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User Requirements

**Stability Message Input Tool
User Requirements
6.2**

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Document History

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|-----------------|-----------------------|---|
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1.0 Introduction

1.1 Proposed Project

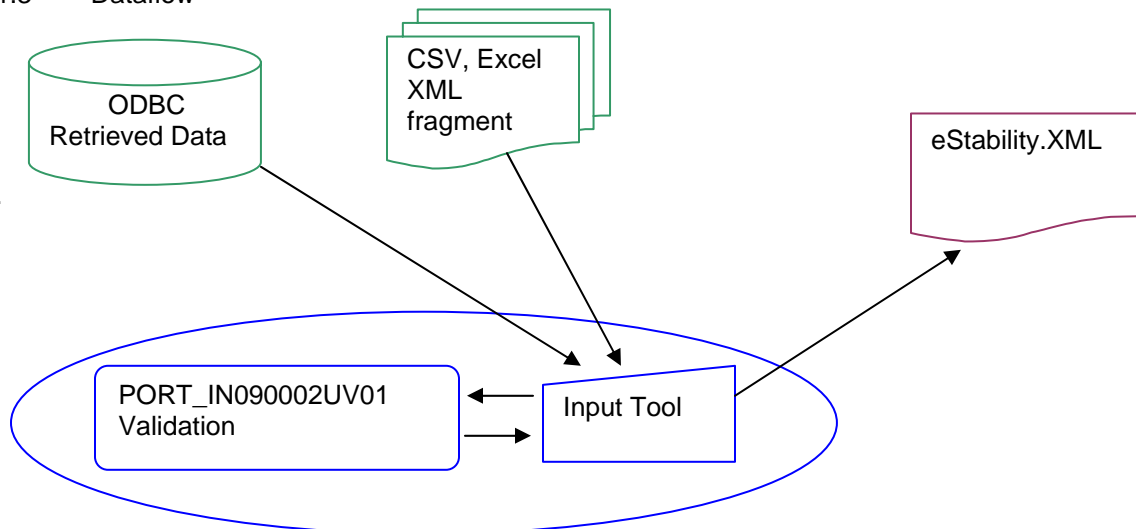
Develop an eStability message input tool based and the PORT_MT090002UV01 schema. The Input Tool will allow the entry and reporting of stability data as an XML file. The Input Tool will allow users to enter data and build a stability message that can be validated against the PORT_MT090002UV01 schema. 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 fields, 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 predefined 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_MT090002UV01. For FDA submissions the message can either contain the message wrapper or it can be left blank if transmission is via CD-ROM.

1.3 Dataflow



1.4 Storyboards

1.4.1 These storyboards define the working practices that are envisioned for using the eStability message input tool (eStability Message Input Tool). The storyboards encompass interactions with the tool, interactions with data sources or a manual step and serve to guide the tool design. The storyboards lay out the sequence of

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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 documents.

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 assembly team enters all of the data in eStability Message Input Tool except the test results and Study Root. They make two copies of this file and edit the storage conditions in each. They make three copies of each of the three files making a total of nine files for each of the studies. Beta's team then opens each study file for BetaBeGone, enters the Study Root information. They then go to the result page and inserts the Excel file for the study. The tool matches the specification to the test results based on Beta's standardized codes. Each study file is validated and saved.

1.4.4 Prepare a Message with the Tool and XML Fragments

Gamma Bios, Inc. resulted from the acquisition of a biologics research lab (Bios) by Gamma Pharm. Both divisions insist on keeping the LIMS systems they had in place at the time of acquisition. The methods and specs are only in the research side LIMS. The commercial testing data, referenced by the method id is stored in the other system. They are planning an UberLIMS implementation to unite the company, but that is two years away. They are preparing an NDA for GBI-245 that aids in tissue repair. Regulatory Operations has requested that each group export what information they have as PORT_MT090002UV01 XML fragments.

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The Bios side exports their data as a Subject complex type. The commercial testing group exports their data as a Component1complex type. The definitionStub of the Test complex object within component matches the testDefintionCodes in the Subject's Component 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, inquiring of them whether 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 profile in the Implementation Guide.

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 clock she realizes this process is too time consuming and she will never get done with all the studies on MeTooFixYou by the end of the day. She copies the validated file on the file server and names it spec123.xml. She opens spec123.xml in eStability Message Input Tool and deletes all the data in the fields except for those on the Specification Tab. She then saves spec123.xml. She can now open each of the stability messages from the lab, and use the insert file option to bring the spec123.xml fragment into the message. She now only has to fill in the study root fields to finish the job.

1.4.6 Prepare a Message with an ODBC Connected Tool

Epsilon In Silico Pharma, LTD is a large company and stores all of its data on HemoSerration in a database. It is just one of twenty drugs they produce which means they have more than one annual report each month. Their headcount is flat. They can only meet their reporting requirements by directly importing the data from the database into eStability Message Input Tool. Their IT department installed an ODBC connection to the database and used a software development tool to map the data from their database to the eStability Message Input Tool.

eSTABILITY MESSAGE INPUT TOOL's custom queries allow Epsilon In Silico Pharma to extract stability data based on the lot number and storage conditions entered into the form. The database does not have test codes or method codes for its test. So, they are added to the messages for HemoSerration. The user enters them in the Test code/Name field(s) and Method Code fields on the specification page. Then the message is validated and saved.

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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_MT090002UV01 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 component1/test/text or component1/component/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 The stability message input tool shall support PORT_IN090004UV01 type messages, PORT_IN090005UV01 and PORT_IN090006UV01 type messages are optional, since the status and purpose of the messages submitted to the FDA will be documented with the eked or RPS. The optional message types will support interoperability between other systems and organizations.
- 2.1.15 The stability message input tool shall open an existing stability message.
- 2.1.16 The stability message input tool shall create new stability messages.
- 2.1.17 The stability message input tool shall save the stability message content regardless of validation status.
- 2.1.18 The stability message input tool shall validate the stability message.
- 2.1.19 The stability message input tool shall provide copy, cut and paste functions.
- 2.1.20 The stability message input tool shall generate component1 as a component3 data type from the data entered as in specifications as a test and test results. There is only one storage condition found in the message. A test needs only to be entered once in the specification. If two storage conditions are entered as is the case of cycled studies, then the tool will generate as many messages as there are storage conditions and place the tests in the StabilityStudy/Component/StudyOnBatch/component2/testing code and title as are found in the results based on the condition code. For example, pH and weight loss are entered in the specification as a tests. On the results page, the pH is entered for storage condition 25°C/60% RH and 40°C/75% RH, but weight loss results are recorded only for 40°C/75% RH. The tool will generate two messages, one for 25°C/60% RH and one for 40°C/75% RH. The component2's of component4 type will be in the respective message and weight loss will only appear as a test in one of the messages. Refer to Component2 – Element: Sample Code section of the eStability Implementation Guide for more examples.
- 2.1.21 The stability message input tool shall support component1/component testing, not displayed on the example layouts.
- 2.1.22 The stability message input tool shall support test result value typing as PQ and ST based on the test result value. If any characters are entered in the value, then it will be typed as ST.
- 2.1.23 The stability message input tool shall validate individual fields 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.
- 2.1.24 The stability message input tool shall allow input of an infinite number of element instances where scrollbars are used in the layouts.

