Stability Message Input Tool
User Requirements
5.2

Document History

Revision	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

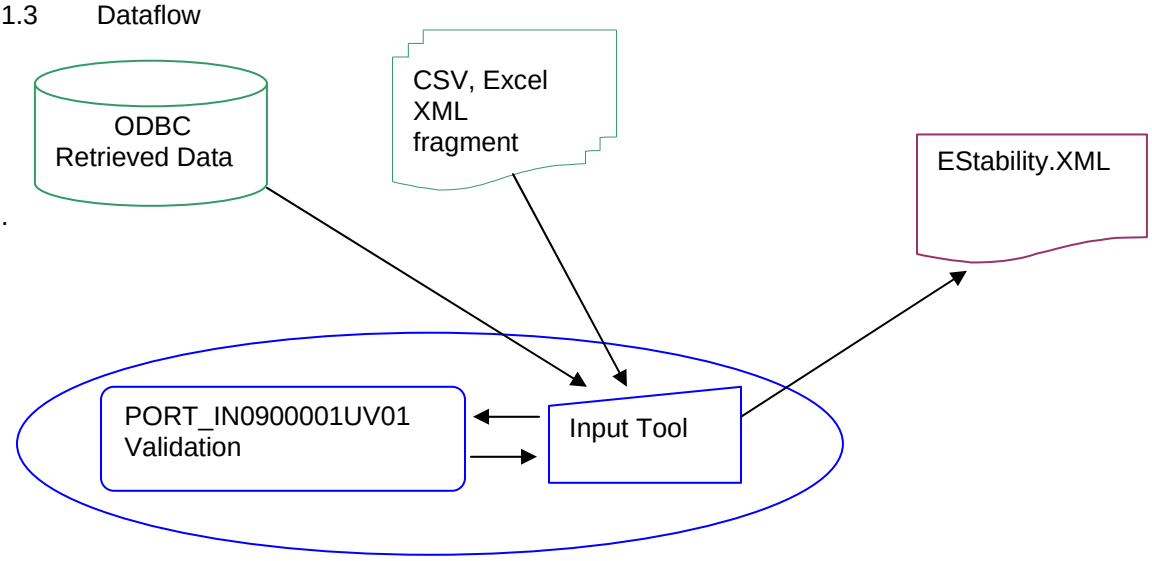
Develop an eStability message input tool based and the PORT_IN0900001UV01 schema. The Input Tool will allow the entry and reporting of stability data as an XML file. The Input Tool will allow users to enter data and build a stability message that can be validated against the PORT_IN0900001UV01 schema. 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.

1.3 Dataflow



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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

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_MT090001UV01 XML fragments.

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 testDefintionCodes 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 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.

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.

2.1.14 The stability message input tool shall support PORT_IN0900001UV01, PORT_IN0900002UV01 and PORT_IN0900003UV01 type messages.

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 one or many Component2 elements from the data entered as in specifications and test results. Component2 explicitly associates the test and storage conditions 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 Component2 elements as there are storage conditions and place the tests in the StabilityStudy/Component/StudyOnBatch/Component2/testing code and tile 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 Component2's and weight loss will only appear as a test in one of them. 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 compont4 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.

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.

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.Subject2 is abbreviated to Subject2.

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_IN090001UV01, PORT_IN0900002UV01 and PORT_IN0900003UV01 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

Language Code	Message/controlActProcess/languageCode … Complex object that is not required. 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
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/testing/component3/test/performer/assignedEntity/assignedTestingSite/id
Testing Site	/stabilityStudy/component1/studyOnBatch/component2/testing/component3/test/performer/assignedEntity/assignedTestingSite/name
Address	/stabilityStudy/component1/studyOnBatch/component2/testing/component3/test/performer/assignedEntity/assignedTestingSite/addr
Country	/stabilityStudy/component1/studyOnBatch/component2/testing/component3/test/performer/assignedEntity/assignedTestingSite/addr
Manufacturer Unique ID	/stabilityStudy/component1/studyOnBatch/subject/instance/

	manufacturedMaterialInstance/asManufacturedProduct/manufacturer/id
Manufacturer	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer/name
Address	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer/addr
Country	/stabilityStudy/component1/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 stabiltyStudy/subject/researchSubject/subjectProduct or subjectSubstance.
Expiration Time	stabiltyStudy/subject/researchSubject/subjectProduct/expirationTime
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/specifiedIngredient/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.

Method Code	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/methodCode
Test Text	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/text
Test Definition	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/Component6/testDefinition This test definition can also be a Component6 which is a singular dependent structure like Component5
Interpretation Code	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/referenceRange/acceptanceCriterion/interpretationCode
Acceptance Criterion Value	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/referenceRange/acceptanceCriterion/value
Acceptance Criterion Text	stabiltyStudy/subject/researchSubject/subjectOf/specification/Component5/testDefinition/referenceRange/acceptanceCriterion/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/manufacturer elements
Assigned Manufacturer	Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer/assignedEntity elements
Batch Lot Number	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/ManufacturedMaterial - lotNumber Text
Batch Quantity	/stabilityStudy/component/studyOnBatch/subject/instance/m

	anufacturedMaterialInstance/batchIngredient/Quantity
Manufacture Date	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/ManufacturedMaterial - existenceTime
Batch Expiry Date	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/ManufacturedMaterial - expirationTime
Manufacturer	Pick list of Organization: manufacturer. Values to populate /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/ManufacturedMaterial - manufacturer elements
Batch Description	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient/ManufacturedMaterial - 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

Container Name	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/code
Container Description	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/desc
Container Lot Number	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/lotNumber Text
Container Quantity	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity numerator and denominator attribute
Container Closure Code	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container/code
Container Capacity	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity value attribute
Unit	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/capacityQuantity unit attribute
Container Description	/stabilityStudy/component1/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/desc

3.8 Test Results Fields

Field Label	**Message Element**
Seq	Left blank for Component3/test /stabilityStudy/component/studyOnBatch/component/testing/component/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/controlVariable/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/code and title
Time Pt	/stabilityStudy/Component1/studyOnBatch/Component2/pauseQuantity value attribute
Pull Date	/stabilityStudy/component/studyOnBatch/component2/testing/effectiveTime or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/effectiveTime

