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Document History

<u>Revision</u>	Date Effective	Comment
1.0	06-Nov-06	New User Requirements.
2.0	16-Nov-06	Split between mandatory and desired. Added correspondence between display fields and message elements and attributes.
3.0	30-Nov-06	Added tables that map from the Implementation Guild to the Input Tool fields. Expiry dating fields must allow TBD. Updated form layout pages.
4.0	05-Dec-06	Removed elements whose optional status was N – not used and where there was no form field. Created new tab for lot specific information. Added fields for storage condition simple elements and Component4.
4.1	11-Dec-06	Added clarification on layout as example and meaning of scrollbars. Make Pull Date and Test Date mandatory.
5.0	25-Jan-07	Added storyboards on use of Input Tool. Implementation based on F column options. Clarified ODBC requirement. Track changes highlighted.
5.1	2-Feb-07	Changes accepted plus minor edits. TOC redo.
5.2	21-Feb-07	Edits Terry Hardin

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1.0 Introduction

1.1 Proposed Project

Develop an eStability message input tool based and the PORT_IN0900001UV01 schema. The Input Tool will allow the entry and reporting of stability data as an XML file. The Input Tool will allow users to enter data and build a stability message that can be validated against the PORT_IN0900001UV01 schema. The message wrapper can either be filled in or empty. The tool will support the three interactions possible with the message: send, revise and retract.

Data entry can be keyboard strokes to field submission, inserted xml fragments from files or any combination of the two. Minimal user input can be achieved if most of the data loaded into the input tool is via file inclusion. The input tool will support XML authoring without requiring users to understand the technical complexities of XML.

1.2 Workflow

The stability data can be entered through the form via keyboard strokes. The stability data can be loaded into the form from Excel files in a predefined format, CSV files in a predefine format, or from a database connection via ODBC. It may take several files to retrieve data. Excel and CSV may be restricted to regular data like specifications and the test results. XML fragments in files may also be accepted. The form will know the mapping to the appropriate fields within the form. The user reviews the data in the form by sight. If blank fields are found, users will manually supply the data to the form. The files are saved into directories on the file system. Versioning of the XML messages is a non-goal of the project. As the data is acquired from multiple sources, the parts are merged to create XML files that can be validated against PORT_IN0900001UV01. For FDA submissions the message can either contain the message wrapper or it can be left blank if transmission is via CD-ROM.





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 actions that might take place in preparing a stability message. Each of these messages created in the different scenarios can be saved on a file system with or without a message wrapper to indicate its status as a new, a revised or retracted message. 1.4.2 Prepare a message with the tool. Alpha Pharmaceuticals has collected its stability data from its testing labs in PDF documents that it has collected over several years. Alpha is preparing this information relating to its new product, FixMyDoggie, for submission by transcribing all of this data into eStability Message Input Tool. They have conducted five studies with the same protocol. After the data from the first study is transcribed, they use the validation feature, to correct their errors until the file is valid. They save the file. They make a copy of the file on the file system and name it FMD_template.xml. FMD_template.xml is then opened in eStability Message Input Tool and they delete all the information on the Test Results page and the Lot Info page. They only delete the Unique Study ID on the Study Info because they used the same protocol on all of the studies. The data on the Specification and Product/Substance pages remain. They clear the testing sites and manufacturers from the organization page. They then clear the Study Root page. They save the file. They make four copies of the file and name them for each of the remaining four studies. They open each file and transcribe the remaining data from the PDF 			
1.4.3 Prepare a Beta Drugs, Inc. The microbial tes is Excel and all th exchange of stat The submission a with three storag worksheets and Message Input T specified by the o the result tab pag	 1.4.3 Prepare a message with the tool and Excel files Beta Drugs, Inc. has multiple testing facilities. Some of the facilities have LIMS systems. The microbial testing lab does not. The one software package they all have in common is Excel and all the LIMS export to Excel. They have standardized on Excel for the exchange of stability data and have standardized codes for all testing. The submission assembly team is preparing an IND for BetaBeGone with nine studies with three storage conditions. They request that all of the labs submit the data in Excel worksheets and provide them the predefined column headers used by eStability Message Input Tool. The facilities with LIMS systems export their data into Excel format specified by the eStability Message Input Tool documentation for data to be entered into the result tab page fields. The microbial testing lab transcribes from their notebooks into 		
Excel. The submission a except the test re storage condition total of nine files BetaBeGone, en inserts the Excel based on Beta's	assembly team enters all of the data in eStability Me esults and Study Root. They make two copies of thi is in each. They make three copies of each of the t for each of the studies. Beta's team then opens ea ters the Study Root information. They then go to the file for the study. The tool matches the specificati standardized codes. Each study file is validated and	essage Input Tool is file and edit the hree files making a ch study file for e result page and on to the test results d saved.	
1.4.4 Prepare a Gamma Bios, Inc Gamma Pharm. the time of acqui commercial testin They are plannin years away. The Regulatory Oper as PORT_MT090	A Message with the Tool and XML Fragments c. resulted from the acquisition of a biologics researd Both divisions insist on keeping the LIMS systems sition. The methods and specs are only in the researd data, referenced by the method id is stored in the g an UberLIMS implementation to unite the compar- ey are preparing an NDA for GBI-245 that aids in tise ations has requested that each group export what in 0001UV01 XML fragments.	ch lab (Bios) by they had in place at arch side LIMS. The e other system. hy, but that is two sue repair. hformation they have	

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	The Bios side exports their data as a Subject2 complex type. The commercial testing group exports their data as a Component1 complex type. The definitionStub of the Test complex object within Component1 matches the testDefinitionCodes in the Subject2 fragment as the method id.			
	Regulatory Operations creates a new file in eStability Message Input Tool. They import the two XML file fragments for each study and fill in the remaining blank mandatory fields. Since the testDefinitionCodes need to be UIDs, they prefix the Test ID on the Specification page with appropriate UID extensions for the new company. The tool validates the new value in the field and informs the user that old value is referenced by other parts of the message. The tool prompts the user if they want to change the old test Id values associated with the results to the new testDefinitionCodes. The user accepts and eStability Message Input Tool updates the unseen definitionStubs in the Test complex. The file is validated and saved.			
	 1.4.5 Edit a Message with the Tool Delta Generics, Inc subcontracts its stability testing to a lab with a LIMS system that provides all of its data in an HL7 optionally message. Delta Generics is preparing its Annual Report on MeTooFixYou, and must edit these messages to make them compliant with the FDA Optionality. Sally Proffer was assigned the task of making the file ready for submission by end of day tomorrow. She must open the file in eStability Message Input Tool , find all fields with bold labels that are empty and type in values for these mandatory fields. She wants to have most of this task done before she leaves for the day. She immediately goes to the specification tab because this is where fields are often left blank and fills them in. She saves her work to a new file and leaves for the day. When she returns the next morning, she opens the saved file and fills in the study root fields, validates the file and then saves it. Her boss then tells her that it was not one file but twenty. 			
	Looking at the clo get done with all validated file on t eStability Message the Specification stability message fragment into the job.	ock she realizes this process is too time consuming the studies on MeTooFixYou by the end of the day. he file server and names it spec123.xml. She open ge Input Tool and deletes all the data in the fields e Tab. She then saves spec123.xml. She can now o s from the lab, and use the insert file option to bring message. She now only has to fill in the study roo	and she will never She copies the s spec123.xml in xcept for those on open each of the g the spec123.xml t fields to finish the	
	1.4.6 Prepare a	Message with an ODBC Connected Tool		
	Epsilon In Silico P HemoSerration in they have more th only meet their rep into eStability Mess the database and u the eStability Mess	harma, LTD is a large company and stores all of its a database. It is just one of twenty drugs they pro- an one annual report each month. Their headcoun porting requirements by directly importing the data f sage Input Tool. Their IT department installed an OI used a software development tool to map the data from age Input Tool.	data on luce which means t is flat. They can rom the database DBC connection to n their database to	
	ESTABILITY MES to extract stability form. The databa added to the mess field(s) and Metho and saved.	SAGE INPUT TOOL 's custom queries allow Epsilo data based on the lot number and storage condition se does not have test codes or method codes for its sages for HemoSerration. The user enters them in od Code fields on the specification page. Then the r	on In Silico Pharma ns entered into the s test. So, they are the Test code/Name nessage is validated	

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2.0 Statement of User Requirements

The stability message input tool shall be capable of loading properly formatted stability data. It shall be able to collate data in all input formats and accept user input until a valid stability message is produced in the form of a single XML file. A layout example for the stability message input tool is in section 5.2. The implementation can contain any number of tabbed pages and layout. The requirements that follow make specific reference to the tab and fields through label identifiers. These tabs and labels are the suggested tabs and labels in the stability message input tool. There is no one-to-one correspondence between the fields in section 5.2 and the elements in the message. Some elements must be generated from information entered in these fields.

