

GUS-OS Laboratory with Stability Checks



An important quality feature of a drug is its stability in the primary packaging and its stability after the packaging being opened. The stability checks that are necessary in the laboratory are indispensable requirements in the pharmaceutical industry and are now becoming just as important for the food industry. This functionality is available as an additional module of the Laboratory Information Management System GUS-OS Laboratory.*

The shelf life of new products and the stability of product variants after opening can be established according to FDA and ICH** guidelines in the development stage using GUS-OS Laboratory. For production lots these stability checks support new launches (ICH checks) and also the complete product-lifecycle (follow-up checks).

The stability checks have fixed test periods for different climatic conditions. Thus the stability check profile consists of several test profiles that must be satisfied before product release. Such a test profile with several test profile lines (test coverage) can be altered for all test periods and for all climatic zones.

When matrixing the test coverage for detailed planning it is possible to parameterise all the stability test profiles for the individual dimensions (time, climate, test method). This ensures enough

data available for continual descriptions of product quality without requiring that the complete test coverage is carried out for every period.

The storing of the stability checks, that are to be carried out, occurs „n“ days before the test period starts. For statistical evaluations standard views are available in table form as well as basic graphics. In addition all the data for the stability check can be exported to Excel for detailed reports, evaluations and graphics.

GUS-OS ERP Management center stability matrix (qt5506_itemProd_page) Apr 24, 2008 1:59:27 PM

Material no.: 150001, Stability matrix: Test080424, Version : 2

Action	Material no.	Stability matrix	Version	Type	Total number samples	Released from	Standard matrix
	150001	Test080424		2/Followup	0		no

Buttons: Maintain detailed plan, show all periods, cancel

Buttons: Rough plan, Detailed plan, Sample distribution

Detailed plan matrix

Climate zone	No.	Version	Test method	Description	0..N	3..N	6..N	9..N
25/60 EMEA Longterm	2997	1	Identität	(Prüfung des Etiketts der Lieferung)	1 - Mandatory	1 - Mandatory		3 - Inb
25/60 EMEA Longterm	51	1	(3- in-Phosphatid)Cholin		1 - Mandatory	1 - Mandatory		3 - Inb
25/60 EMEA Longterm	3283	1	Mikrobiologische Befunde		1 - Mandatory	1 - Mandatory		
25/60 EMEA Longterm	3256	1	Testmethode MH rangikalart		1 - Mandatory			
25/60 EMEA Longterm	97	2	Summe Verunreinigungen		1 - Mandatory			
25/60 EMEA Longterm	3284	1	Testmethode HarF Beurteilend		1 - Mandatory			
25/60 EMEA Longterm	3285	1	Testmethode HarF Numerisch		3 - Inb			
25/60 EMEA Longterm	3287	1	Testmethode HarF klassifizierend		1 - Mandatory			
30/65 EMEA Intermediate	2997	1	Identität	(Prüfung des Etiketts der Lieferung)	1 - Mandatory	4 - Inactive		
30/65 EMEA Intermediate	51	1	(3- in-Phosphatid)Cholin		1 - Mandatory	4 - Inactive		
30/65 EMEA Intermediate	3283	1	Mikrobiologische Befunde			4 - Inactive		
30/65 EMEA Intermediate	3256	1	Testmethode MH rangikalart			4 - Inactive		
30/65 EMEA Intermediate	97	2	Summe Verunreinigungen		1 - Mandatory			
40/75 EMEA Accelerated	2997	1	Identität	(Prüfung des Etiketts der Lieferung)	2 - Conditional	1 - Mandatory	1 - Mandatory	1 - Mandatory
40/75 EMEA Accelerated	51	1	(3- in-Phosphatid)Cholin		2 - Conditional	1 - Mandatory	4 - Inactive	1 - Mandatory
40/75 EMEA Accelerated	3283	1	Mikrobiologische Befunde		2 - Conditional	1 - Mandatory	2 - Conditional	1 - Mandatory
40/75 EMEA Accelerated	3256	1	Testmethode MH rangikalart		2 - Conditional	1 - Mandatory	2 - Conditional	1 - Mandatory
40/75 EMEA Accelerated	97	2	Summe Verunreinigungen		2 - Conditional	1 - Mandatory	1 - Mandatory	1 - Mandatory
40/75 EMEA Accelerated	3284	1	Testmethode HarF Beurteilend		1 - Mandatory	1 - Mandatory	1 - Mandatory	1 - Mandatory
40/75 EMEA Accelerated	3285	1	Testmethode HarF Numerisch		1 - Mandatory			
40/75 EMEA Accelerated	3287	1	Testmethode HarF klassifizierend		1 - Mandatory	1 - Mandatory	1 - Mandatory	1 - Mandatory
40/75 EMEA Accelerated	3289	1	Testmethode HarF Numerisch			1 - Mandatory	1 - Mandatory	1 - Mandatory