Unit	/stabilityStudy/Component1/studyOnBatch/Component2/pauseQuantity unit attribute or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/pauseQuantity
Result	/stabilityStudy/Component1/studyOnBatch/Component2/testing/component3/value or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/value
Unit	/stabilityStudy/Component1/studyOnBatch/Component2/testing/component3/value unit attribute if data type of result is PQ. Not valid for ST data types. or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/value unit attribute.
C button	Button to popup field can be replaced with fixed field for OOS comments or other text info. /stabilityStudy/Component1/studyOnBatch/Component2/testing/component3/text or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/text
Test Date	/stabilityStudy/Component1/studyOnBatch/Component2/testing/component3/effectiveTime or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/effectiveTime
Testing Site	Pick list of testing site from Organizations. The value are entered into /stabilityStudy/Component1/studyOnBatch/Component2/testing/component3/test/performer elements or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component4/test/performer elements.

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)

O – Optional (the information can be provided)

The Stabiltiy Message Input Tool will validate based on the FDA Optionality.

4.1 StabilityStudy
/stabilityStudy

Description: The root element of the document.

Name	Field	Description	H	F
Id:root	ID for Document	Is a global unique identifier for the document. 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
Subject2	*Complex built by form*	a complex structure to describe the researchsubject of the study (exactly one provided).	M	M
Component1	*Complex built by form*	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

4.2 Subject2
/stabilityStudy/subject

Description: Intermediate element

Name	Field	Description	H	F
ResearchSubject	*Complex built by form*	a complex structure to describe the researchsubject (exactly one provided).	M	M

4.3 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	*Complex built by form*	Finished dosage form (exactly one).	M	M
Substance	*Complex built by form*	Active ingredient (exactly one).	M	M
Organization	*Complex built by form*	Research Sponsor.	O	R
Subject3	*Complex built by form*	Reference to the specification used in this study.	M	M

4.4 Product
/stabilityStudy/subject/researchSubject/subjectProduct

Description: Complex structure to describe a finished dosage form.

Name	Field	Description	H	F
expirationTime	Expiration Time	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	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	*Complex built by form*	The formulation of this product (many, if necessary).	O	R

4.5 SpecifiedIngredient
/stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient

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.

Name	Field	Description	H	F
Quantity	Quantity	The quantity of the referenced substance in the product	R	R
Substance	Specified Ingredient	Reference to substance, i.e. active ingredient	M	M

4.6 Substance
/stabilityStudy/subject/researchSubject/subjectSubstance
or
/stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient

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.

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

4.7 Organization
/stabilityStudy/subject/researchSubject/researchSponsor

Description: The research sponsor for the study.

Name	Field	Description	H	F
Id: Root	Study Sponsor OID	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

4.8 Subject3
/stabilityStudy/subject/researchSubject/subjectOf

Description: Reference to the specification (intermediate element).

Name	Field	Description	H	F
Specification	*Complex built by form*	(exactly one)	M	M

4.9 Specification
/stabilityStudy/subject/researchSubject/subjectOf/specification

Description: For this Element the “full” HL7 structure has to be provided for the specification.

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
Component5	*Complex built by form*	The testdefinition and acceptance criteria for these tests.	O	M

4.10 Component5
/stabilityStudy/subject/researchSubject/subjectOf/specification/component

Description: Intermediate element

Name	Field	Description	H	F
TestDefinition	Test Definition		M	M

4.11 TestDefinition
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition
or
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition

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.

Name	Field	Description	H	F
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	*Complex built by form*	The acceptance criterion for this parameter.	O	M
Component6	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

4.12 ReferenceRange
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange
or
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange

Description:
The container for the set of acceptance criteria for a TestDefinition.

Name	Field	Description	H	F
AcceptanceCriterion	*Complex built by form*	One or many acceptance criteria.	O	M

4.13 AcceptanceCriterion
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion
or
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange/acceptanceCriterion

Description: Describes one valid specification limit.

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

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

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
Subject1	*Complex built by form*	The reference to the information on the material the study is performed on (e.g. a batch).	M	M
Component2	*Complex built by form*	The reference to the study design and the results section.	M	M

4.16 Subject1
/stabilityStudy/component/studyOnBatch/subject

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: An intermediate element.

Name	Field	Description	H	F
ManufacturedMaterial	*Complex built by form*		M	M

4.18 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
existenceTime	Production Date	Date of production (use ISO 8601 format)	R	M

expirationTime	Expiration Date	Date of expiration (based on the provided expirationCode of the „Product" element) or the proposed expiration date or the material. Add P proposed exp. time or A for approved exp. Time. P24M-A, P24M-P Also with Product element.	O	M
asManufacturedProduct	*Complex built by form*	A reference to the manufacturer of this material. If this document is part of an application of a new active ingredient, this information has to be provided.	M	R
asContent	*Complex built by form*	A reference to the container/closure system.	M	M
BatchIngredient	*Complex built by form*	A reference to a ManufacturedMaterial, so that a "BatchRecord" can be provided. Using this element leads to a recursive structure.	O	O

4.19 ManufacturedProduct
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct

Description: Intermediate element, holding the manufacturer of the Manufactured Material.

Name	Field	Description	H	F
Manufacturer	*Complex built by form*		M	M

4.20 Manufacturer
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/
manufacturer

Description: The details about a manufacturer or a manufacturing site that produced the "ManufacturedMaterial".

Name	Field	Description	H	F
Id: Root	Manufacturer Unique ID from Organization Manufacturer	Is 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

4.21 Content
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent

Description: The container closure system

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	*Complex built by form*	A reference to the structure for the container closure system.	M	M

4.22 Container
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container

Description: A simple structure to store the makeup to the container closure system.

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 (e.g. Bottle).	R	M

4.23 BatchIngredient
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient

Description:
An intermediate element to store a recursive reference to a "ManufacturedMaterial" to provide a kind of batch record for the product.

