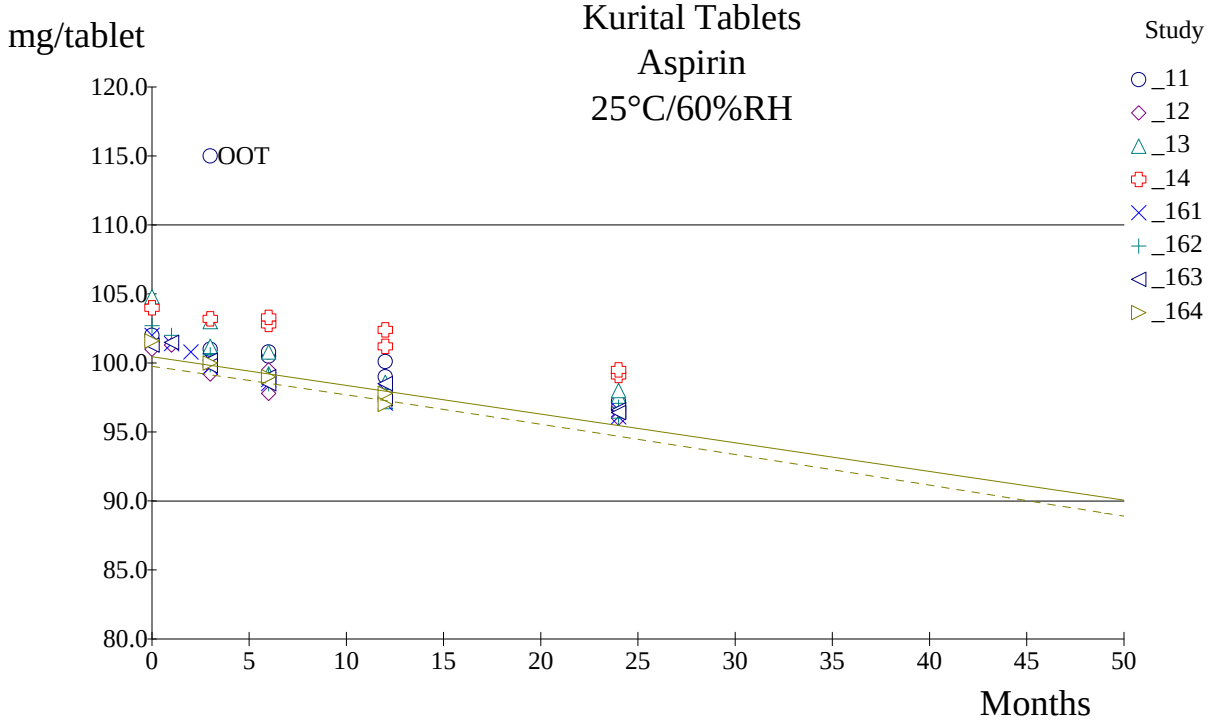
SLIMStat
Version 5.0.0

Shelf Life Projection

Kurital Tablets
Aspirin
25°C/60%RH



Model 2: Common Slope but Different Intercepts (95.0% CI)
Test Category: HPLC High Spec: 110.0 Low Spec: 90.0
Original FDA Data Set with an OOT Result added...
File: C:\Program Files (x86)\SLIM\Demo\Standard Conditions.SST User: Craig Hamilton

SLIMStat Regression Analysis and Pooling of Data.

Original Raw Data (Time in units of Months):

Study 1	_11							
Time :	0.0	3.0	3.0	6.0	6.0	12.0	12.0	24.0
Results:	102.00	101.00	115*	100.50	100.80	100.10	99.00	96.70
Time :	24.0							
Results:	97.20							
Study 2	_12							
Time :	0.0	1.0	3.0	3.0	6.0	6.0	12.0	12.0
Results:	101.00	101.30	99.80	99.20	99.50	97.80	97.40	97.20
Time :	24.0	24.0						
Results:	96.90	96.00						
Study 3	_13							
Time :	0.0	3.0	3.0	6.0	6.0	12.0	12.0	24.0
Results:	104.80	103.00	101.20	100.80	99.20	98.60	97.20	97.60
Time :	24.0							
Results:	98.00							
Study 4	_14							
Time :	0.0	3.0	6.0	6.0	12.0	12.0	24.0	24.0
Results:	104.00	103.20	102.80	103.30	102.40	101.20	99.10	99.50
Study 5	_161							
Time :	0.0	1.0	2.0	3.0	3.0	6.0	6.0	12.0
Results:	102.00	101.40	100.80	100.20	99.70	98.80	98.50	98.00
Time :	12.0	24.0	24.0					
Results:	97.10	96.60	96.10					
Study 6	_162							
Time :	0.0	1.0	3.0	3.0	6.0	6.0	12.0	12.0
Results:	102.70	102.00	100.60	99.90	99.20	98.50	98.10	97.60
Time :	24.0	24.0						
Results:	96.80	96.00						
Study 7	_163							
Time :	0.0	1.0	3.0	3.0	6.0	6.0	12.0	12.0
Results:	101.30	101.50	100.20	99.80	99.00	98.50	98.50	97.40