2.2 Desirable Requirements

- 2.2.1 The stability message input tool shall support restricted access to individual tabs based on password for access.
- 2.2.2 The stability message input tool shall mask the password entry.
- 2.2.3 The stability message input tool shall provide on line help for each field.
- 2.2.4 The stability message input tool shall provide the ability to input data from a database.
- 2.2.5 The stability message input tool shall provide a method to duplicate data records by fill down and fill up operations in tabular data.
- 2.2.6 The stability message input tool shall mark all modifications made to the stability data field data via color or other visual attribute before modifications are saved.

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- 2.2.7 The stability message input tool shall support browsing file folders and saving the file location as a hyper -link in a field.
- 2.2.8 The stability message input tool shall warn when the saved message is not valid.

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3.0 Label to Message Mapping

The following tables link the fields in the Form Layout Examples in section 5.2 to elements and attributes in eStability message. In some cases the mapping is explicit, in others the tool needs to derive the output XML from the data provided.

3.1 Message Info Fields

To save space, MCCI_MT0001000UV01.Message is abbreviated to Message; MCAI_MT700201UV01.ControlActProcess is abbreviated to ControlActProcess and MCAI_MT700201UV01.

| 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 a new study, a revision to a previous study, or a retraction of a previous study. The tool will generate PORT_IN090004UV01, (PORT_IN0900005UV01 and PORT_IN0900006UV01 optional) messages respectively. |
| 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 Number | 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 Process Id | Message/controlActProcess/id |
| Code | Message/controlActProcess/code |
| Text | Message/controlActProcess/text |
| Effective Time | Message/controlActProcess/effectiveTime |
| Priority Code | Message/controlActProcess/priorityCode |
| Reason Code | Message/controlActProcess/reasonCode |

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| Language Code | Message/controlActProcess/languageCode ... Complex object that is not required. This would require many fields. |
| Overseer | Message/controlActProcess/overseer/assignedPerson/assignedPerson/name |
| Author | Message/controlActProcess/authorOrPersormer |
| Data Enterer | Message/controlActProcess/dataEnterer/assignedPerson/assignedPerson/name |
| Recipient | Message/controlActProcess/informationRecipient/assignedPerson |

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 |
| Reason Code for this Document | /stabilityStudy/reasonCode |
| Associated Studies: Seq | /stabilityStudy/componentOf/ sequenceNumber |
| Associated Studies: File Name | /stabilityStudy/componentOf/associatedStudy/id |

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/component/studyOnBatch/component1/testing /performer/assignedEntity/assignedTestingSite /id or /stabilityStudy/component/studyOnBatch/component1/testing /component/test/performer/assignedEntityStub/assignedSiteStub/id |
| Testing Site | /stabilityStudy/component/studyOnBatch/component1/testing /performer/assignedEntity/assignedTestingSite /name |
| Address | /stabilityStudy/component1/studyOnBatch/component1/testing /component/test/performer/assignedEntity/assignedTestingSite/addr |
| Country | /stabilityStudy/component/studyOnBatch/component1/testing |

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| | |
|------------------------|---|
| | g /performer/assignedEntity/assignedTestingSite /addr |
| Manufacturer Unique ID | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer /id |
| Manufacturer | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer /name |
| Address | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer /addr |
| Country | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer /addr |

3.4 Product/Substance Fields

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

3.5 Specification Fields

| Field Label | Message Element |
|--------------------|--|
| Specification Code | stabilityStudy/subject/researchSubject/subjectOf/specification/code |
| Specification Text | stabilityStudy/subject/researchSubject/subjectOf/specification/text |
| Test ID | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/id |

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| Test Name | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/code code and displayName attributes. May use two fields. | | |
| Method Code | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/methodCode | | |
| Test Text | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/text | | |
| Test Definition | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition This test definition can also be a component which is a singular dependent structure . | | |
| Interpretation Code | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion/interpretationCode | | |
| Acceptance Criterion Value | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion/value | | |
| Acceptance Criterion Text | stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion/text | | |
| 3.6 Lot Info Fields | | | |
| Field Label | Message Element | | |
| Manufactured Quantity | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/quantity | | |
| Lot Number | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/lotNumber Text | | |
| Production Date | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/existenceTime | | |
| Expiration Date | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/expirationTime | | |
| Production Description OR URL to PDF | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/desc | | |
| Manufacturer | Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer elements | | |
| Assigned Manufacturer | Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer/assignedEntity elements | | |
| Batch Lot Number | /stabilityStudy/component/studyOnBatch/subject/instance/m | | |
| | | | |

| | | Stability Message Input Tool | Page 16 of 42 |
|------------------------------------|------------------------|--|----------------------|
| Title: | User Requirements | | |
| | | anufacturedMaterialInstance/batchIngredient/Manufactured Material - lotNumber Text | |
| Batch Quantity | | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/Quantity | |
| Manufacture Date | | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/Manufactured Material – existenceTime | |
| Batch Expiry Date | | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/Manufactured Material – expirationTime | |
| Manufacturer | | Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/Manufactured Material - manufacturer elements | |
| Batch Description | | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/Manufactured Material – desc | |
| 3.7 Study Info Fields | | | |
| Field Label | Message Element | | |
| Unique Study ID | | /stabilityStudy/component/studyOnBatch/id | |
| Study Type | | /stabilityStudy/component/studyOnBatch/code | |
| Condition Start Date | | /stabilityStudy/component/studyOnBatch/component2/storage/effectiveTime | |
| Storage Condition Code | | /stabilityStudy/component/studyOnBatch/component2/storage/controlVariable/storageCondition/code | |
| Storage Condition Value | | /stabilityStudy/component/studyOnBatch/component2/storage/controlVariable/storageCondition/value | |
| Condition Description or Reference | | /stabilityStudy/component/studyOnBatch/component2/storage/controlVariable/storageCondition/text | |
| Storage Condition Code | | Storage condition code(s) for the study. | |
| Storage Condition Text Description | | Description of conditions. Used to build Component2(s). | |
| Time Point Code | | /stabilityStudy/component/studyOnBatch/component1/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/component1/testing/title | |
| Pull Date | | /stabilityStudy/component/studyOnBatch/component1/testing/effectiveTime | |
| Description | | /stabilityStudy/component/studyOnBatch/component1/testing | |

