |
| 7% Coat | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 2.000 | 0.32 | 0.006 |
| 2.500 | 0.44 | 0.054 |
| 3.000 | 0.55 | 0.157 |
| 4.000 | 0.93 | 0.264 |
| 5.000 | 1.00 | 0.718 |

|  |  |  |
| --- | --- | --- |
| 5% COAT | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 2.000 | 0.31 | 0.004 |
| 2.500 | 0.41 | 0.036 |
| 3.000 | **0.51** | 0.079 |
| 4.000 | 0.76 | 0.775 |

NEXT CHANGE 5% COAT LOWER LIMIT

5subject data

|  |  |  |
| --- | --- | --- |
| 5% COAT- LOWER LIMIT | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 2.000 | 0.25 | 0.004 |
| 2.500 | 0.32 | 0.036 |
| 3.000 | **0.37** | 0.079 |
| 4.000 | 0.60 | 0.775 |

NEXT CHANGE 5% COAT UPPER LIMIT

|  |  |  |
| --- | --- | --- |
| 5% COAT UPPER LIMIT | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 2.000 | 0.35 | 0.004 |
| 2.500 | 0.55 | 0.036 |
| 3.000 | **0.62** | 0.079 |
| 4.000 | 0.80 | 0.775 |

So there are 5 cases and based on reference data given below find what is total number of real subject data is required to prove all 5 cases lies within confidence interval of 90-110% of reference value invivo

Reference value

|  |  |  |
| --- | --- | --- |
| RLD | In-vitro | In-vivo |
| Time | X=FD | Y=FA |
| 1.000 | 0.02 | 0.052227 |
| 1.500 | 0.08 | 0.245313 |
| 2.000 | 0.2 | 0.506252 |
| 2.500 | 0.33 | 0.75322 |
| 3.000 | 0.46 | 0.946752 |
| 4.000 | 0.65 | 1.141 |

So you have 5 subject of reference real data , now

SIMULATE TO 50 subject data for creating 90-110% confidence interval i.e ±10% variation in vivo to create acceptance criteria , and model to show all above cases are acceptable within this 10% limit.