2.1 Mandatory Requirements

- 2.1.1 The stability message input tool shall provide a graphical user interface with GUI conventions for entering information.
- 2.1.2 The stability message input tool shall allow a user to create, view, update and delete information about products, lot, specification, study and test results that support the creation of a stability message.
- 2.1.3 The stability message input tool shall provide a field for all elements and attributes in the PORT_IN0900001UV01 schema.
- 2.1.4 The stability message input tool shall support the creation of the message wrapper and default to an empty message.
- 2.1.5 The stability message input tool shall provide List of Values pick-list for fields based on identifiers created in fields in prior tab sections of the form. An example is Testing Sites entered on the Organization page are available in the assigned test site pick list on the test results page.
- 2.1.6 The stability message input tool shall support the ISO 8601 date format and provide calendar lookup for all date fields. Date fields can also accept text input for values such as "TBD."
- 2.1.7 The stability message input tool shall support data entry of special characters like μ .
- 2.1.8 The stability message input tool shall provide the ability to input data from CSV files for certain data in a predefined format.
- 2.1.9 The stability message input tool shall provide the ability to input data from Excel files for certain data in a predefined format unless it provides the ability to input data from a database.
- 2.1.10 The stability message input tool shall support a comment field on the test results page via a button to a pop up or as a viewable field on the page. The data maps to component3/test/text and will typically record out of specification investigation findings. A form design may consider that the field will be used infrequently.
- 2.1.11 The stability message input tool shall bold or color labels to indicate mandatory fields.
- 2.1.12 The stability message input tool shall disable appropriate fields based on radio button choices.
- 2.1.13 The stability message input tool shall have a toolbar to provide quick and convenient access to commonly performed user operations. The toolbar can be any style: button, menu or drop-down lists. An example menu is in section 5.1.

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	2.1.14	2.1.14 The stability message input tool shall support PORT_IN0900001UV01, PORT_IN0900002UV01 and PORT_IN0900003UV01 type messages				
	2.1.15	The stabil	ity message input tool shall open an existing stabili	ty message.		
	2.1.16	The stabil	ity message input tool shall create new stability me	ssages.		
	2.1.17	The stabil regardles	ity message input tool shall save the stability mess s of validation status.	age content		
	2.1.18	The stabil	ity message input tool shall validate the stability me	essage.		
	2.1.19	The stabil	ity message input tool shall provide copy, cut and p	aste functions.		
	2.1.20	elements Compone message. storage co generate place the StabilityS are found weight los pH is ente loss resul Compone Guide for The stabil	from the data entered as in specifications and test int2 explicitly associates the test and storage condit A test needs only to be entered once in the specific onditions are entered as is the case of cycled studie as many Component2 elements as there are storage tests in the tudy/Component/StudyOnBatch/Component2/testin in the results based on the condition code. For exa as are entered in the specification as a tests. On the ered for storage condition 25°C/60% RH and 40°C/7 ts are recorded only for 40°C/75% RH. The tool will nt2's and weight loss will only appear as a test in o nt2 – Element: Sample Code section of the eStabili more examples.	results. ions found in the ication. If two es, then the tool will ge conditions and g code and tile as ample, pH and e results page, the 75% RH, but weight I generate two ne of them. Refer to ity Implementation		
	2.1.22	the exam The stabil	tability message input tool shall support test result value typing as PQ and			
	2.1.23	then it will	be typed as ST. ity message input tool shall validate individual fields	s against the		
		schema as the user enters data. When data is entered from an input source, then validation will occur when the user executes a validate command.		an input source, command.		
	2.1.24	The stabil instances	ity message input tool shall allow input of an infinite where scrollbars are used in the layouts.	e number of element		
2.2	Desirat	ole Require	ements			
	2.2.1	The stabil based on	ity message input tool shall support restricted acce password for access.	ss to individual tabs		
	2.2.2	The stabil	ity message input tool shall mask the password ent	ry.		
	2.2.3	The stabil	ity message input tool shall provide on line help for	each field.		
	2.2.4	The stabil database.	ity message input tool shall provide the ability to inp	out data from a		
	2.2.5	The stabil by fill dow	ity message input tool shall provide a method to du n and fill up operations in tabular data.	plicate data records		
	2.2.6	The stabil data field	ity message input tool shall mark all modifications r data via color or other visual attribute before modifi	nade to the stability cations are saved.		
	2.2.7	The stabil file location	ity message input tool shall support browsing file fo on as a hyper -link in a field.	lders and saving the		
	2.2.8	The stabil	ity message input tool shall warn when the saved n	nessage is not valid.		

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30	Label to Message	• Manniı	ng l	
	The following tab elements and attr others the tool ne	les link th ibutes in eds to d	ne fields in the Form Layout Examples in se eStability message. In some cases the merive the output XML from the data provide	ection 5.2 to apping is explicit, in d.
3.1	Message Info Fiel	ds		
	To save space, MCCI_MT0001000UV01.Message is abbreviated to Message; MCAI_MT700201UV01.ControlActProcess is abbreviated to ControlActProcess and MCAI_MT700201UV01.Subject2 is abbreviated to Subject2.			Message; ActProcess and
	Field Label		Message Element	
	Radio Buttons		User selection to indicate use of fields on	the tab
	Message Type		User selection indicates if this message is revision to a previous study, or a retractio study. The tool will generate PORT_IN09 PORT_IN0900002UV01 and PORT_IN09 messages respectively.	s a new study, a n of a previous 00001UV01, 00003UV01
	Message ID		Message/id	
	Creation Time		Message/creationTime	
	Security Text		Message/securityText	
	Version Code		Message/versionCode	
	Interaction ID		Message/interactionId	
	Profile ID		Message/profileId	
	Processing Code		Message/processingCode	
	Sequence Numbe	r	Message/sequenceNumber	
	Processing Mode	Code	Message/processingModeCode	
	Accept Ack Code		Message/acceptAckCode	
	Attachment Text		Message/attachmentText	
	Receiver		Message/receiver/device/id	
	Sender		Message/sender/device/id	
	Attention Line		Message/attentionLine	
	Respond To		Message/respondTo/entityRsp/id	
	Control Act Proces	ss Id	Message/controlActProcess/id	
	Code		Message/controlActProcess/code	
	Text		Message/controlActProcess/text	
	Effective Time		Message/controlActProcess/effectiveTime	e
	Priority Code		Message/controlActProcess/priorityCode	
	Reason Code		Message/controlActProcess/reasonCode	

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	Language Code		Message/controlActProcess/languageCoo	de Complex many fields
	Overseer		Message/controlActProcess/overseer/ass ignedPerson/name	ignedPerson/ass
	Author		Message/controlActProcess/authorOrPers	sormer
	Data Enterer		Message/controlActProcess/dataEnterer/a assignedPerson/name	assignedPerson/
	Recipient		Message/controlActProcess/informationR dPerson	ecipient/assigne

3.2 Study Root Fields

Field Label	Message Element
ID for Document	/stabilityStudy/id
Text or Link to Text	/stabilityStudy/text
Study Code	/stabilityStudy/code
Other	Field to enter study code if Other is checked. Left blank otherwise.
Reason Code for this Document	/stabilityStudy/reasonCode