Title: User Requirements

| | |
|------------------------|---|
| | g/text |
| Container Name | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/code |
| Container Description | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/desc |
| Container Lot Number | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/lotNumber Text |
| Container Quantity | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity numerator and denominator attribute |
| Container Closure Code | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container/code |
| Container Capacity | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity value attribute |
| Unit | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity unit attribute |
| Container Description | /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/desc |

3.8 Test Results Fields

| Field Label | Message Element |
|----------------|--|
| Seq | Left blank for Component1/test if there is a component1/component test(s) /stabilityStudy/component/studyOnBatch/component1/testing/component/test/component1/sequence |
| Condition Code | Pick list of storage conditions from Study Info: Storage Condition Code to be entered into /stabilityStudy/component/studyOnBatch/Component2/storage/controlVariable/storageCondition/code |
| Test Name | Pick List of Names entered in Specification: Test Name. Associated code and title in test is entered in /stabilityStudy/component/studyOnBatch/Component1/testing/code and title |
| Time Pt | /stabilityStudy/component/studyOnBatch/component1/pauseQuantity value attribute |
| Pull Date | /stabilityStudy/component/studyOnBatch/component1/testing/effectiveTime or /stabilityStudy/component/studyOnBatch/component1/testing/component/test/component1/test/effectiveTime |

Title: User Requirements

| | |
|--------------|--|
| Unit | /stabilityStudy/component/studyOnBatch/ component1/pauseQuantity unit attribute or /stabilityStudy/component/studyOnBatch/Component1/testing/com ponent/test/component/test/pauseQuantity |
| Result | /stabilityStudy/component/studyOnBatch/ component1/testing/test/value or /stabilityStudy/component/studyOnBatch/Component1/testing/com ponen/test/component/test/value |
| Unit | /stabilityStudy/component/studyOnBatch/component2/testing/com ponent/test/value unit attribute if data type of result is PQ. Not valid for ST data types. or /stabilityStudy/component/studyOnBatch/component2/testing/com ponent/test/component/test/value unit attribute. |
| C button | Button to popup field can be replaced with fixed field for OOS comments or other text info. /stabilityStudy/component/studyOnBatch/Component2/testing/com ponent/test/text or /stabilityStudy/component/studyOnBatch/Component2/testing/com ponent/test/component/test/text |
| Test Date | /stabilityStudy/component/studyOnBatch/Component2/testing/com ponent/test/effectiveTime or /stabilityStudy/component/studyOnBatch/Component2/testing/com ponent/test/component/test/effectiveTime |
| Testing Site | Pick list of testing site from Organizations. The values are entered into /stabilityStudy/component/studyOnBatch/Component1 /testing/component/test/performer/assignedEntityStub/assignedSit eStub/id or /stabilityStudy/component/studyOnBatch/Component1/testing/com ponent/test/component/test/performer/assignedEntityStub/assigne dSiteStub/id. |

4.0 Mapping Element in Implementation Guide to Input Tool

The following tables register the elements in the eStability Implementation Guide 1.3 (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

| | | Stability Message Input Tool | | Page 19 of 42 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------------------------|---|---|---------------|--|------|-------|-------------|---|---|-----------------|------------------------------|---|---|---|-----------------|------------------------------|---|---|---|------|-------------------------------|---|---|---|------------|-------------------------------|--|---|---|---------|------------------------------|--|---|---|-------------|------------------------------|--|---|---|-----------|------------------------------|---|---|---|
| Title: | | User Requirements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>R – Required (the information should be provided if available) O – Optional (the information can be provided) The Stability Message Input Tool will validate based on the FDA Optionality.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.1 StabilityStudy /stabilityStudy</p> <p>Description: The root element of the document.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>Id:root</td> <td>ID for Document</td> <td>Is a global unique identifier for the document, or OID for this document</td> <td>M</td> <td>M</td> </tr> <tr> <td>Text</td> <td>Text or Link to Text</td> <td>Either a text provided by the submitter or an URI to an external document with further annotations for this submission.</td> <td>O</td> <td>O</td> </tr> <tr> <td>Code</td> <td>Study Code or Other</td> <td>An ACTCODE which describes the type of document sent.</td> <td>R</td> <td>R</td> </tr> <tr> <td>reasonCode</td> <td>Reason Code for this Document</td> <td>An ACTREASON which describes the reason for this document.</td> <td>O</td> <td>M</td> </tr> <tr> <td>Subject</td> <td><i>Complex built by form</i></td> <td>A complex structure to describe the researchSubject of the study (exactly one provided).</td> <td>M</td> <td>M</td> </tr> <tr> <td>ComponentOf</td> <td><i>Complex built by form</i></td> <td>A complex structure that can occur multiple times containing a reference to another eStability message</td> <td>O</td> <td>O</td> </tr> <tr> <td>Component</td> <td><i>Complex built by form</i></td> <td>A complex structure to describe a batch and the studies performed on this batch and reported in this document (one or many provided).</td> <td>M</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | Id:root | ID for Document | Is a global unique identifier for the document, or OID for this document | M | M | Text | Text or Link to Text | Either a text provided by the submitter or an URI to an external document with further annotations for this submission. | O | O | Code | Study Code or Other | An ACTCODE which describes the type of document sent. | R | R | reasonCode | Reason Code for this Document | An ACTREASON which describes the reason for this document. | O | M | Subject | <i>Complex built by form</i> | A complex structure to describe the researchSubject of the study (exactly one provided). | M | M | ComponentOf | <i>Complex built by form</i> | A complex structure that can occur multiple times containing a reference to another eStability message | O | O | Component | <i>Complex built by form</i> | A complex structure to describe a batch and the studies performed on this batch and reported in this document (one or many provided). | M | M |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Id:root | ID for Document | Is a global unique identifier for the document, or OID for this document | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Text | Text or Link to Text | Either a text provided by the submitter or an URI to an external document with further annotations for this submission. | O | O | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Code | Study Code or Other | An ACTCODE which describes the type of document sent. | R | R | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| reasonCode | Reason Code for this Document | An ACTREASON which describes the reason for this document. | O | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Subject | <i>Complex built by form</i> | A complex structure to describe the researchSubject of the study (exactly one provided). | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ComponentOf | <i>Complex built by form</i> | A complex structure that can occur multiple times containing a reference to another eStability message | O | O | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Component | <i>Complex built by form</i> | A complex structure to describe a batch and the studies performed on this batch and reported in this document (one or many provided). | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.2 componentOf /stabilityStudy/</p> <p>Description: The “componentOf” associates the current data file with another data file that has to be part of the same submission.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>sequenceNumber</td> <td>Associated Studies: Seq TBD</td> <td>Defines the sequence in which the associated files have to be interpreted.</td> <td>O</td> <td>R</td> </tr> <tr> <td>associatedStudy</td> <td><i>Complex built by form</i></td> <td>To use e.g. with growth of bacteria, etc.</td> <td>O</td> <td>R</td> </tr> <tr> <td>id</td> <td>Associated Studies: File Name</td> <td>Elements of test one level deep.</td> <td>O</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | sequenceNumber | Associated Studies: Seq TBD | Defines the sequence in which the associated files have to be interpreted. | O | R | associatedStudy | <i>Complex built by form</i> | To use e.g. with growth of bacteria, etc. | O | R | id | Associated Studies: File Name | Elements of test one level deep. | O | M | | | | | | | | | | | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| sequenceNumber | Associated Studies: Seq TBD | Defines the sequence in which the associated files have to be interpreted. | O | R | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| associatedStudy | <i>Complex built by form</i> | To use e.g. with growth of bacteria, etc. | O | R | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| id | Associated Studies: File Name | Elements of test one level deep. | O | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.3 Subject /stabilityStudy/subject</p> <p>Description: Intermediate element</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>ResearchSubject</td> <td><i>Complex built by form</i></td> <td>A complex structure to describe the researchSubject (exactly one provided).</td> <td>M</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | ResearchSubject | <i>Complex built by form</i> | A complex structure to describe the researchSubject (exactly one provided). | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ResearchSubject | <i>Complex built by form</i> | A complex structure to describe the researchSubject (exactly one provided). | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Title: User Requirements

