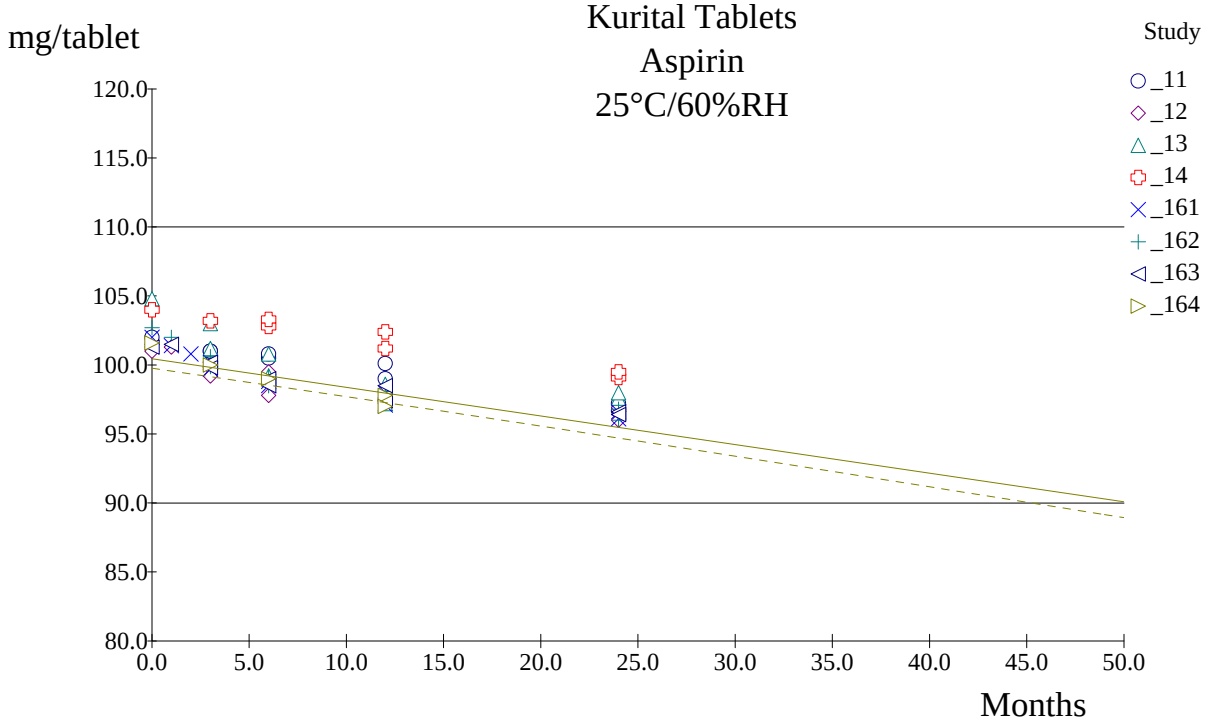
Shelf Life Projection

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...
File: C:\Program Files\SLIM\Standard Conditions.SST User: Craig Hamilton

SLIMStat Regression Analysis and Pooling of Data.

Original Raw Data:

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	101.00	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.