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Time   :      24.0     24.0
Results:     96.60    96.40

Study 8    _164
Time   :       0.0      3.0      6.0     12.0     12.0
Results:    101.60   100.00    99.00    97.80    97.00

Original Raw Data Treatment:
a. Less than (<) results are ignored.
b. Greater than (>) results are ignored.
c. A result marked with a question (?) is "Selected for Testing" and is ignored.
d. Results marked by an asterisk (*) are "Out of Trend (OOT)" and are ignored.
e. Results marked by a pound (#) are "Forcibly Excluded (EXC)" and are ignored.

Step 1.  Fit each individual regression equation and
         compute the residual sum of squares.
1     Study: _11
  OOT[3.0,115.00][Mult.=3,SD= 0.385432721]Expected= 101.265753425±1.156298162(100.109455262 to 102.422051587) mg/tabl
  Linear Least Squares:  Y = -0.20359x + 101.87652 (n = 8)
  Residual Sum of Squares (i = 1) = 0.89135
  R^2 (Coefficient of Determination) = 0.96394
  Standard Deviation of Residuals = 0.38543 mg/tablet
  Standard Error of Slope = 0.01608
  P Value of Slope = 0.00001.  Slope significant (user selected P = 0.25).
2     Study: _12
  Linear Least Squares:  Y = -0.18013x + 100.24914 (n = 10)
  Residual Sum of Squares (i = 2) = 6.54335
  R^2 (Coefficient of Determination) = 0.77705
  Standard Deviation of Residuals = 0.90439 mg/tablet
  Standard Error of Slope = 0.03411
  P Value of Slope = 0.00075.  Slope significant (user selected P = 0.25).
3     Study: _13
  Linear Least Squares:  Y = -0.23397x + 102.38413 (n = 9)
  Residual Sum of Squares (i = 3) = 19.81530
  R^2 (Coefficient of Determination) = 0.63509
  Standard Deviation of Residuals = 1.68249 mg/tablet
  Standard Error of Slope = 0.06703
  P Value of Slope = 0.01012.  Slope significant (user selected P = 0.25).
4     Study: _14
  Linear Least Squares:  Y = -0.19615x + 104.07065 (n = 8)
  Residual Sum of Squares (i = 4) = 1.08023
  R^2 (Coefficient of Determination) = 0.95344
  Standard Deviation of Residuals = 0.42431 mg/tablet
  Standard Error of Slope = 0.01770
  P Value of Slope = 0.00003.  Slope significant (user selected P = 0.25).
5     Study: _161
  Linear Least Squares:  Y = -0.20861x + 100.78187 (n = 11)
  Residual Sum of Squares (i = 5) = 6.41360
  R^2 (Coefficient of Determination) = 0.83553
  Standard Deviation of Residuals = 0.84417 mg/tablet
  Standard Error of Slope = 0.03085
  P Value of Slope = 0.00008.  Slope significant (user selected P = 0.25).
6     Study: _162
  Linear Least Squares:  Y = -0.22256x + 101.16533 (n = 10)
  Residual Sum of Squares (i = 6) = 7.94614
  R^2 (Coefficient of Determination) = 0.81419
  Standard Deviation of Residuals = 0.99663 mg/tablet
  Standard Error of Slope = 0.03759
  P Value of Slope = 0.00035.  Slope significant (user selected P = 0.25).
7     Study: _163
  Linear Least Squares:  Y = -0.18839x + 100.63436 (n = 10)
  Residual Sum of Squares (i = 7) = 4.18927
  R^2 (Coefficient of Determination) = 0.85622
  Standard Deviation of Residuals = 0.72364 mg/tablet
  Standard Error of Slope = 0.02729
  P Value of Slope = 0.00012.  Slope significant (user selected P = 0.25).
8     Study: _164
  Linear Least Squares:  Y = -0.33021x + 101.25938 (n = 5)
  Residual Sum of Squares (i = 8) = 0.60687
  R^2 (Coefficient of Determination) = 0.95391
  Standard Deviation of Residuals = 0.44977 mg/tablet
  Standard Error of Slope = 0.04190
  P Value of Slope = 0.00426.  Slope significant (user selected P = 0.25).
Model using Different Slopes and Different Intercepts
Total residual Sum of Squares for this model = 47.48613