4.4 ResearchSubject
/stabilityStudy/subject

Description: This is the subject of this study. This can either be a “Product” or a “Substance” – only one has to be provided – so the “M” is exclusive on one of the elements. Information about the included “Substances” of a “Product” can be provided.

| Name | Field | Description | H | F |
|--------------|------------------------------|--|---|---|
| Product | <i>Complex built by form</i> | Finished dosage form (exactly one). | M | M |
| Substance | <i>Complex built by form</i> | Active ingredient (exactly one). | M | M |
| StudySponsor | <i>Complex built by form</i> | Research Sponsor. | O | R |
| Subject | <i>Complex built by form</i> | Reference to the specification used in this study. | M | M |

| | | Stability Message Input Tool | | Page 21 of 42 | |
|---|------------------------------|--|---|---------------|--|
| Title: | | User Requirements | | | |
| <p>4.5 Product /stabilityStudy/subject/researchSubject/subjectProduct</p> <p>Description: Complex structure to describe a finished dosage form.</p> | | | | | |
| Name | Field | Description | H | F | |
| expirationTime | Expiration Time | If an interval value is provided (e.g. 24 M) this means that this is a <i>proposed</i> Expiration date, if a date value is provided (e.g. 2/2011) this is the already <i>approved</i> expiration date. | R | M | |
| Desc | Description | A Description of the product provided by the submitter or an URI for additional external documentation. | O | O | |
| Code | Code | 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 | M | |
| formCode | Form 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. | R | M | |
| SpecifiedIngredient | <i>Complex built by form</i> | The formulation of this product (many, if necessary). | O | R | |
| <p>4.6 SpecifiedIngredient /stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient</p> <p>Description: With this element one can map the formulation of the product by referencing substances and providing information on the quantity of the substance used in the product.</p> | | | | | |
| Name | Field | Description | H | F | |
| Quantity | Quantity | The quantity of the referenced substance in the product | R | R | |
| ingredient | Specified Ingredient | Reference to substance, i.e. active ingredient | M | M | |
| <p>4.7 Substance /stabilityStudy/subject/researchSubject/subjectSubstance or /stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient</p> <p>Description: When used as a child of "ResearchSubject" this element describes the substance the study is performed on. As child of "SpecifiedIngredient" this element describes a substance as part of a formulation.</p> | | | | | |
| Name | Field | Description | H | F | |
| Code | Code | an ACTCODE: code of the substance. For FDA implementation, only the "displayName" (i.e. the substance name) is mandatory, the code values might be provided if available. | R | M | |
| Desc | Description | URI for additional documentation. | O | O | |

| | | Stability Message Input Tool | | Page 22 of 42 | | | | | | | | | | | | | | | | | | | | | |
|--|------------------------------|---|---|---------------|--|------|-------|-------------|---|---|----------------|------------------------------|---|---|---|------|--------------------|--|---|---|-----------|------------------------------|---|---|---|
| Title: | | User Requirements | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.8 StudySponsor /stabilityStudy/subject/researchSubject/researchSponsor</p> <p>Description: The research sponsor for the study.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>Id: Root</td> <td>Study Sponsor OID</td> <td>This is a global unique identifier for the sponsoring organization assigned by IANA. This identifier should be the same for one organization within all submissions of one company.</td> <td>M</td> <td>M</td> </tr> <tr> <td>name</td> <td>Study Sponsor</td> <td>Name of the organization sponsoring the study.</td> <td>O</td> <td>M</td> </tr> <tr> <td>addr</td> <td>Address Country</td> <td>Address of the organization.</td> <td>O</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | Id: Root | Study Sponsor OID | This is a global unique identifier for the sponsoring organization assigned by IANA. This identifier should be the same for one organization within all submissions of one company. | M | M | name | Study Sponsor | Name of the organization sponsoring the study. | O | M | addr | Address Country | Address of the organization. | O | M |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| Id: Root | Study Sponsor OID | This is a global unique identifier for the sponsoring organization assigned by IANA. This identifier should be the same for one organization within all submissions of one company. | M | M | | | | | | | | | | | | | | | | | | | | | |
| name | Study Sponsor | Name of the organization sponsoring the study. | O | M | | | | | | | | | | | | | | | | | | | | | |
| addr | Address Country | Address of the organization. | O | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.9 SubjectOf /stabilityStudy/subject/researchSubject/subjectOf</p> <p>Description: Reference to the specification (intermediate element).</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>Specification</td> <td><i>Complex built by form</i></td> <td>(exactly one)</td> <td>M</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | Specification | <i>Complex built by form</i> | (exactly one) | M | M | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| Specification | <i>Complex built by form</i> | (exactly one) | M | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.10 Specification /stabilityStudy/subject/researchSubject/subjectOf/specification</p> <p>Description: For this Element the "full" HL7 structure has to be provided for the specification.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>Text</td> <td>Specification Text</td> <td>URI for additional documentation.</td> <td>O</td> <td>R</td> </tr> <tr> <td>Code</td> <td>Specification Code</td> <td>an ACTCODE: Specification identifier. i.e. the name and version of the specification (as displayName).</td> <td>O</td> <td>M</td> </tr> <tr> <td>Component</td> <td><i>Complex built by form</i></td> <td>The testdefinition and acceptance criteria for these tests.</td> <td>O</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | Text | Specification Text | URI for additional documentation. | O | R | Code | Specification Code | an ACTCODE: Specification identifier. i.e. the name and version of the specification (as displayName). | O | M | Component | <i>Complex built by form</i> | The testdefinition and acceptance criteria for these tests. | O | M |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| Text | Specification Text | URI for additional documentation. | O | R | | | | | | | | | | | | | | | | | | | | | |
| Code | Specification Code | an ACTCODE: Specification identifier. i.e. the name and version of the specification (as displayName). | O | M | | | | | | | | | | | | | | | | | | | | | |
| Component | <i>Complex built by form</i> | The testdefinition and acceptance criteria for these tests. | O | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.11 Component /stabilityStudy/subject/researchSubject/subjectOf/specification/component</p> <p>Description: Intermediate element</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>TestDefinition</td> <td>Test Definition</td> <td></td> <td>M</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | TestDefinition | Test Definition | | M | M | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| TestDefinition | Test Definition | | M | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.12 TestDefinition /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition n or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition n/component/testDefinition</p> <p>Description: This is the definition of a method performed during the study or the definition of a parameter of a method. The recursive structure will not be implemented further than one level – methods and method parameters. Either the external document or the method parameters and the reference range have to be provided.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | | | | | | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | |

