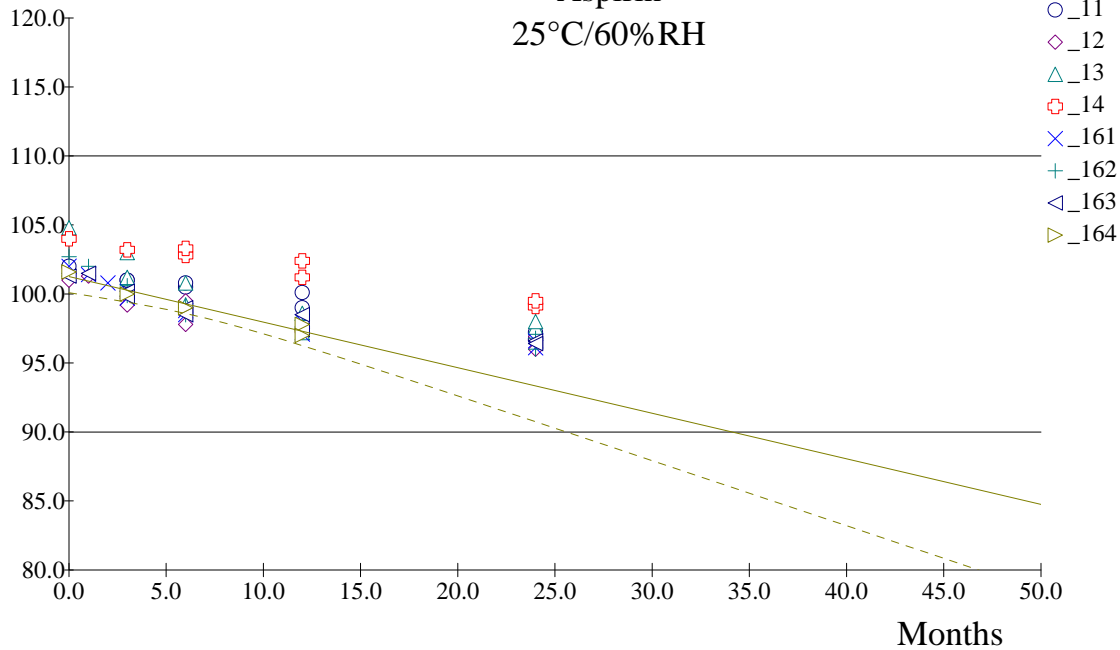


# Shelf Life Projection

Kurital Tablets  
Aspirin  
25°C/60%RH

mg/tablet

Study



Simple Least Squares with Sy/x Pooling (ICH Guideline Calculations) (95.0% CI)

Test Category: HPLC High Spec: 110.0 Low Spec: 90.0

Original FDA Data Set...

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

SLIMStat Simple Least Squares with Sy/x Pooling (ICH Guideline Calculations).

Original Raw Data:

Study	Time	Results
Study 1 _11	0.0	102.00
	3.0	101.00
	6.0	100.50
	24.0	97.20
Study 2 _12	0.0	101.00
	1.0	101.30
	3.0	99.80
	24.0	96.90
Study 3 _13	0.0	104.80
	3.0	103.00
	6.0	100.80
	24.0	98.00
Study 4 _14	0.0	104.00
	3.0	103.20
	6.0	102.80
	24.0	99.10
Study 5 _161	0.0	102.00
	1.0	101.40
	2.0	100.80
	24.0	97.10
Study 6 _162	0.0	102.70
	1.0	102.00
	3.0	100.60
	24.0	96.80
Study 7 _163	0.0	101.30
	1.0	101.50
	3.0	100.20
	24.0	97.40

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.

STATISTICAL ANALYSIS

LOWER ONE-TAILED CONFIDENCE INTERVAL  
PROBABILITY LEVEL = 95.0% (equivalent to two-tail 90.0% probability)

Pooled Residual Sum of Squares = 47.54341067  
Pooled Number of Degrees of Freedom = 56  
Pooled Mean Sum of Squares = 0.84898948  
Pooled Sy/x = 0.92140625

1 Study: \_11  
Linear Least Squares:  $Y = -0.20063492x + 101.81746030$  (n = 9)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 47 Months.

2 Study: \_12  
Linear Least Squares:  $Y = -0.18012520x + 100.24913930$  (n = 10)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 45 Months.

3 Study: \_13  
Linear Least Squares:  $Y = -0.23396825x + 102.38412700$  (n = 9)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 43 Months.

4 Study: \_14  
Linear Least Squares:  $Y = -0.19615134x + 104.07064580$  (n = 8)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 56 Months.

5 Study: \_161  
Linear Least Squares:  $Y = -0.20860855x + 100.78187230$  (n = 11)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 42 Months.

6 Study: \_162  
Linear Least Squares:  $Y = -0.22256366x + 101.16532930$  (n = 10)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 41 Months.

7 Study: \_163  
Linear Least Squares:  $Y = -0.18839095x + 100.63435770$  (n = 10)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 45 Months.

8 Study: \_164  
Linear Least Squares:  $Y = -0.33020833x + 101.25937500$  (n = 5)  
One Sided Lower Confidence Interval (95.0% CI).  
The expiration date was determined when the low specification was exceeded.  
Expiration Date = 25 Months.

Analysis Complete.

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HISTORY INFORMATION

File Version: 1  
File Status : ACTIVE  
File Name : C:\Program Files\SLIM\Test\Standard Conditions.SST  
Created : 20 March 2008 at 14:05:23 by Administrator (User ID = 1)  
Last Saved : 09 May 2008 at 15:51:11 by Daniel Robinson (User ID = 2)