Step 2.  Fit each individual regression equation with
         different intercepts and a common slope.
1     Study: _11
  Linear Least Squares:  Y = -0.20766x + 101.92085 (n = 8)
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  Residual Sum of Squares (i = 1) = 0.90091
2     Study: _12
  Linear Least Squares:  Y = -0.20766x + 100.49975 (n = 10)
  Residual Sum of Squares (i = 2) = 7.07644
3     Study: _13
  Linear Least Squares:  Y = -0.20766x + 102.12109 (n = 9)
  Residual Sum of Squares (i = 3) = 20.25118
4     Study: _14
  Linear Least Squares:  Y = -0.20766x + 104.19585 (n = 8)
  Residual Sum of Squares (i = 4) = 1.15644
5     Study: _161
  Linear Least Squares:  Y = -0.20766x + 100.77389 (n = 11)
  Residual Sum of Squares (i = 5) = 6.41427
6     Study: _162
  Linear Least Squares:  Y = -0.20766x + 101.02975 (n = 10)
  Residual Sum of Squares (i = 6) = 8.10217
7     Study: _163
  Linear Least Squares:  Y = -0.20766x + 100.80975 (n = 10)
  Residual Sum of Squares (i = 7) = 4.45038
8     Study: _164
  Linear Least Squares:  Y = -0.20766x + 100.45059 (n = 5)
  Residual Sum of Squares (i = 8) = 2.33683
Model using Common Slope and Different Intercepts
Total residual Sum of Squares for this model = 50.68862

Step 3.  Fit a single regression line assuming identical
         degradation curves.
  Linear Least Squares:  Y = -0.19350x + 101.30690 (n = 71)
Model using Common Slope and Common Intercept
Total residual Sum of Squares for this model = 140.77086

Step 4.  Partition the total sum of squares (SStot) into
         sum of squares due to regression (SSreg) and
         residual sum of squares (SSres).
Partition: 322.06000(SStot) = 274.57387(SSreg) + 47.48613(SSres)

                              STATISTICAL ANALYSIS

Standard Conditions Data Models
--------------------------------------------------------------------------------
Model 1: Common Slope and Common Intercept
Model 2: Common Slope but Different Intercepts
Model 3: Common Intercept but Different Slopes
Model 4: Different Intercepts and Different Slopes
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LOWER ONE-TAILED CONFIDENCE INTERVAL
PROBABILITY LEVEL = 95.0% (equivalent to two-tail 90.0% probability)

Key to Sources of Variation
--------------------------------------------------------------------------------
Source   Alternative hypothesis                  Null hypothesis
--------------------------------------------------------------------------------
A = Separate intercepts, separate slopes  Common intercept, common slope
B = Separate intercepts, common slope     Common intercept, common slope
C = Separate intercepts, separate slopes  Separate intercepts, common slope
D = Residual
E = Full Model
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                           TABLE OF STATISTICAL ANALYSIS
--------------------------------------------------------------------------------
Source          SS        DF               MS           F           P
--------------------------------------------------------------------------------
A           93.285        14            6.663      7.7175     0.00000
B           90.082         7           12.869     14.9052     0.00000
C            3.202         7            0.457      0.5299     0.80812
D           47.486        55            0.863
E       703192.324        16        43949.520
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                                DECISION RULES
If the p-value of test C < 0.25, then Model 3 or 4 is applicable.
If the p-value of test C >= 0.25, then test for B.
If the p-value of test B < 0.25, then Model 2 is applicable.
If the p-value of test B >= 0.25, then Model 1 is applicable.

Final results based on the decision rules:
Pooling Allowed (Model 2), Common Slope but Different Intercepts.
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1 Study: _11
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 52 Months.
Trend (CI) at 36 Months = 94.4 - 0.8 (>=93.7) mg/tablet.
2 Study: _12
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 46 Months.
Trend (CI) at 36 Months = 93.0 - 0.8 (>=92.3) mg/tablet.
3 Study: _13
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 53 Months.
Trend (CI) at 36 Months = 94.6 - 0.8 (>=93.9) mg/tablet.
4 Study: _14
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 62 Months.
Trend (CI) at 36 Months = 96.7 - 0.8 (>=96.0) mg/tablet.
5 Study: _161
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 47 Months.
Trend (CI) at 36 Months = 93.3 - 0.8 (>=92.5) mg/tablet.
6 Study: _162
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 48 Months.
Trend (CI) at 36 Months = 93.6 - 0.8 (>=92.8) mg/tablet.
7 Study: _163
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 47 Months.
Trend (CI) at 36 Months = 93.3 - 0.8 (>=92.6) mg/tablet.
8 Study: _164
One Sided Lower Confidence Interval (95.0% CI).
The expiration date was determined when the low specification was exceeded.
Expiration Date = 45 Months.
Trend (CI) at 36 Months = 93.0 - 0.9 (>=92.0) mg/tablet.

Pooled expiration date based on _164

Analysis Complete.

HISTORY INFORMATION
File Version: 5
File Status : ACTIVE
File Name : C:\Program Files (x86)\SLIM\Demo\Standard Conditions.SST
Created : 22 November 2010 at 17:32:34 by Administrator (User ID = 1)
Last Saved : 26 February 2011 at 23:04:41 by Administrator (User ID = 1)