It is possible to carry out the detailed planning of a stability specification by just one click. Checks can be classified different.

* since Release 2.0

** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

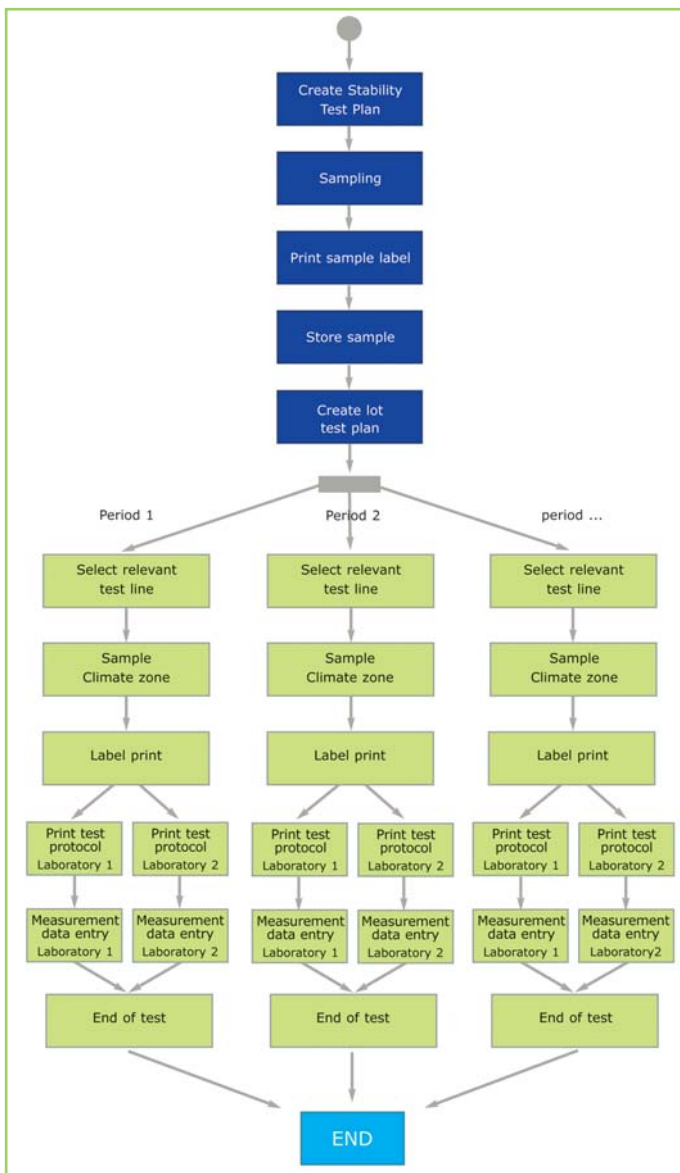
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GUS-OS Laboratory fulfills 21 CFR Part 11

In regulation 21 CFR Part 11 the FDA has stipulated the requirements for electronic recording of GMP relevant information as well as for electronic signatures. This is to ensure that electronically stored information and electronic signatures satisfy the same requirements as the paper form. This includes manufacturing audit trails, data entries, management of quality controls as well as the archiving of electronic data and documents. In addition only competent and authorized personnel are allowed to release processes and authorize documents.

GUS-OS Laboratory/Stability complies with the regulations for 21 CFR Part 11.



Stability Test Plan Diagram for Follow-up and ICH Test