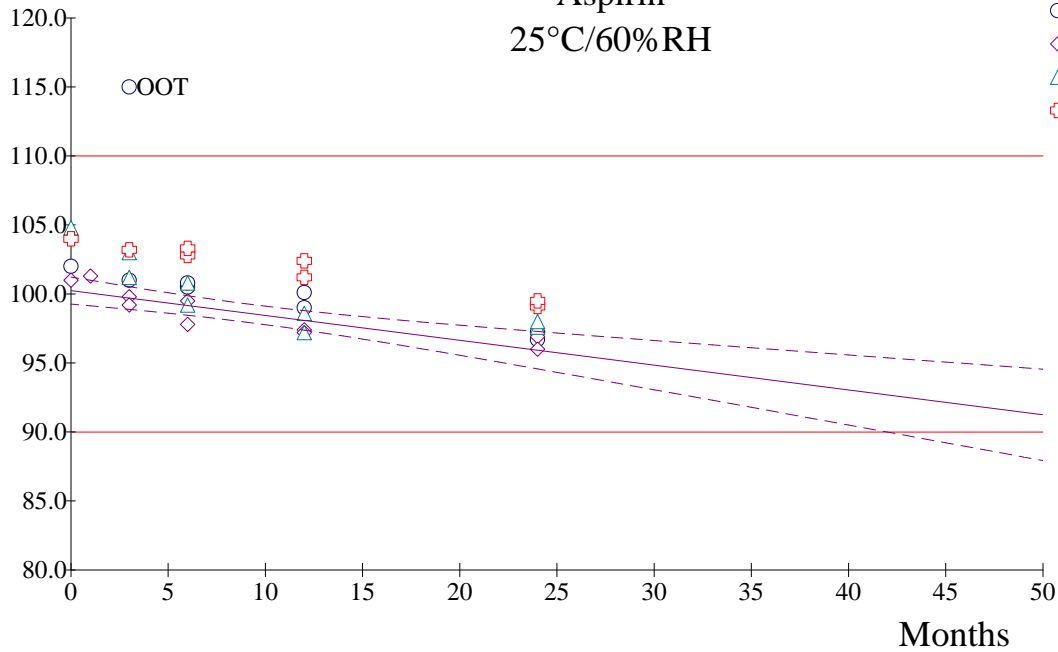


Shelf Life Projection

Kurital Tablets
Aspirin
25°C/60%RH

mg/tablet

Study



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

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

OOT Result added...

File: C:\Program Files (x86)\SLIM\Demo\StandardConditionsSyx.SST User: Craig Hamilton

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

Original Raw Data (Time in units of Months):

Study 1	A34							
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	B32							
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	C35							
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	D16							
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

Original Raw Data Treatment:

- Less than (<) results are ignored.
- Greater than (>) results are ignored.
- A result marked with a question (?) is "Selected for Testing" and is ignored.
- Results marked by an asterisk (*) are "Out of Trend (OOT)" and are ignored.
- Results marked by a pound (#) are "Forcibly Excluded (EXC)" and are ignored.

STATISTICAL ANALYSIS

TWO-TAILED CONFIDENCE INTERVAL
PROBABILITY LEVEL = 95.0%

Pooled Residual Sum of Squares = 28.33024
Pooled Number of Degrees of Freedom = 27

Pooled Mean Sum of Squares = 1.04927
Pooled Sy/x = 1.02434

1 Study: A34

OOT[3.0,115.00][Mult.=3,SD= 0.385432721]Expected= 101.265753425±1.156298162(100.109455262 to 102.422051587) mg/tablet

Linear Least Squares: $Y = -0.20359x + 101.87650$ (n = 8)

Two Sided Confidence Interval (95.0% CI).

The expiration date was determined when the low specification was exceeded.

Expiration Date = 43 Months.

Trend (CI) at 36 Months = 94.5 +/- 2.3 (92.2 to 96.9) mg/tablet.

2 Study: B32

Linear Least Squares: $Y = -0.18013x + 100.24910$ (n = 10)

Two Sided Confidence Interval (95.0% CI).

The expiration date was determined when the low specification was exceeded.

Expiration Date = 41 Months.

Trend (CI) at 36 Months = 93.8 +/- 2.2 (91.5 to 96.0) mg/tablet.

3 Study: C35

Linear Least Squares: $Y = -0.23397x + 102.38410$ (n = 9)

Two Sided Confidence Interval (95.0% CI).

The expiration date was determined when the low specification was exceeded.

Expiration Date = 41 Months.

Trend (CI) at 36 Months = 94.0 +/- 2.3 (91.7 to 96.2) mg/tablet.

4 Study: D16

Linear Least Squares: $Y = -0.19615x + 104.07060$ (n = 8)

Two Sided 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 = 97.0 +/- 2.3 (94.7 to 99.3) mg/tablet.

Analysis Complete.

HISTORY INFORMATION

File Version: 2

File Status : ACTIVE

File Name : C:\Program Files (x86)\SLIM\Demo\StandardConditionsSyx.SST

Created : 26 February 2011 at 22:58:20 by Administrator (User ID = 1)

Last Saved : 26 February 2011 at 23:02:20 by Administrator (User ID = 1)