3.3 Organization Fields

Field Label	Message Element
Study Sponsor OID	/stabilityStudy/ResearchSubject.researchSponsor/id
Study Sponsor	/stabilityStudy/ResearchSubject.researchSponsor/name
Address	/stabilityStudy/ResearchSubject.researchSponsor/address
Country	/stabilityStudy/ResearchSubject.researchSponsor/address
Testing Site Unique ID	/stabilityStudy/component1/studyOnBatch/component2/testi ng/component3/test/performer/assignedEntity/assignedTesti ngSite/id
Testing Site	/stabilityStudy/component1/studyOnBatch/component2/testi ng/component3/test/performer/assignedEntity/assignedTesti ngSite/name
Address	/stabilityStudy/component1/studyOnBatch/component2/testi ng/component3/test/performer/assignedEntity/assignedTesti ngSite/addr
Country	/stabilityStudy/component1/studyOnBatch/component2/testi ng/component3/test/performer/assignedEntity/assignedTesti ngSite/addr
Manufacturer Unique ID	/stabilityStudy/component1/studyOnBatch/subject/instance/

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			manufacturedMaterialInstance/asManufactufacturer/id	turedProduct/man
	Manufacturer		/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asManufact ufacturer/name	subject/instance/ turedProduct/man
	Address		/stabilityStudy/component1/studyOnBatch/	subject/instance/

	manufacturedMaterialInstance/asManufacturedProduct/man ufacturer/addr
Country	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/asManufacturedProduct/man ufacturer/addr

3.4 Product/Substance Fields

Field Label	Message Element
Finished Product/API radio buttons	Indicates that this message is about stabiltyStudy/ subject/researchSubject/subjectProduct or subjectSubstance.
Expiration Time	stabiltyStudy/subject/researchSubject/subjectProduct/expiration Time
Description	stabiltyStudy/subject/researchSubject/subjectProduct/desc
Code	stabiltyStudy/subject//researchSubject/subjectProduct/code
Form Code	stabiltyStudy/subject/researchSubject/subjectProduct/formCode
Specified Ingredient	stabiltyStudy/subject/researchSubject/subjectProduct/specifiedIn gredient/substance/code
Quantity	stabiltyStudy/subject/ researchSubject/subjectProduct/specificedIngredient/quantity
Code	stabiltyStudy/subject/researchSubject/subjectSubstance/code
Description	stabiltyStudy/subject/researchSubject/subjectSubstance/desc

3.5 Specification Fields

Field Label	Message Element
Specification Code	stabiltyStudy/subject/researchSubject/subjectOf/specification/ code
Specification Text	stabiltyStudy/subject/researchSubject/subjectOf/specification/ text
Test ID	stabiltyStudy/subject/researchSubject/subjectOf/specification/ Component5/testDefinition/id
Test Name	stabiltyStudy/subject/researchSubject/subjectOf/specification/ Component5/testDefinition/code code and displayName attributes. May use two fields.

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	Method Code		stabiltyStudy/subject/researchSubject/subje Component5/testDefinition/methodCode	ctOf/specification/
	Test Text		stabiltyStudy/subject/researchSubject/subje Component5/testDefinition/text	ctOf/specification/
	Test Definition		stabiltyStudy/subject/researchSubject/subje Component5/testDefinition/Component6/test test definition can also be a Component6 w	ctOf/specification/ stDefinition This hich is a singular

	dependent structure like Component5
Interpretation Code	stabiltyStudy/subject/researchSubject/subjectOf/specification/ Component5/testDefinition/referenceRange/acceptanceCriter ion/interpretationCode
Acceptance Criterion Value	stabiltyStudy/subject/researchSubject/subjectOf/specification/ Component5/testDefinition/referenceRange/acceptanceCriter ion/value
Acceptance Criterion Text	stabiltyStudy/subject/researchSubject/subjectOf/specification/ Component5/testDefinition/referenceRange/acceptanceCriter ion/text

3.6 Lot Info Fields

Field Label	Message Element
Manufactured Quantity	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/quantity
Lot Number	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/lotNumber Text
Production Date	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/existenceTime
Expiration Date	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/expirationTime
Production Description OR URL to PDF	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/desc
Manufacturer	Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/asManufacturedProduct/man ufacturer elements
Assigned Manufacturer	Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/asManufacturedProduct/man ufacturer/assignedEntity elements
Batch Lot Number	/stabilityStudy/component/studyOnBatch/subject/instance/m anufacturedMaterialInstance/batchIngredient/Manufactured Material - lotNumber Text
Batch Quantity	/stabilityStudy/component/studyOnBatch/subject/instance/m

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	anufacturedMaterialInstance/batchIngredient/Quantity
	and active divide mainstance/batching redient/ Quantity
Manufacture Date	/stabilityStudy/component/studyOnBatch/subject/instance/m anufacturedMaterialInstance/batchIngredient/Manufactured Material - existenceTime
Batch Expiry Date	/stabilityStudy/component/studyOnBatch/subject/instance/m anufacturedMaterialInstance/batchIngredient/Manufactured Material - expirationTime
Manufacturer	Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component/studyOnBatch/subject/instance/m anufacturedMaterialInstance/batchIngredient/Manufactured Material - manufacturer elements
Batch Description	/stabilityStudy/component/studyOnBatch/subject/instance/m anufacturedMaterialInstance/batchIngredient/Manufactured Material - desc

3.7 Study Info Fields

Field Label	Message Element
Unique Study ID	/stabilityStudy/component1/studyOnBatch/id
Study Type	/stabilityStudy/component1/studyOnBatch/code
Condition Start Date	/stabilityStudy/component/studyOnBatch/component/storage /effectiveTime
Storage Condition Code	/stabilityStudy/component/studyOnBatch/component/storage /controlVariable/storageCondition/code
Storage Condition Value	/stabilityStudy/component/studyOnBatch/component/storage /controlVariable/storageCondition/value
Condition Description or Reference	/stabilityStudy/component/studyOnBatch/component/storage /controlVariable/storageCondition/text
Storage Condition Code	Storage condition code(s) for the study. They must correspond to the storage conditions entered above. Plural only for cycled studies or studies with container orientations.
Storage Condition Text Description	Description of conditions. Used to build Component2(s).
Time Point Code	/stabilityStudy/component/studyOnBatch/component/testing/ code Corresponds to the Time Points entered on the Results tab. Used to group the results into components.
Time Point Name	/stabilityStudy/component/studyOnBatch/component/testing/ title
Pull Date	/stabilityStudy/component/studyOnBatch/component/testing/ effectiveTime
Description	/stabilityStudy/component/studyOnBatch/component/testing/ text

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Fitle:	User	Requirements			
Container Nar	ne	/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/	/subject/instance/ code		
Container Des	scription	/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/	'subject/instance/ desc		
Container Lot	Number	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/asContent/lotNumber Text			
Container Qua	antity	/stabilityStudy/component1/studyOnBatch/subject/instance/ manufacturedMaterialInstance/asContent/capacityQuantity numerator and denominator attribute			
Container Clos Code	sure	/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/	'subject/instance/ container/code		
Container Cap	oacity	/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/ value attribute	/subject/instance/ capacityQuantity		
Unit		/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/ unit attribute	/subject/instance/ capacityQuantity		
Container Des	scription	/stabilityStudy/component1/studyOnBatch/ manufacturedMaterialInstance/asContent/	/subject/instance/ desc		

3.8 Test Results Fields

Field Label	Message Element
Seq	Left blank for Component3/test
	/stabilityStudy/component/studyOnBatch/component/testing/comp onent/test/component4/sequence
Condition Code	Pick list of storage conditions from Study Info: Storage Condition Code to be entered into /stabilityStudy/Component1/studyOnBatch/Component2/storage/c ontrolVariable/storageCondition/code
Test Name	Pick List of Names entered in Specification: Test Name. Associated code and title in test is entered in /stabilityStudy/Component1/studyOnBatch/Component2/testing/co de and title
Time Pt	/stabilityStudy/Component1/studyOnBatch/Component2/pauseQu antity value attribute
Pull Date	/stabilityStudy/component/studyOnBatch/component2/testing/effe ctiveTime
	or
	/stabilityStudy/component/studyOnBatch/component/testing/comp onent/test/component4/test/effectiveTime