Name	Field	Descriptionn	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
Manufactured Material	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

4.24 Component2
/stabilityStudy/component/studyOnBatch/component

Description: For each combination of storage time (pauseQuantity) and "Storage" (storage condition) one Component2 has to be provided.

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 pauseQuanitity, the connection between the storage to the concerning testing section is done by the value of the pauseQuantity.	R	M
Storage	*Complex built by form*	A structure to describe the used storage condition.	M	M
Testing	*Complex built by form*	A structure to store the results of measurement.	M	M

4.25 Storage
/stabilityStudy/component/studyOnBatch/component/storage

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").

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 condition.	O	O
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	*Complex built by form*	Reference to the predefined storage conditions (one or many may be used).	M	M
Component3	*Complex built by form*	not used	N	N

4.26 ControlVariable
/stabilityStudy/component/studyOnBatch/component/storage/controlVariable

Description: Intermediate element

Name	Field	Description	H	F

StorageCondition	*Complex built by form*		M	M

4.27 StorageCondition

/stabilityStudy/component/studyOnBatch/component/storage/controlVariable/storageCondition

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.

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, eg	M	M

4.28 Testing
/stabilityStudy/component/studyOnBatch/component/testing

Description: This is a representation of “pulling a sample from the climatic chamber”.

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	Pulldate (use ISO 8601 notation).	O	M
Code	Time Point Code	an ACTCODE: pauseDescription. Something done with the sample, e.g. freeze sample.	M	R
Component3	*Complex built by form*	A reference to the tests performed with this sample.	M	M

4.29 Component3
/stabilityStudy/component/studyOnBatch/component/testing/component

Description: Intermediate element

Name	Field	Description	H	F
Test	*Complex built by form*		O	M

4.30 Test
/stabilityStudy/component/studyOnBatch/component/testing/component/test
or
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test

Description: Representation of a test performed on a sample.
It applies the same scheme as in “TestDefinition”, there might be parameters for a Test which are represented by the “Component4” reference.

Name	Field	Description	H	F
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 Component4 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	*Complex built by form*	A reference to a testing site.	M	M
Definition	*Complex built by form*	Reference to a specification for this test.	O	M
Component4		Recursive reference to a "Test".	R	R

4.31 Performer
/stabilityStudy/component/studyOnBatch/component/testing/component/test/performer
or
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/performer

Description: Intermediate element

Name	Field	Description	H	F
AssignedEntity	*Complex built by form*		M	M

4.32 AssignedEntity
/stabilityStudy/component/studyOnBatch/component/testing/component/test/performer/assignedEntity
or
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/performer/assignedEntity

Description: Intermediate element, a reference to a TestingSite who is performing the test on behalf of the ResearchSponsor.

Name	Field	Description	H	F
TestingSite	*Complex built by form*		M	M

4.33 TestingSite
/stabilityStudy/component/studyOnBatch/component/testing/component/test/performer/assignedEntity/
assignedTestingSite
or
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/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

4.34 Definition
/stabilityStudy/component/studyOnBatch/component/testing/component/test/definition
or
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/definition

Description: Intermediate element which reference the test definition.

Name	Field	Description	H	F
DefinitionStub	*Complex built by form*		M	M

DefinitionStub
/stabilityStudy/component/studyOnBatch/component/testing/component/test/definition/definitionStub
or
/stabilityStudy/component/studyOnBatch/component/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

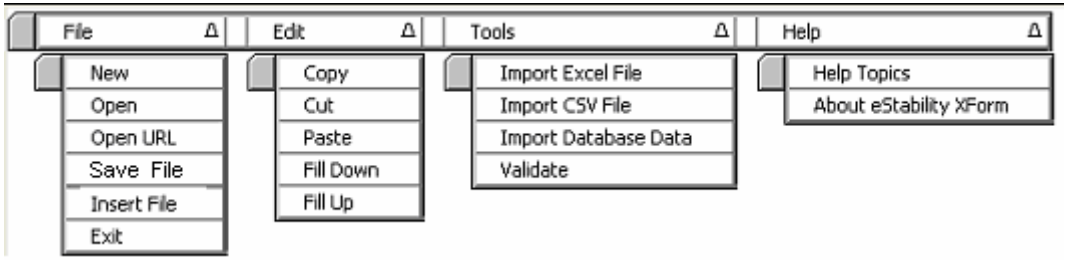
4.35 Component4
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component

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).