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|--|---|--|---|---------------|--|------|-------|-------------|---|---|---------------------|------------------------------|--|---|---|------|---------------------------|-----------------------------------|---|---|-------|----------------------------|-----------------------------|---|---|
| Title: | | User Requirements | | | | | | | | | | | | | | | | | | | | | | | |
| Id: Root | Test ID | Global unique identifier for this TestDefinition (OID) | R | M | | | | | | | | | | | | | | | | | | | | | |
| Text | Test Text | URI for additional documentation for this test, e.g. SOP or Specification document for this method. | O | R | | | | | | | | | | | | | | | | | | | | | |
| Code | Test Name/code (field may be two) | an ACTCODE: Test code. Attributes code and displayName | R | R | | | | | | | | | | | | | | | | | | | | | |
| methodCode | Method Code | an ACTREASON: Method type. | O | M | | | | | | | | | | | | | | | | | | | | | |
| ReferenceRange | <i>Complex built by form</i> | The acceptance criterion for this parameter. | O | M | | | | | | | | | | | | | | | | | | | | | |
| Component | Second Component Button – Opens form for additional test definition | Recursive reference to TestDefinition to define the method parameter of this method (i.e. a test assay, for which the next level can be the ingredients or impurities). Only one additional level may be provided. | O | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.13 ReferenceRange /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange</p> <p>Description: The container for the set of acceptance criteria for a TestDefinition.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>AcceptanceCriterion</td> <td><i>Complex built by form</i></td> <td>One or many acceptance criteria.</td> <td>O</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | AcceptanceCriterion | <i>Complex built by form</i> | One or many acceptance criteria. | O | M | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| AcceptanceCriterion | <i>Complex built by form</i> | One or many acceptance criteria. | O | M | | | | | | | | | | | | | | | | | | | | | |
| <p>4.14 AcceptanceCriterion /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange/acceptanceCriterion</p> <p>Description: Describes one valid specification limit.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th>F</th> </tr> </thead> <tbody> <tr> <td>InterpretationCode</td> <td>Interpretation Code</td> <td>e.g. not more than (NMT), not less than (NLT), ...</td> <td>M</td> <td>M</td> </tr> <tr> <td>Text</td> <td>Acceptance Criterion Text</td> <td>URI for additional documentation.</td> <td>O</td> <td>O</td> </tr> <tr> <td>Value</td> <td>Acceptance Criterion Value</td> <td>The value of the criterion.</td> <td>M</td> <td>M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | InterpretationCode | Interpretation Code | e.g. not more than (NMT), not less than (NLT), ... | M | M | Text | Acceptance Criterion Text | URI for additional documentation. | O | O | Value | Acceptance Criterion Value | The value of the criterion. | M | M |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | |
| InterpretationCode | Interpretation Code | e.g. not more than (NMT), not less than (NLT), ... | M | M | | | | | | | | | | | | | | | | | | | | | |
| Text | Acceptance Criterion Text | URI for additional documentation. | O | O | | | | | | | | | | | | | | | | | | | | | |
| Value | Acceptance Criterion Value | The value of the criterion. | M | M | | | | | | | | | | | | | | | | | | | | | |

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| Title: | | User Requirements | | | |
| 4.15 Component /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 | <i>Complex built by form</i> | | M | M | |
| 4.16 StudyOnBatch /stabilityStudy/component/studyOnBatch | | | | | |
| 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 ID | 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 | |
| Subject | <i>Complex built by form</i> | The reference to the information on the material the study is performed on (e.g. a batch). | M | M | |
| Component2 | <i>Complex built by form</i> | The reference to the storage conditions used | M | M | |
| Component1 | <i>Complex built by form</i> | The reference to the study design and the results section. | M | M | |
| 4.17 Subject /stabilityStudy/component/studyOnBatch/subject | | | | | |
| Description: An intermediate element. | | | | | |
| Name | Field | Description | H | F | |
| Instance | <i>Complex built by form</i> | The Instance of the material. | M | M | |
| 4.18 Instance /stabilityStudy/component/studyOnBatch/subject/instance | | | | | |
| Description: An intermediate element. | | | | | |
| Name | Field | Description | H | F | |
| ManufacturedMaterial | <i>Complex built by form</i> | | M | M | |
| 4.19 ManufacturedMaterial /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance | | | | | |
| 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 | |

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| Title: | | User Requirements | | | |
| existenceTime | Production Date | Date of production (use ISO 8601 format) | R | M | |
| expirationTime | Expiration Date | <p>Date of expiration (based on the provided expirationCode of the "Product" element) or the proposed expiration date or the material.</p> <p>Date of expiration (based on the provided expirationCode of the "Product" element) or the proposed expiration date of the material.</p> <p>Interpretation for a product: if an interval value is provided this means that this is a <i>proposed</i> Expiration date, if a date value is provided this is the already <i>approved</i> expiration date</p> <p>Interpretation for "substances" (i.e. intermediates or APIs): if an interval value is provided this means that this is a <i>proposed</i> retest period, if a date value is provided this is the already <i>approved</i> retest date.</p> | O | M | |
| AsManufacturedProduct | <i>Complex built by form</i> | <p>A reference to the manufacturer of this material.</p> <p>If this document is part of an application of a new active ingredient, this information has to be provided.</p> | M | R | |
| asContent | <i>Complex built by form</i> | A reference to the container/closure system. | M | M | |
| BatchIngredient | <i>Complex built by form</i> | <p>A reference to a ManufacturedMaterial, so that a "BatchRecord" can be provided.</p> <p>Using this element leads to a recursive structure.</p> | O | O | |
| <p>4.20 ManufacturedProduct /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct</p> <p>Description: Intermediate element, holding the manufacturer of the Manufactured Material.</p> | | | | | |
| Name | Field | Description | H | F | |
| Manufacturer | <i>Complex built by form</i> | | M | M | |