		Stability Message Input Tool	Page 17 of 38
Title:		User Requirements	
Unit		/stabilityStudy/Component1/studyOnBatch/Comp antity unit attribute or /stabilityStudy/component/studyOnBatch/compor onent/test/component4/test/pauseQuantity	oonent2/pauseQu nent/testing/comp
Res	ult	/stabilityStudy/Component1/studyOnBatch/Comp mponent3/value or /stabilityStudy/component/studyOnBatch/compor onent/test/component4/test/value	ponent2/testing/co nent/testing/comp
Unit		/stabilityStudy/Component1/studyOnBatch/Comp mponent3/value unit attribute if data type of resul for ST data types. or /stabilityStudy/component/studyOnBatch/compor onent/test/component4/test/value unit attribute.	oonent2/testing/co It is PQ. Not valid nent/testing/comp
C bu	utton	Button to popup field can be replaced with fixed f comments or other text info. /stabilityStudy/Component1/studyOnBatch/Comp mponent3/text or /stabilityStudy/component/studyOnBatch/compor	ield for OOS ponent2/testing/co nent/testing/comp
Test	Date	onent/test/component4/test/text /stabilityStudy/Component1/studyOnBatch/Comp mponent3/effectiveTime or /stabilityStudy/component/studyOnBatch/compor onent/test/component4/test/effectiveTime	ponent2/testing/co
Test	ing Site	Pick list of testing site from Organizations. The v into /stabilityStudy/Component1/studyOnBatch/Comp mponent3/test/performer elements or /stabilityStudy/component/studyOnBatch/compor onent/test/component4/test/performer elements.	value are entered ponent2/testing/co nent/testing/comp

4.0 Mapping Element in Implementation Guide to Input Tool

The following tables register the elements in the eStability Implementation Guild 0.6 (IG) to fields in the Form Layout Examples in section 5.2. Following the notation in the IG, the tables have two columns to indicate HL7 optionality (H) and the FDA optionality (F). Valid values for the columns are:

M – Mandatory (the information has to be provided in any case

R – Required (the information should be provided if available)

		S	tabili	ity Message Input Tool	Page 18 of	38		
Title:	Title: User Requirements							
O – Op The Stabiltiy M	tional (the essage Inp	informatic ut Tool w	on can ill valio	n be provided) date based on the FDA Optionality.				
4.1 Stabil /stabil	ityStudy ityStudy							
Description: The	e root elem	ient of the	docu	ment.		ц	-	
Id:root	ID for Do	cument	Is a g	global unique identifier for the docum is document	ent. OID	M	M	
text	Text or Li Text	nk to	Eithe an ex this s	er a text provided by the submitter or kternal document with further annota submission.	an URI to tions for	0	0	
code	Study Co or Other	de	an A sent.	CTCODE which describes the type o	f document	R	R	
reasonCode	Reason C for this Documer	Code nt	an Ao docu	CTREASON which describes the rea ment.	ison for this	0	М	
Subject2	Complex form	built by	a cor of the	complex structure to describe the researchsubject f the study (exactly one provided).				
Component1	Complex form	built by	a cor studi docu	nplex structure to describe a batch a es performed on this batch and repo ment (one or many provided).	nd the rted in this	Μ	Μ	
4.2 Subje /stabil Description: Inte Name ResearchSubj	ct2 ityStudy/su ermediate Field ject <i>Com</i>	ibject element plex built	Des a c	scription		H M	F	
	by fo	rm	res	earchsubject (exactly one provided).				
4.3 Resea /stabil Description: Thi	archSubjec ityStudy/su is is the sul	t Ibject bject of th	is stuc	dy. This can either be a "Product" or	a "Substanc	e" –		
Information ab	o be provid	luded "Si	ne ivi ihstan	is exclusive on one of the elements bees" of a "Product" can be provided	•			
Name	Field			Description		Н	F	
Product	Complex form	built by		Finished dosage form (exactly one).		Μ	Μ	
Substance	Complex form	built by	1	Active ingredient (exactly one).		Μ	Μ	
Organization	Complex form	built by		Research Sponsor.		0	R	
Subject3	Complex form	built by		Reterence to the specification used in study.	n this	Μ	Μ	

				Sta	ability Message Input Tool Page 19 of	38	
Title:			User	Req	uirements		
4.4 Pro /sta	duct bilityStud	ly/su	ıbject/r	esea	archSubject/subjectProduct		
Description: (struc	cture to	o des	scribe a finished dosage form.		
Name		Fiel	d		Description	Η	F
expirationTi	me	Exp Tin	piratior ne	1	The "expected" expiration period (e.g. 24 Months) for NDA, or the existing expiration period for ongoing studies. Either a valid time period (ISO8601, e.g. P24M) or 'TBD' (to be determined) for user in IND.	R	М
Desc		De	scriptic	on	A Description of the product provided by the submitter or an URI for additional external documentation.	0	0
Code		Co	de		an ACTCODE: ProductCode (i.e. a unique identifier of the product). For FDA implementation, only the "displayName" (i.e. the product name) is mandatory, the code values might be provided if available. For NDA this is a new identifier. For ongoing studies the identifier should be identical to an already submitted code.	R	Μ
formCode		Foi	rm Coc	n Code an ACTCODE: Formtype of this product. For FDA implementation, only the "displayName" (i.e. the product name) is mandatory, the code values might be provided if available.			
SpecifiedIng	gredient	Co bui	mplex ilt by fo	orm	The formulation of this product (many, if necessary).	0	R
4.5 Spe /sta Description: \ substances Name Quantity Substance	cifiedIng bilityStud With this of and prov Field Quantity Specifie Ingredie	redie ly/su elerr riding y ed	ent ibject/r nent on g inforr	esea ne ca natio Des The Ref	archSubject/subjectProduct/specifiedIngredient on map the formulation of the product by referencing on on the quantity of the substance used in the product cription e quantity of the referenced substance in the product erence to substance, i.e. active ingredient	t. Н М	F R M
4.6 Sub /sta or /sta Description: V the study is substance a Name Fiel Code Code	ostance bilityStud bilityStud When use performe as part of d de	ly/su ed as ed or a fo Des	ibject/r ibject/r s a chil n. As c rmulati scription ACTC	esea d of child on. n	archSubject/subjectSubstance archSubject/subjectProduct/specifiedIngredient "ResearchSubject" this element describes the substa of "SpecifiedIngredient" this element describes a E: code of the substance.	nce H R	F
Desc Des	scription	Fo su pro UF	or FDA bstanc ovided RI for a	impl e na if av dditi	ementation, only the "displayName" (i.e. the me) is mandatory, the code values might be ailable. onal documentation.	0	0

			Stability	Messag	e Input Tool	Page 20 of	38	
Title:			User Requiremen	nts				
4.7	Organ /stabili	ization ityStudy/st	ubject/researchSut	oject/resea	chSponsor			
Descript	tion: The	e research	sponsor for the st	udy.			п	-
Name Id:	Study		a alobal unique id	entifier for	he sponsoring organiz	ration	H M	M
Root	Spons OID	or as	ssigned by IANA.	This identif	er should be the same ons of one company.	e for one	101	
name	Study Spons	or	ame of the organiz	ation spon	soring the study.		0	М
addr	Addre Count	ss Ao ry	ddress of the orga	nization.			0	М
							•	
4.8	Subjeo /stabili	ct3 ityStudy/st	ubject/researchSub	oject/subjec	tOf			
Descript	tion: Re	ference to	the specification (i	intermediat	e element).			
Name	oction	Field	built by form		Description	H	F /	Λ
Specin	cation	Complex	built by form		(exactly one)	N	1 IV	/1
4.9 Descript	Specif /stabili tion: For	ication ityStudy/su	ubject/researchSut	oject/subjec	tOf/specification s to be provided for the	e specificatio	n.	
Name		Field		Description	•	•	Н	F
text		Specifica	tion Text	URI for ac	ditional documentation	n.	0	R
code		Specifica	tion Code	an ACTC the name (as displa	DDE: Specification ide and version of the spe yName).	ntifier. i.e. ecification	0	Μ
Compo	onent5	Complex	built by form	The testd for these	efinition and acceptance	ce criteria	0	Μ
4.10 Descript Name	Comp /stabili tion: Inte	onent5 ityStudy/su ermediate	ubject/researchSub element	oject/subjec	tOf/specification/comp	ponent	н	F
TestDe	finition	Test De	finition				Μ	Μ
 4.11 TestDefinition <pre>/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinitio n or</pre>								
parame – meth and the	eter of a ods and e refere	a method. d method p nce range	The recursive stru parameters. Either have to be provide	icture will n r the extern ed.	ot be implemented furt al document or the me	her than one thod parame	leve ters	el