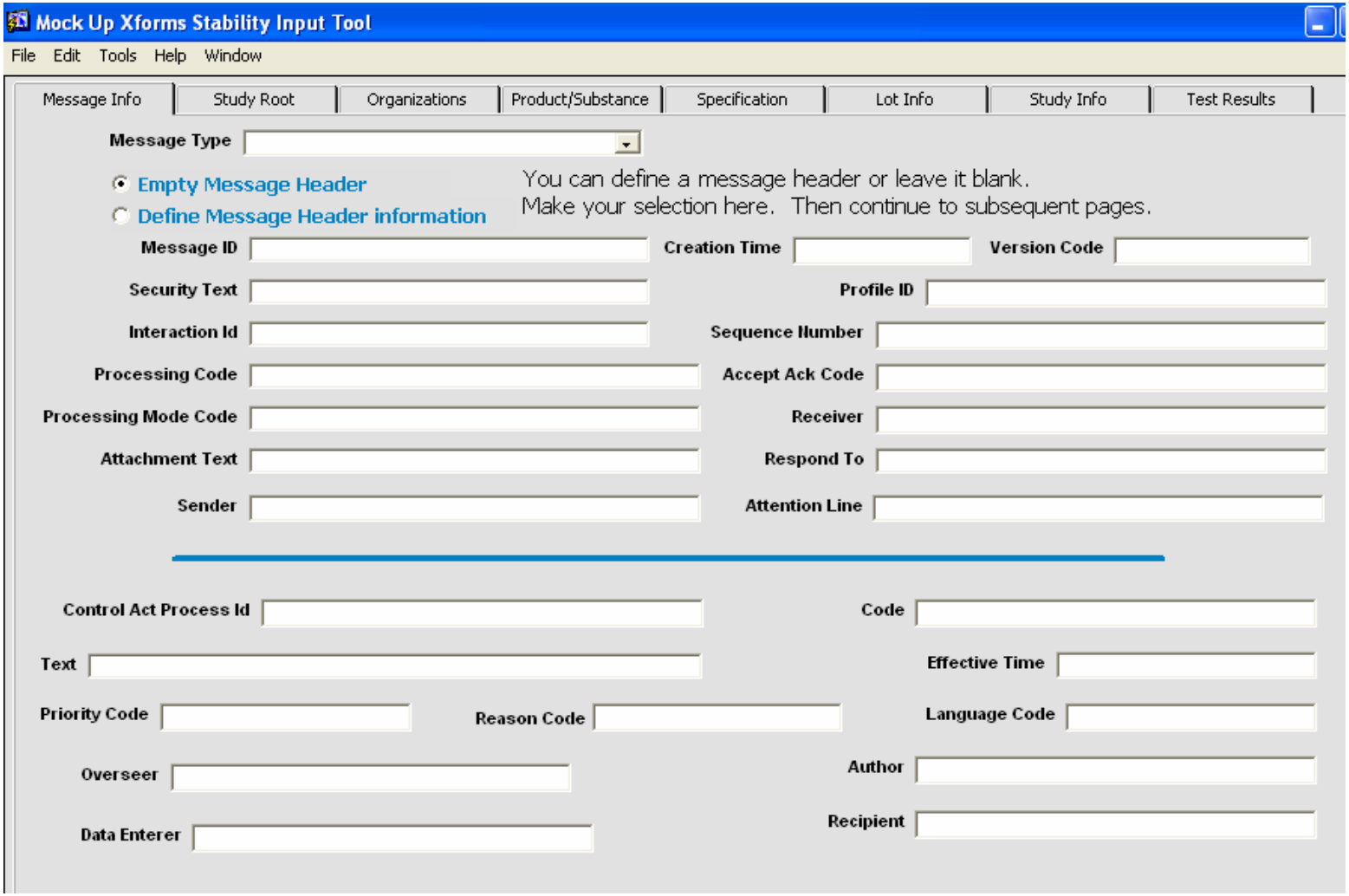
Name	Field	Description	H	F
sequenceNumber	Seq	The sequence of parameters of the test. Used only when a Compoent6 has been defined for the parent test. The form will place the Component4 in context Component3/test	O	R
pauseQuantity	Time Point and Time Unit	To use e.g. with growth of bacteria, etc.	O	R
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

