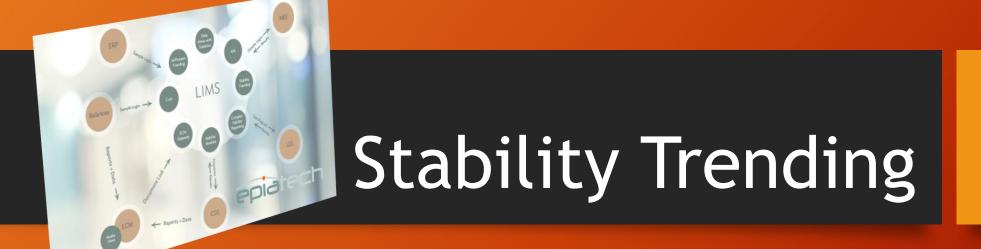
Stability Trending





Overview

- Epiatech Stability Trending module is a vendor independent solution for establishing and monitoring of Stability Trends.
- Standalone Windows application developed for known customer connects to two different LIMS Systems from different vendors.
- Collects LIMS data based on defined query parameters, calculates Stability limits for required Quality Attributes and creates reports according specifications.
- Solves the problem of different test names during longer periods.
- Automated limit evaluations implemented as separate activity and are LIMS System specific.



Stability Trending

Get Stability Data from LIMS

Stability Data is extracted from LIMS System using query criteria that also defines trending group what goes together.

Product Code					1	4	1		-				1
Froduct Lode		Product Code	Sample Type	Lot	Study	Study Type	Packaging (S	Start Date	Orient	Storage	Timepo	Requester Co	Sample
101000000000000000000000000000000000000	•		STABILITY D		07SD20070054	SD	BP-AL-XX-X	2007-06-01	n/a	3075	1M		07335471
itudy Type		111111	STABILITY D		07SD20070054	SD	BP-AL-XX-X	2007-06-01	n/a	3075	ЗМ	-Franklin, Inter-	07341747
SD	•	1111111111111111	STABILITY D	110011000	07SD20070054	SD	BP-AL-XX-X	2007-06-01	n/a	3075	6M	1.4886. 11.0-	07353849
	Ľ	11111100011100	STABILITY D	100011-0004	07SD20070034	SD	BP-AL-XX-X	2007-05-10	n/a	3075	9M	1.0000	07361719
Gample Type		1111100011100	STABILITY D	1100111000	07SD20070054	SD	BP-AL-XX-X	2007-06-01	n/a	3075	9M	1.4666. 11.0-	07364397
STABILITY DEVELOPMENT	-	1111120011100	STABILITY D		07SD20070092	SD	BP-AL-XX-X	2007-11-28	n/a	3075	3M		07364389
Packaging	_	11110301110	STABILITY D		07SD20070093	SD	BP-AL-XX-X	2007-11-30	n/a	3075	3M	+	07364387
		111128011-040	STABILITY D		07SD20070034	SD	BP-AL-XX-X	2007-05-10	n/a	3075	12M	1.1010.010	07373029
BP-AL-XX-XXX-X	•	111128-0111-0-00	STABILITY D		07SD20070054	SD	BP-AL-XX-X	2007-06-01	n/a	3075	12M		07375597
Drientation		11111200111100	STABILITY D	1.100-10-0400	07SD20070092	SD	BP-AL-XX-X	2007-11-28	n/a	3075	6M	110.000	07375589
n/a	•	CONTRACTOR	STABILITY D		07SD20070093	SD	BP-AL-XX-X	2007-11-30	n/a	3075	6M		07375587
	<u> </u>	1111 Carlot And	STABILITY D	1.100-10-0401	07SD20070091	SD	BP-AL-XX-X	2007-11-28	n/a	3075	6M	Hank Linie 1-	07375591
Storage Condition		111123411112	STABILITY D		07SD20070092	SD	BP-AL-XX-X	2007-11-28	n/a	3075	9M		07386877
3075	-		STABILITY D	The state state of the	07SD20070093	SD	BP-AL-XX-X	2007-11-30	n/a	3075	9M		07386873
	_	1 THE REAL PROPERTY.	STABILITY D		07SD20080053	SD	BP-AL-XX-X	2008-07-15	n/a	3075	TO		07388599
Selected Shelf Life / Retest Period		11110301-100	STABILITY D		07SD20080054	SD	BP-AL-XX-X	2008-07-15	n/a	3075	TO		07388612
48M	•	11110301110	STABILITY D		07SD20080055	SD	BP-AL-XX-X	2008-07-15	n/a	3075	TO		07388615
		1111 Calery And	STABILITY D		07SD20080063	SD	BP-AL-XX-X	2008-07-24	n/a	3075	TO		07388638
Search			STABILITY D		07SD20080054	SD	BP-AL-XX-X	2008-07-15	n/a	3075	3M		07392334
Seartsh		11111111111111111	STABILITY D		07SD 20080055 07SD 20080053	SD SD	BP-AL-XX-X BP-AL-XX-X	2008-07-15	n/a n/a	3075	ЗМ ЗМ		07392332