		Sta	bility Me	essage Input Tool	Page 21 of	38		
Title:		User Requ	irements					
Name Id: Root	Field Test II)	Descriptio Global ur	n nique identifier for this TestDe	finition	н R	F	
text	Test T	ext	(OID) URI for a SOP or S	additional documentation for the specification document for this	his test, e.g.	0	R	
code	Test N (field r	lame/code nay be	an ACTC displayN	CODE: Test code. Attributes c ame	ode and	R	R	
methodCode	Metho	d Code	an ACTR	FASON: Method type		0	М	
ReferenceRang	Comp form	lex built by	The acce	eptance criterion for this paran	neter.	0	M	
Component6	Secon Comp Buttor form fo additic definit	d onent – Opens or onal test ion	Recursiv method p assay, fo ingredier level may	e reference to TestDefinition to barameter of this method (i.e. or which the next level can be nots or impurities). Only one ac y be provided.	o define the a test the Iditional	0	M	
4.12 Kelefen /stability: n/referer or /stability: n/compo Description: The container for	Study/su nceRang Study/su nent/tes	ubject/resea je ubject/resea utDefinition/r	rchSubjec rchSubjec eferenceR nce criteria	t/subjectOf/specification/comp t/subjectOf/specification/comp ange	oonent/testDe	finit	io	
Acceptanc Cor	ı nnlex hı	ilt by form		Description	teria	H O	F	
eCriterion						Ŭ	IVI	
4.13 AcceptanceCriterion /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinitio n/referenceRange/acceptanceCriterion or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinitio n/component/testDefinition/referenceRange/acceptanceCriterion								
Name	IDES ON	e valio spec eld	incation in	Description		н	F	
InterpretationCo	de Ir	terpretation	Code	e.g. not more than (NMT), n than (NLT),	ot less	M	M	
Text	ext Acceptance Criterion URI for additional documentation. Text				ation.	0	0	
Value	A V	cceptance (alue	Criterion	The value of the criterion.		М	М	