Step 1.  Fit each individual regression equation and
         compute the residual sum of squares.
1     Study: _11
  Linear Least Squares:  Y = -0.20063492x + 101.81746032 (n = 9)
  Residual Sum of Squares (i = 1) = 0.94863492
  Standard Deviation of Residuals = 0.36812943 mg/tablet
  Standard Error of Slope = 0.01466663
  P Value of Slope = 0.000002627871.  Slope significant (user selected P = 0.25).
2     Study: _12
  Linear Least Squares:  Y = -0.18012520x + 100.24913928 (n = 10)
  Residual Sum of Squares (i = 2) = 6.54334898
  Standard Deviation of Residuals = 0.90438854 mg/tablet
  Standard Error of Slope = 0.03411209
  P Value of Slope = 0.000745852799.  Slope significant (user selected P = 0.25).
3     Study: _13
  Linear Least Squares:  Y = -0.23396825x + 102.38412698 (n = 9)
  Residual Sum of Squares (i = 3) = 19.81530159
  Standard Deviation of Residuals = 1.68248547 mg/tablet
  Standard Error of Slope = 0.06703183
  P Value of Slope = 0.010123119806.  Slope significant (user selected P = 0.25).
4     Study: _14
  Linear Least Squares:  Y = -0.19615134x + 104.07064579 (n = 8)
  Residual Sum of Squares (i = 4) = 1.08023483
  Standard Deviation of Residuals = 0.42431019 mg/tablet
  Standard Error of Slope = 0.01769688
  P Value of Slope = 0.000032117668.  Slope significant (user selected P = 0.25).
5     Study: _161
  Linear Least Squares:  Y = -0.20860855x + 100.78187227 (n = 11)
  Residual Sum of Squares (i = 5) = 6.41360491
  Standard Deviation of Residuals = 0.84416987 mg/tablet
  Standard Error of Slope = 0.03085091
  P Value of Slope = 0.000082536238.  Slope significant (user selected P = 0.25).
6     Study: _162
  Linear Least Squares:  Y = -0.22256366x + 101.16532935 (n = 10)
  Residual Sum of Squares (i = 6) = 7.94614028
  Standard Deviation of Residuals = 0.99662808 mg/tablet
  Standard Error of Slope = 0.03759121
  P Value of Slope = 0.000353441007.  Slope significant (user selected P = 0.25).
7     Study: _163
  Linear Least Squares:  Y = -0.18839095x + 100.63435766 (n = 10)
  Residual Sum of Squares (i = 7) = 4.18927017
  Standard Deviation of Residuals = 0.72364271 mg/tablet
  Standard Error of Slope = 0.02729464
  P Value of Slope = 0.000124262163.  Slope significant (user selected P = 0.25).
8     Study: _164
  Linear Least Squares:  Y = -0.33020833x + 101.25937500 (n = 5)
  Residual Sum of Squares (i = 8) = 0.60687500
  Standard Deviation of Residuals = 0.44976846 mg/tablet
  Standard Error of Slope = 0.04190470
  P Value of Slope = 0.004258652557.  Slope significant (user selected P = 0.25).
Model using Different Slopes and Different Intercepts
Total residual Sum of Squares for this model = 47.54341067

Step 2.  Fit each individual regression equation with
         different intercepts and a common slope.
1     Study: _11
  Linear Least Squares:  Y = -0.20723098x + 101.88342091 (n = 9)
  Residual Sum of Squares (i = 1) = 0.97604496
2     Study: _12
  Linear Least Squares:  Y = -0.20723098x + 100.49580192 (n = 10)
  Residual Sum of Squares (i = 2) = 7.05978618
3     Study: _13
  Linear Least Squares:  Y = -0.20723098x + 102.11675425 (n = 9)
  Residual Sum of Squares (i = 3) = 20.26567712
4     Study: _14
  Linear Least Squares:  Y = -0.20723098x + 104.19113691 (n = 8)
  Residual Sum of Squares (i = 4) = 1.15080562
5     Study: _161
  Linear Least Squares:  Y = -0.20723098x + 100.77022556 (n = 11)
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  Residual Sum of Squares (i = 5) = 6.41502576
6   Study: _162
  Linear Least Squares: Y = -0.20723098x + 101.02580192 (n = 10)
  Residual Sum of Squares (i = 6) = 8.11138589
7   Study: _163
  Linear Least Squares: Y = -0.20723098x + 100.80580192 (n = 10)
  Residual Sum of Squares (i = 7) = 4.43876219
8   Study: _164
  Linear Least Squares: Y = -0.20723098x + 100.44772447 (n = 5)
  Residual Sum of Squares (i = 8) = 2.34909406
Model using Common Slope and Different Intercepts
Total residual Sum of Squares for this model = 50.76658178

Step 3. Fit a single regression line assuming identical
         degradation curves.
  Linear Least Squares: Y = -0.19384923x + 101.31393868 (n = 72)
Model using Common Slope and Common Intercept
Total residual Sum of Squares for this model = 140.84407303

Step 4. Partition the total sum of squares (SStot) into
         into sum of squares due to regression (SSreg) and
         residual sum of squares (SSres).
Partition: 324.27875000(SStot) = 276.73533933(SSreg) + 47.54341067(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

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		

TABLE OF STATISTICAL ANALYSIS

Source	SS	DF	MS	F	P
A	93.301	14	6.664	7.8497	0.00000
B	90.077	7	12.868	15.1571	0.00000
C	3.223	7	0.460	0.5424	0.79865
D	47.543	56	0.849		
E	713393.267	16	44587.079		

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.

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.
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.
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.

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.
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.
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.
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.
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.

Pooled expiration date based on _164

Analysis Complete.

HISTORY INFORMATION
File Version: 0
File Status : ACTIVE
File Name : C:\Program Files\SLIM\Standard Conditions.SST
Created : 18 January 2006 at 15:08:44 by Administrator (User ID = 1)
Last Saved : 18 January 2006 at 15:08:44 by Administrator (User ID = 1)