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|--|---|---|---|---------------|--|
| Title: | | User Requirements | | | |
| <p>4.21 Manufacturer /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer</p> <p>Description: The details about a manufacturer or a manufacturing site that produced the "ManufacturedMaterial".</p> | | | | | |
| Name | Field | Description | H | F | |
| Id: Root | Manufacturer Unique ID from Organization Manufacturer | A global unique identifier of the manufacturing site. (OID) | M | M | |
| Name | Manufacturer | Name of the manufacturer (or manufacturing site). | R | M | |
| Addr | Address and Country | Address | O | M | |
| assignedEntity | Assigned Manufacturer | One or many references to a "Manufacturer" who produced this product in behalf of the "Manufacturer" or who partial produced the product. | O | O | |
| <p>4.22 Content /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent</p> <p>Description: The container closure system</p> | | | | | |
| Name | Field | Description | H | F | |
| Quantity | Container Quantity (Fill) | The actual quantity of "ManufacturedMaterial" in the container expressed as a ratio. The denominator defaults to 1. | R | R | |
| Container | <i>Complex built by form</i> | A reference to the structure for the container closure system. | M | M | |
| <p>4.23 Container /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container</p> <p>Description: A simple structure to store the makeup to the container closure system.</p> | | | | | |
| Name | Field | Description | H | F | |
| Desc | Container Description | A verbal Description of the container closure system or a reference to an external PDF which holds this Description. | O | O | |
| lotNumberText | Container Lot Number | The lot number of the production lot for this container | O | O | |
| capacityQuantity | Container Capacity and Unit | The capacity of the container, not necessarily identical to "quantity of the "Content" element (e.g. 100 ml bottle, even if the quantity of tablets in the bottle is 50). | R | R | |
| capTypeCode | Container Closure Code | The code for the used closure system (e.g. plastic cap). | O | O | |
| Code | Container Name | an ENTITYCODE – Type of Container | R | M | |

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|---|--|--|---|---------------|--|
| Title: | | User Requirements | | | |
| | | (e.g. Bottle). | | | |
| <p>4.24 BatchIngredient /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient</p> <p>Description: An intermediate element to store a recursive reference to a “ManufacturedMaterial” to provide a kind of batch record for the product.</p> | | | | | |
| Name | Field | Description | H | F | |
| Quantity | Batch Quantity | The actual quantity of referenced material used to produce the product (e.g. the referenced material might be used in parts for this product). | O | R | |
| ingredient | Batch Lot Number Manufacture Date Batch Expiry Date Manufacturer Batch Description | This is a recursive link to ManufacturedMaterial. Each field group creates one instance of a ManufacturedMaterial. | M | M | |
| <p>4.25 component2 /stabilityStudy/component/studyOnBatch/component2</p> <p>Description: The message contains one component2 that identifies the storage time (pauseQuantity) and “Storage” (storage condition) of the study Note the data type of component2 is Component4.</p> | | | | | |
| Name | Field | Description | H | F | |
| pauseQuantity | Time Pt and Unit | Storage time of the batch in a climatic chamber. The unit of the pauseQuantity has to be homogenous for all xml files, which are connected to the concerning study. For more than one pauseQuantity, the connection between the storage to the concerning testing section is done by the value of the pauseQuantity. | R | M | |
| Storage | <i>Complex built by form</i> | A structure to describe the used storage condition. | M | M | |
| <p>4.26 Storage /stabilityStudy/component/studyOnBatch/component2/storage</p> <p>Description: Reference to one or many predefined storage condition (e.g. one reference to “25°/60%” and one to “upright” – or alternatively one reference to “25°/60% upright”).</p> | | | | | |
| Name | Field | Description | H | F | |
| Text | Storage Condition Text Description | A textual Description of this storage condition or an external reference to PDF to describe this storage | O | O | |

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|---|------------------------------------|--|----------|---------------|--|
| Title: | | User Requirements | | | |
| | | condition. | | | |
| EffectiveTime/high | Condition Start Date | The Time the product is put on stability. The date the stability storage is started for this condition. | O | M | |
| Code | Condition Code | An ACTCODE: fixed code value, may be used for other purposes in future versions. | M | M | |
| ControlVariable | <i>Complex built by form</i> | Reference to the predefined storage conditions (one or many may be used). | M | M | |
| <p>4.27 ControlVariable /stabilityStudy/component/studyOnBatch/component2/storage/controlVariable</p> <p>Description: Intermediate element</p> | | | | | |
| Name | Field | Description | H | F | |
| StorageCondition | <i>Complex built by form</i> | | M | M | |
| <p>4.28 StorageCondition /stabilityStudy/component/studyOnBatch/component2/storage/controlVariable/storageCondition</p> <p>Description: A structure to describe one storage condition. Dependent of the internal company definitions this condition might be simple (e.g. 25°) or complex (e.g. 25° C/60% RH upright). Complex definitions can be made up of many ControlVariables referencing simple StorageConditions.</p> | | | | | |
| Name | Field | Description | H | F | |
| Text | Condition Description or Reference | A textual Description or an external reference. | O | O | |
| Value | Storage Condition Value | e.g. "25°" or "60%" or "upright." A complex like "25° C/60% RH upright" requires 3 values. | M | M | |
| Code | Storage Condition Code | an ACTCODE: StorageCondition code of the complex storage condition, | M | M | |
| <p>4.29 Testing /stabilityStudy/component/studyOnBatch/component1/testing</p> <p>Description: This is a representation of "pulling a sample from the climatic chamber".</p> | | | | | |
| Name | Field | Description | H | F | |
| Title | Time Point Name | A title that labels a collection of related tests across "pauseQuantities", e.g. "Batch Release", "1 month", "6 month" | M | M | |
| Text | Time Point Name | A textual Description or an external reference. | O | O | |
| EffectiveTime/high | Pull Date | Pull date (use ISO 8601 notation). | O | M | |
| Code | Time Point Code | An ACTCODE: pauseDescription. Something done with the sample, e.g. freeze sample. | M | R | |