L

Title: User Requirements 4.14 Component1 /stabilityStudy/component Description: Reference to the batch and result information for one study on one batch. Many of these elements can be provided. Name Field Description StudyOnBatch M /stabilityStudy/component/studyOnBatch M Description: The container for the batch information and results for the study performed on one batch. H Mame Field Description Id: Root Unique Study Is a global unique identifier for the study, should be the M M M StudyType an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the by form M M Compoent2 Complex built The reference to the study design and the results M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description H F Instance Complex built by form The Instance of the material. M M 4.17 Instance Field Description H F Instance Field Description H				Stability Me	ssage	e Inp	out Tool	Page 22 of	38	
4.14 Component1 /stabilityStudy/component Description: Reference to the batch and result information for one study on one batch. Many of these elements can be provided. Hame Field StudyOnBatch Complex built by form 4.15 StudyOnBatch //stabilityStudy/component/studyOnBatch M Description: The container for the batch information and results for the study performed on one batch. H Name Field Description ID same in all submitted files for this study. (OID) code Study Type an ACTCODE: study type Subject1 Complex built The reference to the information on the material the by form M Component2 Complex built The reference to the study design and the results M 4.16 Subject1 //stabilityStudy/component/studyOnBatch/subject Escription H F Instance Complex built by form The Instance of the material. M M 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Escription H F Mamu facturedMaterial Complex built by form The Instance//stabilityStudy/component/studyOnBatch/subject/instance//stabilityStudy/component/studyOnBatch/sub	Title:		User F	Requirements						
4.14 Component1 /stabilityStudy/component Description: Reference to the batch and result information for one study on one batch. Many of these elements can be provided. Name Field Description H F StudyOnBatch Complex built by form M M 4.15 StudyOnBatch /stabilityStudy/component/studyOnBatch M M Description: The container for the batch information and results for the study performed on one batch. H F Id: Root Unique Study Is a global unique identifier for the study, should be the ID M M code StudyType an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the by form M M Component2 Complex built The reference to the study design and the results M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description H F Instance Complex built by form The Instance of the material. M M 4.17 Instance Field Description H F ManufacturedMaterial Complex built										
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Intermediate element. Pield Description H F A.15 StudyOnBatch Complex built by form M M 4.15 StudyOnBatch /stabilityStudy/component/studyOnBatch Description: The container for the batch information and results for the study performed on one batch. H F Name Field Description H F Id: Root Unique Study Is a global unique identifier for the study, should be the ID M M Code Study Type an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the M M M Component2 Complex built The reference to the study design and the results M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description H F Instance Complex built by form The instance of the material. M M 4.17 Instance Field Description H F Mame Field Description H F Mame Field Descri	Description: Refere	ence to t	the bate	ch and result in	formatic	on to	r one study on on	e batch. Ma	iny o	t
StudyOnBatch Complex built by form M M 4.15 StudyOnBatch ////////////////////////////////////	Name	Field	Iovided		Descrip	otion			н	F
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Description: The container for the batch information and results for the study performed on one batch. Name Field Description H F Id: Root Unique Study Is a global unique identifier for the study, should be the same in all submitted files for this study. (OID) M M Code Study Type an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the by form M M Component2 Complex built The reference to the study design and the results M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject /stabilityStudy/component/studyOnBatch/subject Description: An intermediate element. Name Field Description H F Name Field Description H F M M 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description H F MamufacturedMaterial Complex built by form The Instance N M M 4.17 Instance Field Description H F F Mamufacture	4.15 StudyOnl /stabilityS	Batch Study/co	mpone	nt/studyOnBatc	ch					
Name Field Description H F Id: Root Unique Study Is a global unique identifier for the study, should be the ID M M code Study Type an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the by form M M Component2 Complex built The reference to the study design and the results by form M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description H F Name Field Description H F Instance Complex built by form The Instance of the material. M M 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description H F Name Field Description H F ManufacturedMaterial Complex built by form M M 4.18 ManufacturedMaterial Description H F ManufacturedMaterial Complex built by form M	Description: The constraints batch.	ontainer	for the	batch informat	ion and	resu	ults for the study p	performed or	n one	9
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code Study Type an ACTCODE: study type O R Subject1 Complex built The reference to the information on the material the by form M M Component2 Complex built The reference to the study design and the results M M Component2 Complex built The reference to the study design and the results M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject M M Description: An intermediate element. Name Field Description H F Instance Complex built by form The Instance of the material. M M 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description H F Mame Field Description H F ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce M M Description: Description the stability study. M M 4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description <	Id: Root Ui	nique Si)	tudy	Is a global uni same in all sul	que idei bmitted	ntifie files	er for the study, sh for this study. (O	iould be the ID)	М	Μ
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Dy form Study is performed on (e.g. a batch). Component2 Complex built The reference to the study design and the results M M 4.16 Subject1 section. M M 4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description H F Instance Complex built by form The Instance of the material. M M 4.17 Instance Complex built by form The Instance of the material. M M 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Name Field Description H F ManufacturedMaterial Complex built by form M M M 4.18 ManufacturedMaterial Complex built by form M M 4.18 ManufacturedMaterial Description H F quantity Manufactured Quantity Total amount of material in the batch. Q R desc Production Description A textual Description or/and external reference to	Subject1 C	omplex	built	The reference	to the i	nforr	mation on the mat	terial the	Μ	М
4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description: An intermediate element. Name Field Instance Complex built by form 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Name Field /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Name Field ManufacturedMaterial Complex built by form 4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description: Describes the produced material used in the stability study. Name Field Quantity Manufactured Quantity Manufactured Quantity Total amount of material in the batch. desc Production Description QR URL to PDF describing details of this production. A textual Description or/and external reference to a pdf document describing details of this production. lotNumberText Lot Number Company internal lot number. R Production Date Pate of production (use ISO R M	D) Component? C	/ TOIM	built	Study is perfor	to the s	i (e.g	j. a batch). / design and the r	oculto	М	М
4.16 Subject1 /stabilityStudy/component/studyOnBatch/subject Description: An intermediate element. Name Field Instance Complex built by form 4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Name Field Name Field Description: An intermediate element. Name Field Value Omplex built by form 4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description: Describes the produced material used in the stability study. Name Field Quantity Manufactured Quantity Manufactured Quantity Total amount of material in the batch. desc Production Description OR URL to PDF A textual Description or/and external reference to a pdf document describing details of this production. O lotNumberText Lot Number Company internal lot number. R Production Date Pate of production (use ISO) R M	by form section.					IVI				
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4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Name Field ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description: Describes the produced material used in the stability study. Name Field quantity Manufactured Quantity Total amount of material in the batch. O desc Production Description OR URL to PDF IotNumberText Lot Number Production Date Date of production (use ISO Bate of production (use ISO R	Instance Con	nnlex hu	ilt by fo	nm		The I	Instance of the ma	aterial	п М	г М
4.17 Instance /stabilityStudy/component/studyOnBatch/subject/instance Description: An intermediate element. Instance Name Field Description ManufacturedMaterial Complex built by form M 4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce M Description: Describes the produced material used in the stability study. Name Field quantity Manufactured Quantity Total amount of material in the batch. O desc Production Description A textual Description or/and our use this production. O O lotNumberText Lot Number Company internal lot number. R M existenceTime Production Date Date of production (use ISO) R M		101011.00	int by re							
NameFieldDescriptionHFManufacturedMaterialComplex built by formMM4.18ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ceMMDescription: Describes the produced material used in the stability study.NameFieldDescriptionHFquantityManufactured QuantityTotal amount of material in the batch.ORdescProduction Description OR URL to PDFA textual Description or/and document describing details of this production.OOlotNumberTextLot NumberCompany internal lot number.RMexistenceTimeProduction DateDate of production (use ISO) RMM	4.17 Instance /stabilityS	Study/co ermedia	ompone ite elerr	nt/studyOnBatc	ch/subje	ect/in	stance			
ManufacturedMaterial Complex built by form M M 4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description: Describes the produced material used in the stability study. Name Field Description H F quantity Manufactured Quantity Total amount of material in the batch. O R desc Production Description A textual Description or/and or external reference to a pdf document describing details of this production. O O lotNumberText Lot Number Company internal lot number. R M existenceTime Production Date Date of production (use ISO R M	Name	F	Field	1. 11. L. C			Description		H	F
4.18 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstan ce Description: Describes the produced material used in the stability study. Name Field Description H F quantity Manufactured Quantity Total amount of material in the batch. O R desc Production Description OR URL to PDF A textual Description or/and external reference to a pdf document describing details of this production. O O lotNumberText Lot Number Company internal lot number. R M existenceTime Production Date Date of production (use ISO 8601 format) R M	Manufacturedivia		Jompie	x built by form					IVI	IVI
Description: Describes the produced material used in the stability study.NameFieldDescriptionHFquantityManufactured QuantityTotal amount of material in the batch.ORdescProduction Description OR URL to PDFA textual Description or/and external reference to a pdf document describing details of this production.OOlotNumberTextLot NumberCompany internal lot number.RMexistenceTimeProduction DateDate of production (use ISORM	4.18 Manufact /stabilityS ce	turedMa Study/co	iterial mpone	nt/studyOnBatc	ch/subje	ect/in	stance/manufactu	uredMaterial	Insta	ın
quantityManufactured QuantityTotal amount of material in the batch.ORdescProduction Description OR URL to PDFA textual Description or/and external reference to a pdf document describing details of this production.OOlotNumberTextLot NumberCompany internal lot number.RMexistenceTimeProduction DateDate of production (use ISO 8601 format)RM	Description: Descri Name	ibes the	produc Field	ced material use	ed in the	e sta Desc	bility study. cription		н	F
descProduction Description OR URL to PDFA textual Description or/and external reference to a pdf document describing details of this production.OOIotNumberTextLot NumberCompany internal lot number.RMexistenceTimeProduction DateDate of production (use ISO 8601 format)RM	quantity		Manufa	actured Quantit	y	Tota bato	al amount of mate	rial in the	0	R
OR URL to PDF external reference to a pdf document describing details of this production. IotNumberText Lot Number Company internal lot number. R M existenceTime Production Date Date of production (use ISO 8601 format) R M	desc		Produc	ction Description	n	A te	xtual Description	or/and	0	0
IotNumberText Lot Number Company internal lot number. R M existenceTime Production Date Date of production (use ISO R M 8601 format) R M R M			OR UF	RL to PDF		exte doci this	ernal reference to ument describing production.	a pdf details of		
existenceTime Production Date Date of production (use ISO R M	lotNumberText		Lot Nu	mber		Con	npany internal lot	number.	R	Μ
	existenceTime		Produc	ction Date		Date 860	e of production (u 1 format)	se ISO	R	Μ

	Stability Mess	age Input Tool	Page 23 of	38	
Title:	User Requirements				
expirationTime	Expiration Date	Date of expiration (bathe provided expiration) the provided expiration the "Product" element proposed expiration of material. Add P proposed exp. for approved exp. Tim P24M-A, P24M-P Also with Product ele	ased on onCode of t) or the date or the time or A ne. ment.	0	Μ
asManufacturedProdu ct	Complex built by form	A reference to the ma of this material. If this document is pa application of a new a ingredient, this inform to be provided.	anufacturer art of an active nation has	Μ	R
asContent	Complex built by form	A reference to the	tem	М	М
BatchIngredient	Complex built by form	A reference to a ManufacturedMateria "BatchRecord" can be Using this element le recursive structure.	II, so that a e provided. ads to a	0	0
4.19 ManufacturedPr /stabilityStudy/co ce/asManufactu Description: Intermediate	oduct omponent/studyOnBatch/s redProduct element, holding the man ield	subject/instance/manufactu ufacturer of the Manufactu	uredMaterial	Insta H	an F
Manufacturer C	Complex built by form			М	Μ
4.20 Manufacturer /stabilityStudy/co ce/asManufactu manufacturer Description: The details a "ManufacturedMaterial". Name	omponent/studyOnBatch/s redProduct/ bout a manufacturer or a Field	subject/instance/manufactu manufacturing site that pro	uredMaterial	Insta	an F
Id: Root	Manufacturer Unique ID from Organization Manufacturer	Is a global unique identific manufacturing site. (OID)	er of the	M	M
name	Manufacturer	Name of the manufacture manufacturing site).	er (or	R	М
addr	Address and Country	Address		0	М
assignedEntity	Assigned Manufacturer	One or many references "Manufacturer" who product product in behalf of the "Manufacturer" or who pa produced the product.	to a uced this ırtial	0	0