Limit Calculation

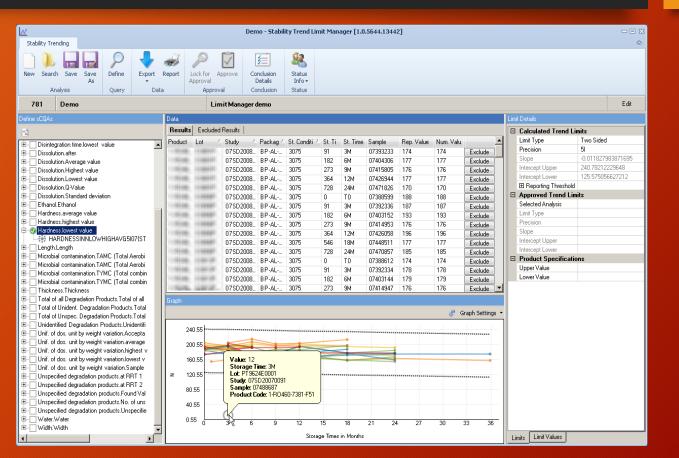
Once data is extracted from LIMS System it is presented to the user in well designed user interface.

Left side lists Stability Quality Attributes (tests) and application allows grouping of different tests under same name

By selecting individual Quality Attribute, Application calculates stability trend limits based on available data.

Data with calculated stability trend limits is displayed in the chart.

Many other features: data exclusion with eSignature, entering conclusions for report, final approval, data export, ...





Data with Limits displayed

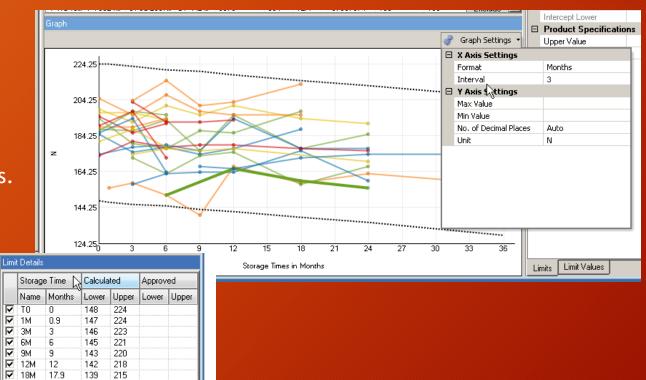
✓ 24M

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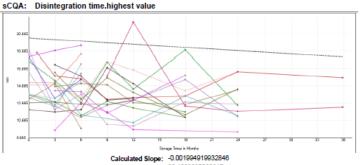
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Chart displays data and stability limits. Many chart configuration options are available to configure chart output.





Report (PDF) and Export (XLS)



Calculated Intercept-Upper Limit: 20.1529237520817 Calculated Intercept-Lower Limit: N/A

Time Point	Time Point Months	Lower Trend Limit Calculated	Upper Trend Limit Calculated		
то	0	N/A	20.153		
1M	0.9	N/A	20.097		
3M	3	N/A	19.971		
6M	6	N/A	19.790		
9M	9	N/A	19.608		
12M	12	N/A	19.427		
18M	17.9	N/A	19.064		
24M	23.9	N/A	18.701		
36M	35.9	N/A	17.974		

Comments: N/A

Disintegration time.highest value Analysis Data:

Lot	Study	Product Code	Packaging	Storage Condition	Time Point	Reported Value	Numeric Value
	07SD20070034		BP-AL-XX-XXX-X (Schedule 1)	3075	9M	15.8	15.8
pere	07SD20070034	100001-00110	BP-AL-XX-XXX-X (Schedule 1)	3075	12M	22	22
-	07SD20070034	100001-00110	BP-AL-XX-XXX-X (Schedule 1)	3075	18M	12.3	12.3
proper l'	07SD20070034	100001-00110	BP-AL-XX-XXX-X	3075	24M	11.7	11.7

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	Office Document	Edit	Page Se	tup Window										
	A	В	С	D		E	F	G	Н	1	J	K	L	М
1 Disintegration time.highest value]												
2				Ī										
3	Product Code	Lot	Study	Packaging (Sch	edule)	Storage Condition	Study Type	Sample Type	Orientation	Sample	Timepoint	Timepoint Days	Reported Value	Numeric Value
4	101201-001201		07SD20070034	BP-AL-XX-XXX-X (Sch	edule 1)	3075	SD	STABILITY DEVELOPMENT	n/a	07361719	9M	273	15.8	15.8
5			07SD20070034	BP-AL-XX-XXX-X (Sch	edule 1)	3075	SD	STABILITY DEVELOPMENT	n/a	07373029	12M	364	22	22
6			07SD20070034	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a	07394884	18M	546	12.3	12.3
7		and a second second second	07SD20070034	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a	07417411	24M	728	11.7	11.7
8			07SD20070034	BP-AL-XX-XXX-X (Sch	· · · · ·	3075	SD	STABILITY DEVELOPMENT	n/a	07462521	36M	1092	12.2	12.2
9		and the second second	07SD20070054	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a	07335471	1M	28	18.45	18.45
10			07SD20070054	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a		3M	91	15.83	15.83
11			07SD20070054	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a	07353849	6M	182	15.5	15.5
12	14108-121141		07SD20070054	BP-AL-XX-XXX-X (Sch		3075		STABILITY DEVELOPMENT	n/a	07364397	9M	273	13.1	13.1
13	101101-101101		07SD20070054	BP-AL-XX-XXX-X (Sch	edule 1)	3075	SD	STABILITY DEVELOPMENT	n/a	07375597	12M	364	13.3	13.3