| | | Stability Message Input Tool | | Page 29 of 42 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|-------------------------------|---|---|---------------|--|------|-------|-------------|---|---|--|--------------------|------------------------------|---|---|---|--|------|--------------------------|---|---|---|--|-------|-----------------|--|---|---|--|---------------|-----------|--|---|---|--|-----------|-------------------------------|--------------------------------|---|---|--|------------|------------------------------|---|---|---|--|-----------|--|----------------------------------|---|---|--|
| Title: | | User Requirements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Component | <i>Complex built by form</i> | A reference to the tests performed with this sample. | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Performer | <i>Complex built by form</i> | A reference to a testing site. A list of all testing sites involved in this testing. | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.30 Component /stabilityStudy/component/studyOnBatch/component1/testing/component</p> <p>Description: Intermediate element</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th colspan="2">F</th> </tr> </thead> <tbody> <tr> <td>Test</td> <td><i>Complex built by form</i></td> <td></td> <td>O</td> <td colspan="2">M</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | | Test | <i>Complex built by form</i> | | O | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test | <i>Complex built by form</i> | | O | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.31 Test /stabilityStudy/component/studyOnBatch/component1/testing/component/test or /stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test</p> <p>Description: Representation of a test performed on a sample. It applies the same scheme as in "TestDefinition"; there might be parameters for a Test that are represented by the "Component" reference.</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th colspan="2">F</th> </tr> </thead> <tbody> <tr> <td>Title</td> <td>Test Name.</td> <td>Alternative name of the measured result. This attribute can be used to identify "specified unknowns", since all of these results point to the same specification. If not in the pick list, the user can free text enter the name.</td> <td></td> <td colspan="2"></td> </tr> <tr> <td>Text</td> <td>C button to pop up field</td> <td>A textual Description or an external reference.</td> <td>O</td> <td colspan="2">O</td> </tr> <tr> <td>Value</td> <td>Result and Unit</td> <td>Result value is mandatory on one of the two possible levels, on the first level, if Component has no child elements.</td> <td>M</td> <td colspan="2">M</td> </tr> <tr> <td>effectiveTime</td> <td>Test Date</td> <td>Testing date, mandatory on the first level, omitted on the second level (ISO8601).</td> <td>M</td> <td colspan="2">M</td> </tr> <tr> <td>Performer</td> <td><i>Testing Site Unique Id</i></td> <td>A reference to a testing site.</td> <td>M</td> <td colspan="2">M</td> </tr> <tr> <td>Definition</td> <td><i>Complex built by form</i></td> <td>Reference to a specification for this test.</td> <td>O</td> <td colspan="2">M</td> </tr> <tr> <td>Component</td> <td></td> <td>Recursive reference to a "Test".</td> <td>R</td> <td colspan="2">R</td> </tr> </tbody> </table> | | | | | | Name | Field | Description | H | F | | Title | Test Name. | Alternative name of the measured result. This attribute can be used to identify "specified unknowns", since all of these results point to the same specification. If not in the pick list, the user can free text enter the name. | | | | Text | C button to pop up field | A textual Description or an external reference. | O | O | | Value | Result and Unit | Result value is mandatory on one of the two possible levels, on the first level, if Component has no child elements. | M | M | | effectiveTime | Test Date | Testing date, mandatory on the first level, omitted on the second level (ISO8601). | M | M | | Performer | <i>Testing Site Unique Id</i> | A reference to a testing site. | M | M | | Definition | <i>Complex built by form</i> | Reference to a specification for this test. | O | M | | Component | | Recursive reference to a "Test". | R | R | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Title | Test Name. | Alternative name of the measured result. This attribute can be used to identify "specified unknowns", since all of these results point to the same specification. If not in the pick list, the user can free text enter the name. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Text | C button to pop up field | A textual Description or an external reference. | O | O | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Value | Result and Unit | Result value is mandatory on one of the two possible levels, on the first level, if Component has no child elements. | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| effectiveTime | Test Date | Testing date, mandatory on the first level, omitted on the second level (ISO8601). | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Performer | <i>Testing Site Unique Id</i> | A reference to a testing site. | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Definition | <i>Complex built by form</i> | Reference to a specification for this test. | O | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Component | | Recursive reference to a "Test". | R | R | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4.32 Performer /stabilityStudy/component/studyOnBatch/component1/testing/component/test/performer/assignedEntityStub/assignedSiteStub</p> <p>Description: Intermediate element</p> <table border="1"> <thead> <tr> <th>Name</th> <th>Field</th> <th>Description</th> <th>H</th> <th colspan="2">F</th> </tr> </thead> <tbody> <tr> <td>AssignedEntityStub</td> <td><i>Testing Site</i></td> <td>A reference to the Testing Site Unique Id entered in Organization page</td> <td>M</td> <td colspan="2">M</td> </tr> </tbody> </table> <p>AssignedEntityStub /stabilityStudy/component/studyOnBatch/component1/testing/performer/assigned</p> | | | | | | Name | Field | Description | H | F | | AssignedEntityStub | <i>Testing Site</i> | A reference to the Testing Site Unique Id entered in Organization page | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | Field | Description | H | F | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| AssignedEntityStub | <i>Testing Site</i> | A reference to the Testing Site Unique Id entered in Organization page | M | M | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| Title: | | User Requirements | | | |
| Entity/assignedTestingSite/id or /stabilityStudy/component/studyOnBatch/component1/testing/component/test/performer/assignedEntityStub/assignedSiteStub/id Description: Intermediate element, a reference to a TestingSite who is performing the test on behalf of the ResearchSponsor. | | | | | |
| Name | Field | Description | H | F | |
| TestingSite | <i>Complex built by form</i> | | M | M | |
| TestingSite /stabilityStudy/component/studyOnBatch/component1/testing//performer/assignedEntity/assignedTestingSite Description: The details about a tester who performs the tests on behalf of the ResearchSponsor. | | | | | |
| Name | Field | Description | H | F | |
| Id: root | Testing Site Unique ID from Organization page | Is a global unique identifier of the testing site. OID of the testing site company | M | M | |
| Name | Testing Site on Results tab | The name of the testing site. | O | M | |
| Addr | Address and Country from organization tab | The address of the testing site. | O | M | |
| 4.33 Definition /stabilityStudy/component/studyOnBatch/component1/testing/component/test/definition or /stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test/definition Description: Intermediate element which reference the test definition. | | | | | |
| Name | Field | Description | H | F | |
| DefinitionStub | <i>Complex built by form</i> | The unique identifier (id) of the referenced specification. The tool matches the definition from the test name to the specification. | M | M | |
| DefinitionStub /stabilityStudy/component/studyOnBatch/component1/testing/component/test/definition/definitionStub or /stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test/definition/definitionStub Description: | | | | | |
| Name | Field | Description | H | F | |
| Id: root | Test Id on specification tab based on Test Name entered on Results page | Is the unique identifier (id) of the referenced specification (TestDefinition). OID of the referenced specification. | M | M | |

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4.34 Component

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/component

Description: If a test has parameters (e.g. Assay and ingredients) this structure is used to store the parameters (sequenceNumber)

or

Use this structure to indicate the point in time after the sample was drawn from the chamber, when the test was performed (pauseQuantity).