5.0 Form Layout Examples

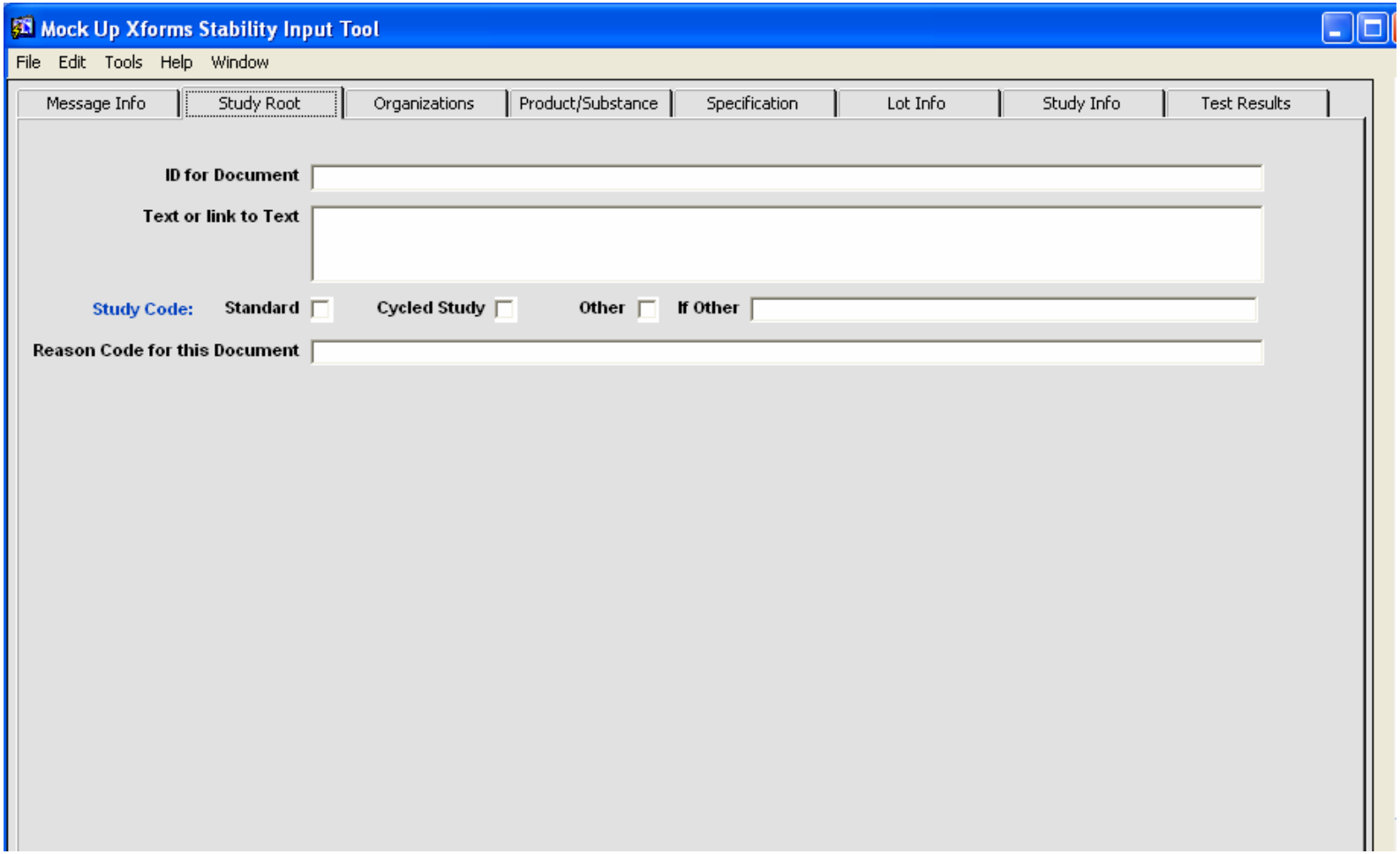
5.1 Tool Bar Example



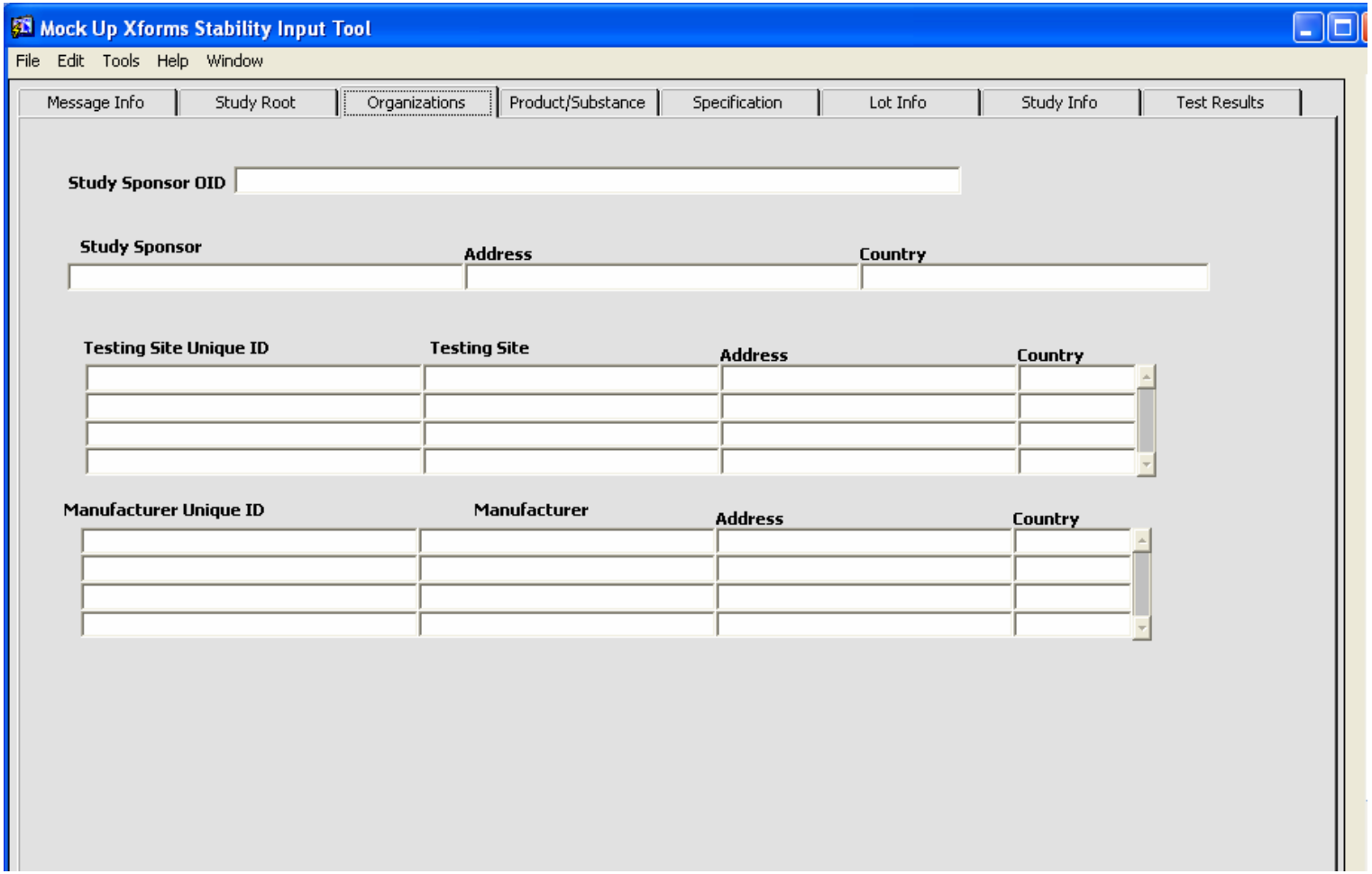
5.2 Message Info



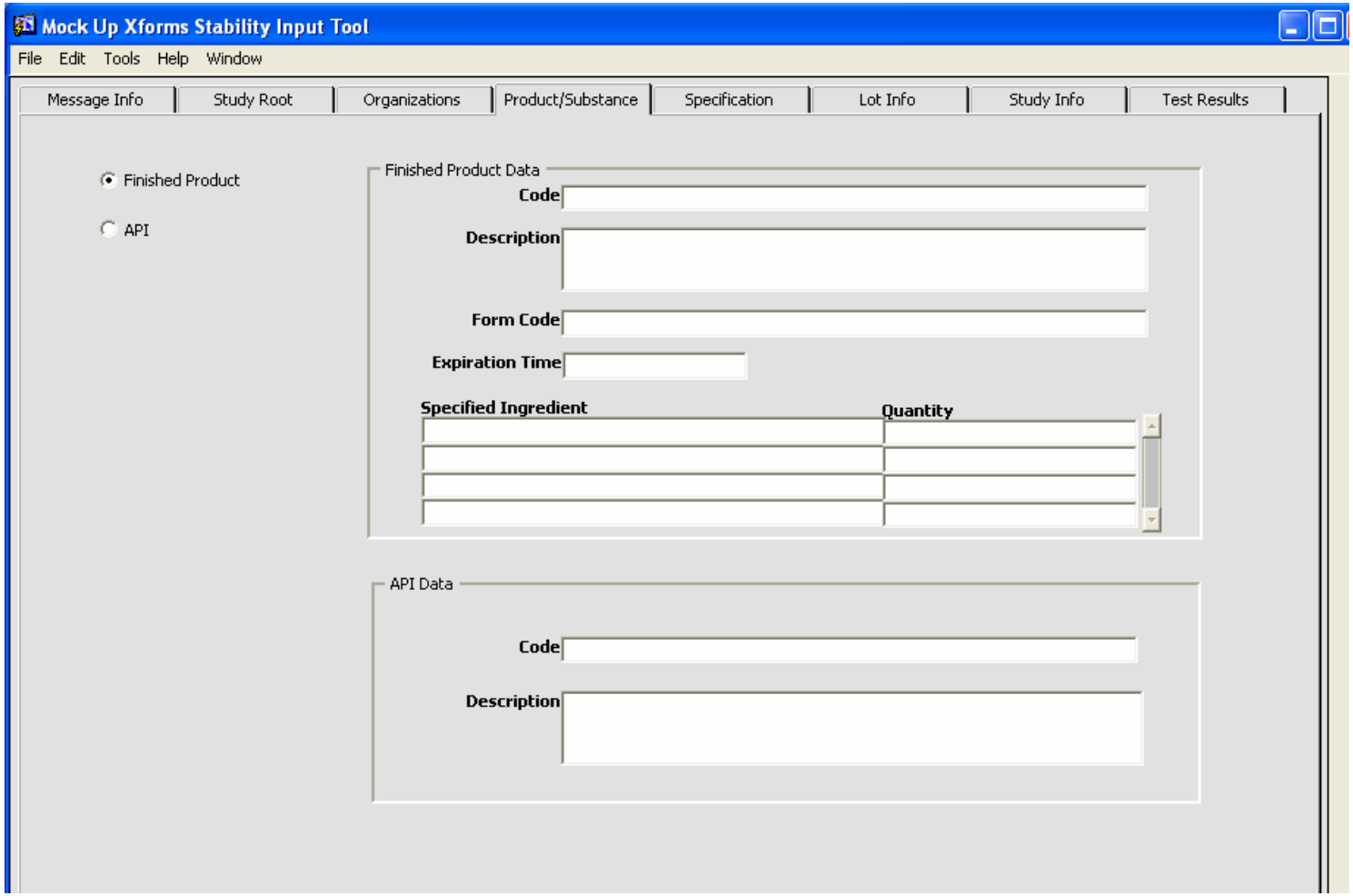
5.3 Study Root



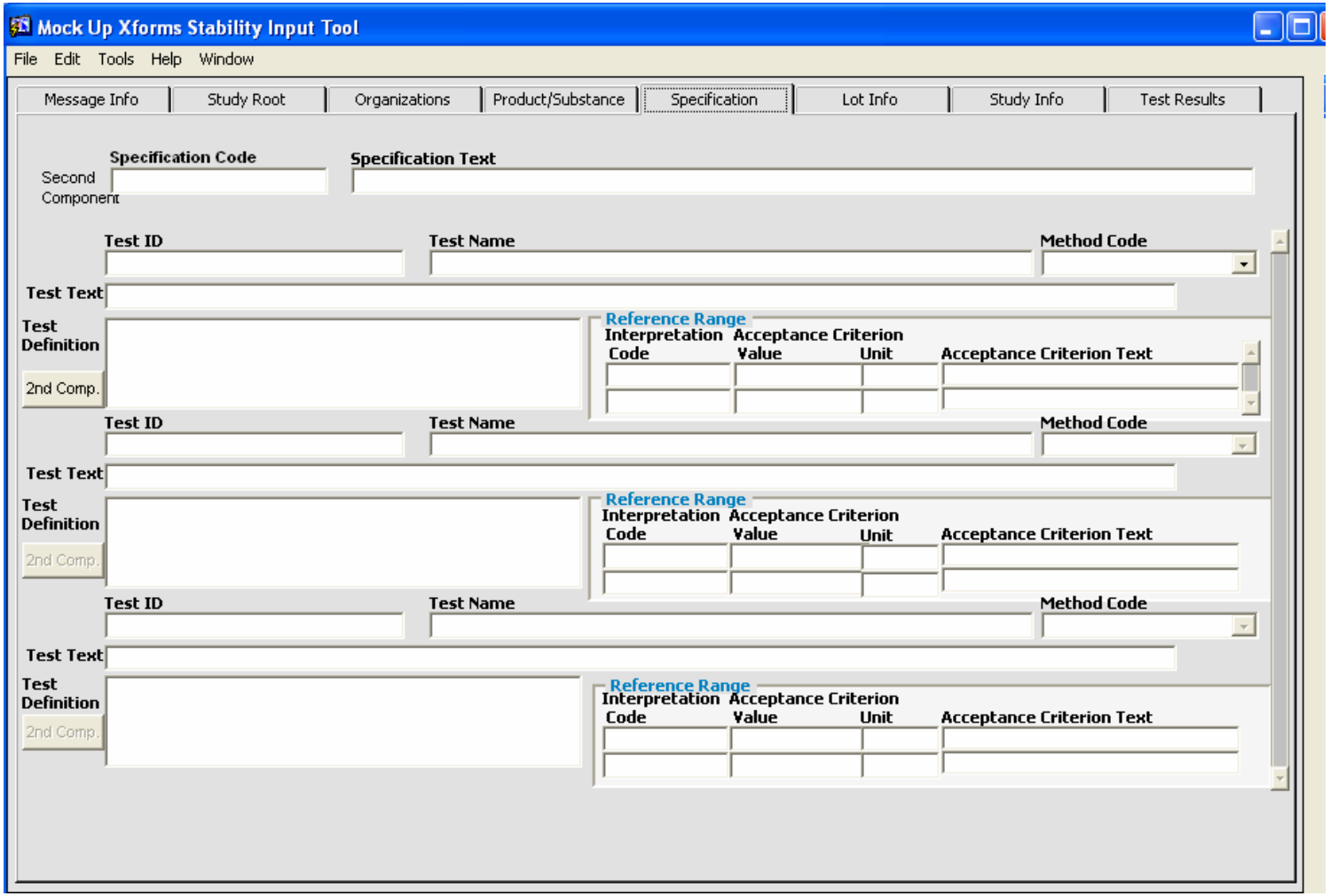