	Stability Message Input Tool Page 24 of 3					
Title:		User Requiremen	ts			
4.21 Cont /stab ce/as	ent ilityStudy/ sContent	component/studyOnE	Batch/subject/instance/manufactu	uredMaterialIn	sta	n
Description: Th	ne contain	er closure system	Description			-
Quantity	Containe	er Quantity (Fill)	The actual quantity of "ManufacturedMaterial" in the expressed as a ratio. The de defaults to 1.	container nominator	R	R
Container	Complex	built by form	A reference to the structure for container closure system.	or the	М	М
4.22 Cont /stab ce/as Description: A	ainer ilityStudy/ sContent/c simple str	component/studyOnE container ucture to store the m	Batch/subject/instance/manufactu	uredMaterialIn ystem.	sta	n
Desc	Cor	a Antainer Description	A verbal Description of the cont	ainer		
Desc		itainer Description	closure system or a reference to an external pdf which holds this Description.		Ű	U
lotNumberTe	xt Cor	tainer Lot Number	The lot number of the production lot for this container		0	0
capacityQuar	ntity Cor and	itainer Capacity Unit	The capacity of the container, n necessarily identical to "quantity "Content" element (e.g. 100 ml even if the quantity of tablets in is 50).	ot y of the bottle, the bottle	R	ĸ
capTypeCod	e Cor Coo	ntainer Closure le	The code for the used closure system			0
Code	Cor	tainer Name	an ENTITYCODE – Type of Container R (e.g. Bottle).			Μ
4.23 Batcl /stab ce/ba Description: An intermedia a kind of batc	hIngredier ilityStudy/ atchIngred ate eleme ch record f	it component/studyOnE ient nt to store a recursive or the product.	Batch/subject/instance/manufactu	uredMaterialIn aterial" to prov	sta vide	n
Name		Field	Descriptionn	ncod (н	F
Guantity Batch Quantity		material used to produce the (e.g. the referenced material used in parts for this product	e product might be	0	К	
ManufacturedBatch Lot NumberMaterialManufacture DateBatch Expiry DateManufacturerBatch DescriptionBatch Description		This is a recursive link to ManufacturedMaterial. Each group creates one instance of ManufacturedMaterial.	n field of a	M	Μ	

		Stability Mess	age Input Tool	Page 25 of	38		
Title:		User Requirements					
4.24 Component2 /stabilityStudy/component/studyOnBatch/component							
Description: For eac	h com	bination of storage time ((pauseQuantity) and "Stora	age" (storage			
condition) one Con	pone	nt2 has to be provided.				_	
Name	Field Time	Dt and Linit	Description	hatah in a	H D	F	
pauseQuantity	TITLE		climatic chamber. The unit of the paus has to be homogene	eQuantity	ĸ		
			xml files, which are to the concerning st For more than one	connected udy.			
			pauseQuanitity, the				
			connection between	n the			
			storage to the conce	erning			
			testing section is do	ne by the			
Storage	Com	olex built by form	A structure to descr	ibe the	М	М	
Otorage	Com	nex built by form	used storage condit	ion.	111	IVI	
Testing	Com	olex built by form	A structure to store	the results	М	М	
Ū			of measurement.				
/stabilityStu Description: Referen "25°/60%" and one	udy/co ce to to "ur	omponent/studyOnBatch/ one or many predefined s pright" – or alternatively o	component/storage storage condition (e.g. one ne reference to "25°/60% (reference to	I		
Name	Fiel	d	Description	pingine /i	Н	F	
Text	Sto De:	rage Condition Text scription	A textual Description storage condition of external reference describe this storage condition.	on of this r an to pdf to ge	0	0	
EffectiveTime/high	Со	ndition Start Date	The Time the produ stability. The date storage is started for condition.	uct is put on the stability or this	0	М	
Code	Со	ndition Code	an ACTCODE: fixe value, may be used purposes in future	d code d for other versions.	М	М	
ControlVariable	Со	mplex built by form	Reference to the pr storage conditions many may be used	redefined (one or).	М	М	
Component3	Co	mplex built by form	not used		Ν	Ν	
4.26 ControlVar /stabilityStu Description: Interme	iable udy/cc diate (omponent/studyOnBatch/	component/storage/control	Variable			
Name		Field	Description				
Hame		T IGIU					

		Stabilit	y Mo	essage Input Tool	Page 2	6 of∶	38				
Title: User Requirements											
StorageCond	dition	Complex built b	by foi	rm		М	Ν	1			
4.27 Stora /stabilityStud Description: A definitions th Complex def StorageCond	ageConditio ly/componer structure to is condition finitions can	n nt/studyOnBatch/ describe one sto might be simple (be made up of m	comp orage (e.g. any (conent/storage/controlVariable condition. Dependent of the 25°) or complex (e.g. 25° C/60 ControlVariables referencing s	e/storage(internal c 0% RH up simple	Conc comp origh	litio any t).	n ′			
Name	Field		Des	cription		Н		F			
Text	Condition I Reference	Description or	A te refe	extual Description or an extern erence.	al	0		0			
Value	Storage Co	ondition Value	e.g con req	. "25°" or "60%" or "upright." A nplex like "25° C/60% RH upri uires 3 values.	A ght"	Μ		M			
Code	Storage Co	ondition Code	an the	ACTCODE: Storagecondition complex storage condition, ec	code of	Μ		Μ			
/stat Description: T Name Title	his is a repr	omponent/studyO esentation of "pul ield Time Point Name	Ing a	tch/component/testing a sample from the climatic cha Description A title that labels a collection tests across "pauseQuantitie	of relate	d	H M	F M			
Text	т	ime Point Name		"Batch Release", "1 month", A textual Description or an e	"	0	0				
EffectiveTim	e/hiah F	Pull Date		Pulldate (use ISO 8601 nota		0	М				
Code	T	ime Point Code		an ACTCODE: pauseDescription. Something done with the sample, e.g			M	R			
Component3	3 (f	Complex built by orm		A reference to the tests performed this sample.	ormed wit	th	M	М			
4.29 Com /stat Description: Ir	nponent3 bilityStudy/co ntermediate	omponent/studyC element	nBat	tch/component/testing/compor	nent						
Name Field	nlov huilt hu	form		Description			<u>н</u>	F			
	olex built by	101111				[0				
4.30 Test /stab or /stab t/tes Description: R	 4.30 Test /stabilityStudy/component/studyOnBatch/component/testing/component/test or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component t/test Description: Representation of a test performed on a sample. 										
are represen	e same sche ited by the "	me as in "TestDe Component4" refe	rinitio	on", there might be parameters ce.	s for a Te	st W	nich	1			

		Stability M	Stability Message Input Tool Page 27 of									
Title:		User Requirements	Jser Requirements									
Name	Field	d	Description			Н	F					
Text	C b field	utton to pop up d	A textual Des reference.	cription or an ex	ternal	0	0					
Value	Res	sult and Unit	Result value i two possible l Component4	s mandatory on evels, on the firs has no child eler	one of the st level, if ments.	М	М					
effectiveTime	Tes	st Date	Testing date, level, omitted (ISO8601).	mandatory on th on the second le	e first evel	М	М					
Performer	Col	mplex built by form	A reference to	o a testing site.		Μ	Μ					
Definition	Col	mplex built by form	Reference to	a specification for	or this test.	0	Μ					
Component4		, ,	Recursive ref	erence to a "Tes	t".	R	R					
4.31 Performer /stabilityStu or /stabilityStu t/test/perfor	udy/cc udy/cc rmer	omponent/studyOnBa omponent/studyOnBa	atch/componen atch/componen	t/testing/compor t/testing/compor	nent/test/perl	orm pon	er en					
Description: Interme	diate (element	Description			н	F					
AssignedEntity (Comp	lex huilt hy form	Description			M	M					
4.32 AssignedE /stabilityStu assignedEr or /stabilityStu t/test/perfor	ntity udy/co ntity udy/co rmer/a diate o	omponent/studyOnBa omponent/studyOnBa assignedEntity element, a reference	atch/componen atch/componen e to a TestingSi	t/testing/compor t/testing/compor te who is perforn	nent/test/perf nent/test/com ning the test	orm pon on	er/ en					
Name	Field	I	Description	1		1	F					
TestingSite	Cor	nplex built by form		-	Ň	N	Μ					
TestingSite Complex built by form M M 4.33 TestingSite /stabilityStudy/component/studyOnBatch/component/testing/component/test/performer/ assignedEntity/ assignedTestingSite or or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/component/studyOnBatch/component/testing/component/test/comp												
Description: The details about a	teste	r who performs the t	ests on behalf	of the Research	Sponsor.							
Name		Field		Description		Н	F					
ld: root		Testing Site Uniq Organization pag	ue ID from e	Is a global unio identifier of the site. OID of the site company	testing testing testing	Μ	Μ					
Name		Testing Site on R	esults tab	The name of th site.	e testing	0	М					