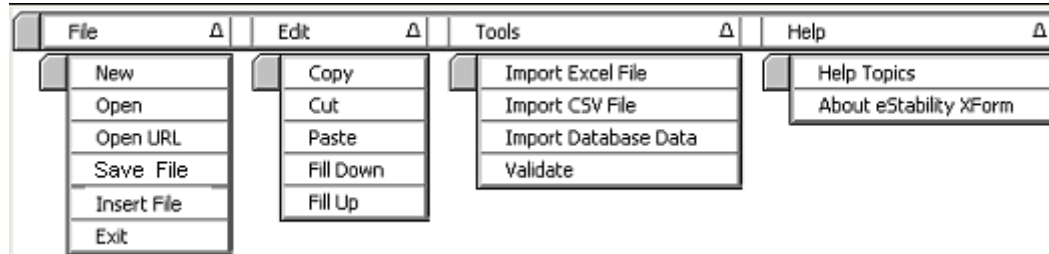
| Name | Field | Description | H | F |
|----------------|---|---|---|---|
| sequenceNumber | Seq | The sequence of parameters of the test. Used only when a component has been defined for the parent test. The form will place the component in context Component1/test | O | R |
| pauseQuantity | Time Point and Time Unit | To use e.g. with growth of bacteria, etc. | O | R |
| Test | C button to pop up field Result and Unit Testing Site Unique ID from Organization page Testing Site on Results tab Address and Country from organization tab | Elements of test one level deep. | O | M |

Title:

User Requirements

5.0 Form Layout Examples

5.1 Tool Bar Example



Title:

User Requirements

5.2 Message Info

Mock Up Xforms Stability Input Tool

File Edit Tools Help Window

Message Info
Study Root
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.
 Define Message Header information Make your selection here. Then continue to subsequent pages.

Message ID **Creation Time** **Version Code**

Security Text **Profile ID**

Interaction Id **Sequence Number**

Processing Code **Accept Ack Code**

Processing Mode Code **Receiver**

Attachment Text **Respond To**

Sender **Attention Line**

Control Act Process Id **Code**

Text **Effective Time**

Priority Code **Reason Code** **Language Code**

Overseer **Author**

Data Enterer **Recipient**

Title:

User Requirements

5.3 Study Root

Title: User Requirements

5.4 Organizations

The screenshot shows a software window titled "Mock Up Xforms Stability Input Tool" with a menu bar (File, Edit, Tools, Help, Window) and a tabbed interface. The "Organizations" tab is active. The form contains the following fields:

- Study Sponsor OID**: A single-line text input field.
- Study Sponsor**: A table with 3 columns: Study Sponsor, Address, Country.
- Testing Site**: A table with 4 columns: Testing Site Unique ID, Testing Site, Address, Country.
- Manufacturer**: A table with 4 columns: Manufacturer Unique ID, Manufacturer, Address, Country.

| Study Sponsor | Address | Country |
|---------------|---------|---------|
| | | |

| Testing Site Unique ID | Testing Site | Address | Country |
|------------------------|--------------|---------|---------|
| | | | |
| | | | |
| | | | |

| Manufacturer Unique ID | Manufacturer | Address | Country |
|------------------------|--------------|---------|---------|
| | | | |
| | | | |
| | | | |

Title:

User Requirements

5.5 Product/Substance

The screenshot displays a software window titled "Mock Up Xforms Stability Input Tool" with a menu bar (File, Edit, Tools, Help, Window) and a tabbed interface. The "Product/Substance" tab is active, showing two main sections: "Finished Product Data" and "API Data".

Finished Product Data:

- Finished Product
- API
- Code:** [Text Input Field]
- Description:** [Text Input Field]
- Form Code:** [Text Input Field]
- Expiration Time:** [Text Input Field]
- Specified Ingredient** and **Quantity** table:

| Specified Ingredient | Quantity |
|----------------------|----------|
| | |
| | |
| | |
| | |

API Data:

- Code:** [Text Input Field]
- Description:** [Text Input Field]

Title: User Requirements

5.6 Specification

Mock Up Xforms Stability Input Tool

File Edit Tools Help Window

Message Info | Study Root | Organizations | Product/Substance | **Specification** | Lot Info | Study Info | Test Results

Specification Code **Specification Text**
 Second Component

Test ID **Test Name** **Method Code**

Test Text

Test Definition

2nd Comp.

Reference Range
 Interpretation Code Value Unit Acceptance Criterion Text

| Code | Value | Unit | Acceptance Criterion Text |
|----------------------|----------------------|----------------------|---------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Test ID **Test Name** **Method Code**

Test Text

Test Definition

2nd Comp.

Reference Range
 Interpretation Code Value Unit Acceptance Criterion Text

| Code | Value | Unit | Acceptance Criterion Text |
|----------------------|----------------------|----------------------|---------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Test ID **Test Name** **Method Code**

Test Text

Test Definition

2nd Comp.

Reference Range
 Interpretation Code Value Unit Acceptance Criterion Text

| Code | Value | Unit | Acceptance Criterion Text |
|----------------------|----------------------|----------------------|---------------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

Title: User Requirements

5.8 Study Info

Mock Up Xforms Stability Input Tool

File Edit Tools Help Window

Message Info | Study Root | Organizations | Product/Substance | Specification | Lot Info | **Study Info** | Test Results

Unique Study ID Study Type

Storage Conditions

| Storage Condition Code | Storage Condition Value | Condition Description or Reference |
|------------------------|-------------------------|------------------------------------|
| | | |
| | | |
| | | |

Condition

| Start Date | Storage Condition Code | Storage Condition Text Description |
|------------|------------------------|------------------------------------|
| | | |
| | | |
| | | |

Study Time Points

| Time PointCode | Time Point Name | Pull Date | Description |
|----------------|-----------------|-----------|-------------|
| | | | |
| | | | |
| | | | |
| | | | |

Container Closure

Container Name Container Lot Number

Container Quantity Container Capacity Unit

Container Closure Code

Container Description

| | Stability Message Input Tool | Page 42 of 42 |
|---|-------------------------------------|----------------------|
| Title: | User Requirements | |
| <p data-bbox="284 331 495 363">6.0 Glossary</p> <p data-bbox="305 426 1323 541">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.</p> <p data-bbox="305 562 1299 625">Excel An automated version of the paper-based spreadsheet that makes it easier to manipulate, process, and view the data.</p> <p data-bbox="305 646 1258 699">ODBC Open DataBase Connectivity. Standardised interface, or middleware, for accessing a database from a program.</p> <p data-bbox="305 720 1291 835">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.</p> <p data-bbox="305 846 1307 898">User Individual who is granted access to us the Stability Message Input Tool.</p> <p data-bbox="305 909 1339 1087">XForms 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.</p> <p data-bbox="305 1098 1315 1276">XML (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.</p> | | |