5.4 Organizations



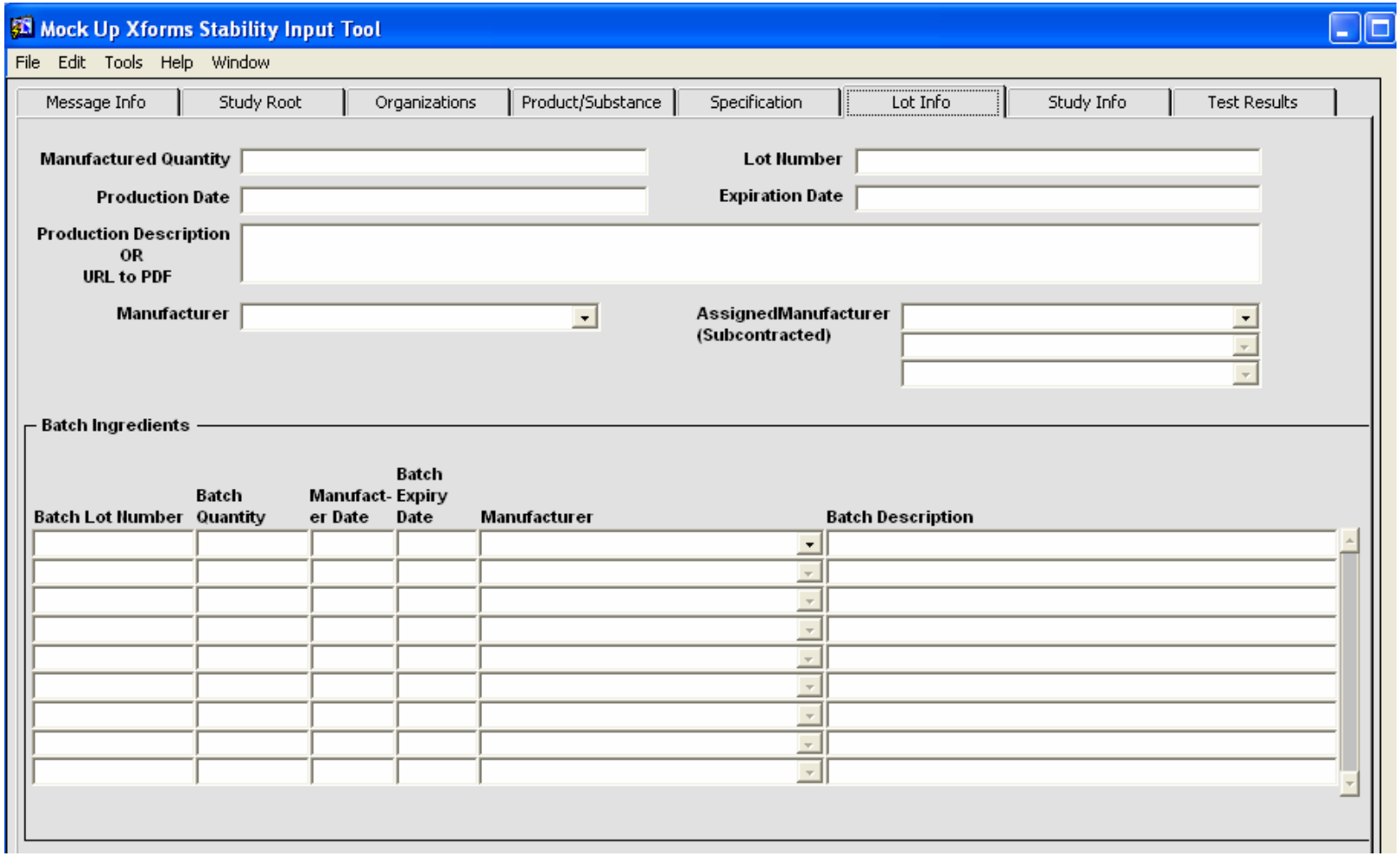
5.5 Product/Substance



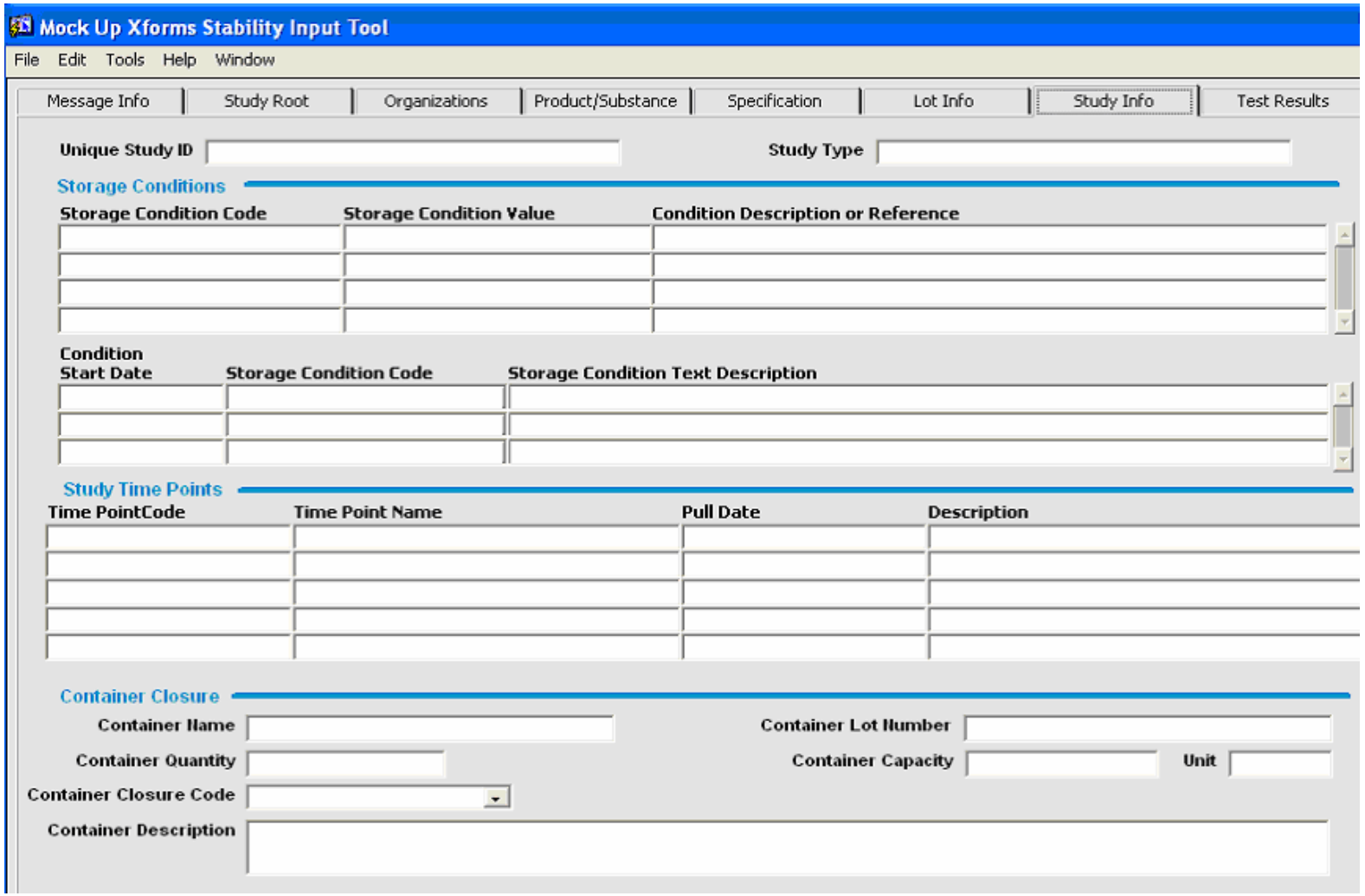
5.6 Specification



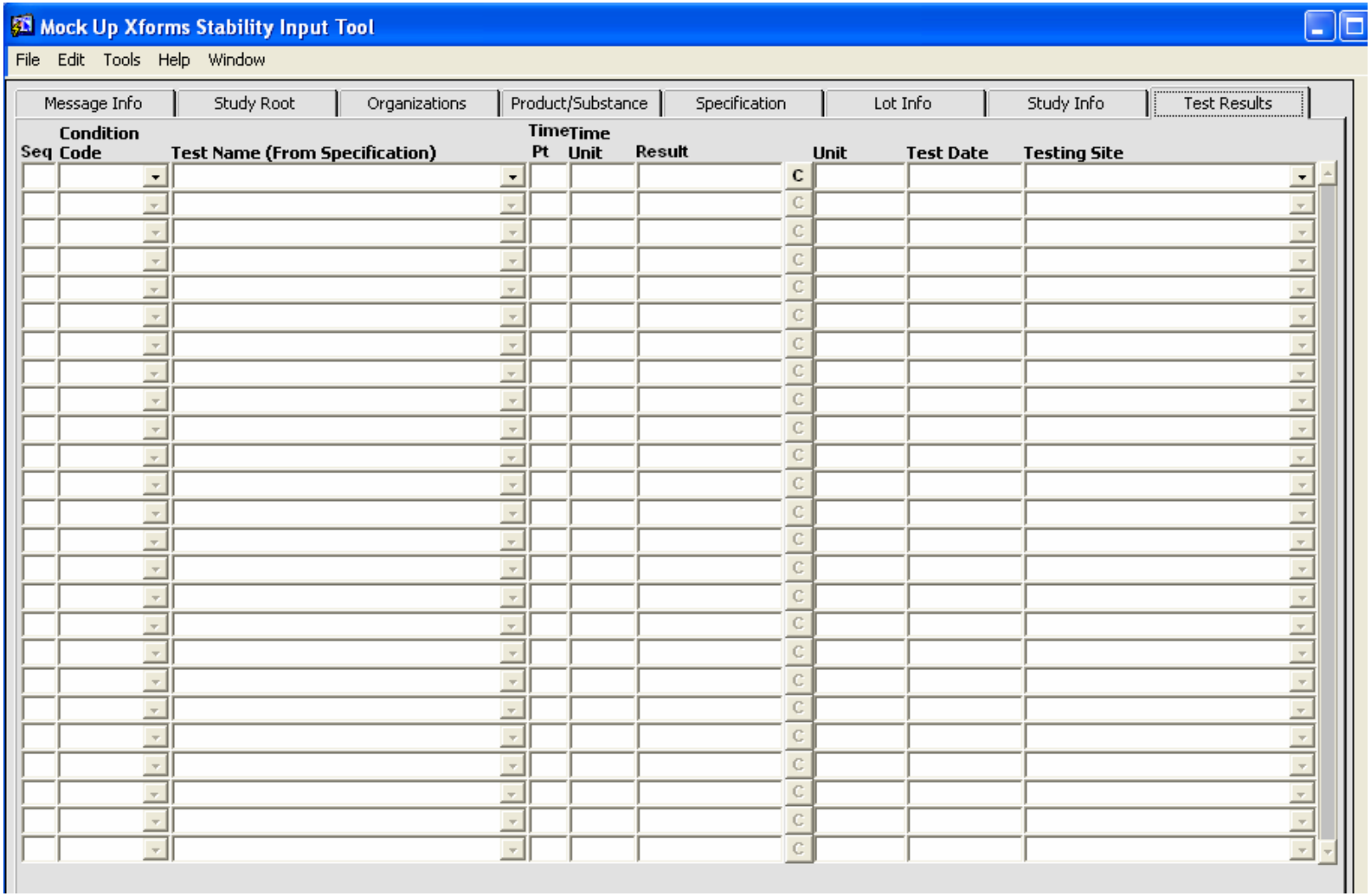
5.7 Lot Info


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
Manufactured Quantity
Lot Number
Production Date
Expiration Date
Production Description OR URL to PDF
Manufacturer
AssignedManufacturer (Subcontracted)
Batch Ingredients
Batch Lot Number
Batch Quantity
Manufact-er Date
Batch Expiry Date
Manufacturer
Batch Description

5.8 Study Info



5.9 Test Results



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 Message Input Tool.
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.
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.