	Stability N	Stability Message Input Tool Page 28 of 3								
Title:	User Requirements	3								
Addr	Address and Cou organization tab	ntry from	The address of testing site.	the	0	Μ				
4.34 Definition /stabilityStudy/component/studyOnBatch/component/testing/component/test/definition or /stabilityStudy/component/studyOnBatch/component/testing/component/test/componen t/test/definition										
Description: Intermediate	element which refere	ence the test de	efinition.			-				
Name	Field Complex built by for	Descript	lion		H M	F				
					IVI	IVI				
DefinitionStub /stabilityStudy/componen Stub or /stabilityStudy/componen finition/ definitionStub Description:	nt/studyOnBatch/com nt/studyOnBatch/com	nponent/testing	/component/test J/component/test	/definition/de	efiniti test/	on de				
Name Field		Description			Н	F				
Id: root Test Id on sp	ecification tab	Is the unique identifier (id) of the M M								
based on Tes	st Name entered	referenced sp	ecification (Testl	Definition).						
on Results pa	age	OID of the ref								
4.35 Component4 /stabilityStudy/co t Description: If a test has p the parameters (sequence or Use this structure to indi when the test was perfor	omponent/studyOnBa parameters (e.g. Assa ceNumber) cate the point in time med (pauseQuantity	atch/componer ay and ingredie after the samp	nt/testing/compor ents) this structur ble was drawn fro	nent/test/com e is used to om the cham	npon store ber,	en 9				
Name Field		Description			Н	F				
sequenceNumber Seq		The sequer	nce of parameters	s of the	0	R				
		test. Used has been de The form wi context Cor	only when a Con efined for the par ill place the Com nponent3/test	npoent6 rent test. ponent4 in						
pauseQuantity Time	e Point and Time	To use e.g. etc.	with growth of ba	acteria,	0	R				
test C bu Res Test from Test tab Add from	utton to pop up field ult and Unit ting Site Unique ID o Organization page ting Site on Results ress and Country o organization tab	Elements of	f test one level d	eep.	0	М				

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Title:		User Requirements	
Title: 5.0 5.1	Form Layout Examples Tool Bar Example	User Requirements	

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Title:	User Requirements	•
5.2 Message Info		
🚳 Mock Up Xforms Stability	nput Tool	
File Edit Tools Help Window		
Message Info Study Re	ot Organizations Product/Substance Specification Lot Info	Study Info Test Results
Message Type		
Empty Message	Header You can define a message header or leave it blank.	
O Define Messag	e Header information Make your selection here. Then continue to subsec	quent pages.
Message ID	Creation Time Vers	ion Code
Security Text	Profile ID	
Interaction Id	Sequence Humber	
Processing Code	Accept Ack Code	
Processing Mode Code	Receiver	
Attachment Text	Respond To	
Sender	Attention Line	
Control Act Process Id	Code	
Text	Effective Tim	ne 📃
Priority Code	Reason Code Language Co	ode
,		,
Overseer	Author	
Data Enterer	Recipient	

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Title:	User Requirements	
Title: 5.3 Study Root Image: Study Root in the state of the study Root in the	User Requirements	tudy Info Test Results

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Title:		User Requirements	
5.4	Organizations		
	Mock Up Xforms Stability Inp	ıt Tool	
	Message Info Study Root	Organizations Product/Substance Specification Lot Info S	Study Info Test Results
	Study Sponsor OID		
	Study Sponsor	Address Country	
	Testing Site Unique ID	Testing Site Address C	ountry
	Manufacturer Unique ID	Manufacturer Address Co	suntry

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Title:		User Requirements	
Title: 5.5	Product/Substance Mock Up Xforms Stability Inpu File Edit Tools Help Window Message Info Study Root © Finished Product © API	t Tool Tool Organizations Product/Substance Specification Lot Info Study Info Finished Product Data Code Form Code Expiration Time Specified Ingredient Quantity API Data Code Description	

	Stability Message Input Tool	Page 34 of 38			
Title:	User Requirements				
5.6 Specification					
Mock Up Xforms Stability Inp	ıt Tool				
Message Info Study Root	Organizations Product/Substance Specification Lot Info Stud	Info Test Results			
Specification Code Second Component	Specification Text				
Test ID	Test Name	Method Code			
Test Text					
Definition	Interpretation Acceptance Criterion Code Value Unit Acceptance	ance Criterion Text			
2nd Comp. Test ID	Test Name	Method Code			
Test Text					
Test Definition	Reference Range Interpretation Acceptance Criterion Code Value Unit Acceptance	e Criterion Text			
Test ID	Test Name	Method Code			
Test Text					
Test Definition 2nd Comp	Reference Range Interpretation Acceptance Criterion Code Value Unit Acceptance	e Criterion Text			

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5.7 Lot Info Mock Up Xforms Stability Input Tool File Edit Tools Help Window Message Info Study Root O Manufactured Quantity Production Description OR URL to PDF Manufacturer Batch Ingredients	ganizations Product/Substance Specification Lot Info Study Info Lot Humber Expiration Date AssignedManufacturer (Subcontracted)	Test Results
Batch Manufact- er Date Batch Lot Humber Quantity Image: Stress Stres	Batch Expiry Batch Description Date Manufacturer Batch Description Image: Comparison of the second secon	

	Stability	Message Input Too	bl	Page 36 of 38
Title:	User Requirements			
5.8 Study Info Mock Up Xforms Stability Input Too				
File Edit Tools Help Window				N
Message Info Study Root	Organizations Product/Substanc	e Specification L	ot Info Study	Info Test Results
Unique Study ID		Study Type		
Storage Condition Code Stor	age Condition Value	ondition Description or Refere	ence	
	I			
	[
Condition Start Date Storage Condition	Code Storage Condition	Text Description		
Study Time Deinte				Y
Time PointCode Time Point	Name	Pull Date	Description	
Container Closure		Container Lot Num	ber	
Container Quantity		Container Capa	city	Unit
Container Closure Code	•			
Container Description				

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Title:				User	r Requiremer	nts												
5.9	Test	Results																
	ST M	ock Up Xfor	ms Stability I	nput Tr	ool													
	File	Edit Tools H	lelp Window															
	M	essage Info	Study Roo	t I	Organizations	Pr	oduct/	/Substar	nce	Specification		Lot	Info		Study Info	Test Resu	lts	
	C	Condition		-			Time	Time	D									
	Seq	Code 🗸	Test Name (Fr	om Spe	cification)	-	Pt	Unit	Result		C Un	nit	Test D	ate	Testing Site		-	1
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6.0 Glossary		
CSV	In computers, a CSV (comma-separated values) file contains the values in a table as a series of ASCII text lines organized so that each column value is separated by a comma from the next column's value and each row starts a new line.	
Excel	An automated version of the paper-based spreadsheet that makes it easier to manipulate, process, and view the data.	
ODBC	Open DataBase Connectivity. Standardised interface, or middleware, for accessing a database from a program.	
Stability Study	This is a study of a drug at specified time points where the drug is stored in specified conditions to see how the drug changes over time. Stability studies are used to determine Expiration dates and are required for NDA's.	
User	Individual who is granted access to us the Stability Input Tool.	Message
XForms XML	 XML format for the specification of user interfaces, specifically web forms. XForms was designed to be the next generation of HTML / XHTML forms, but is generic enough that it can also be used in a standalone manner to describe any user interface, and even perform simple and common data manipulation tasks. (Extensible Markup Language) is a W3C initiative that allows information and services to be encoded with meaningful structure and semantics that computers and humans can understand. XML is great for information exchange, and can easily be extended to include user-specified and industry-specified tags. 	