Establishment of Health Level 7 (HL7) Standard for Submission of XML Stability Data

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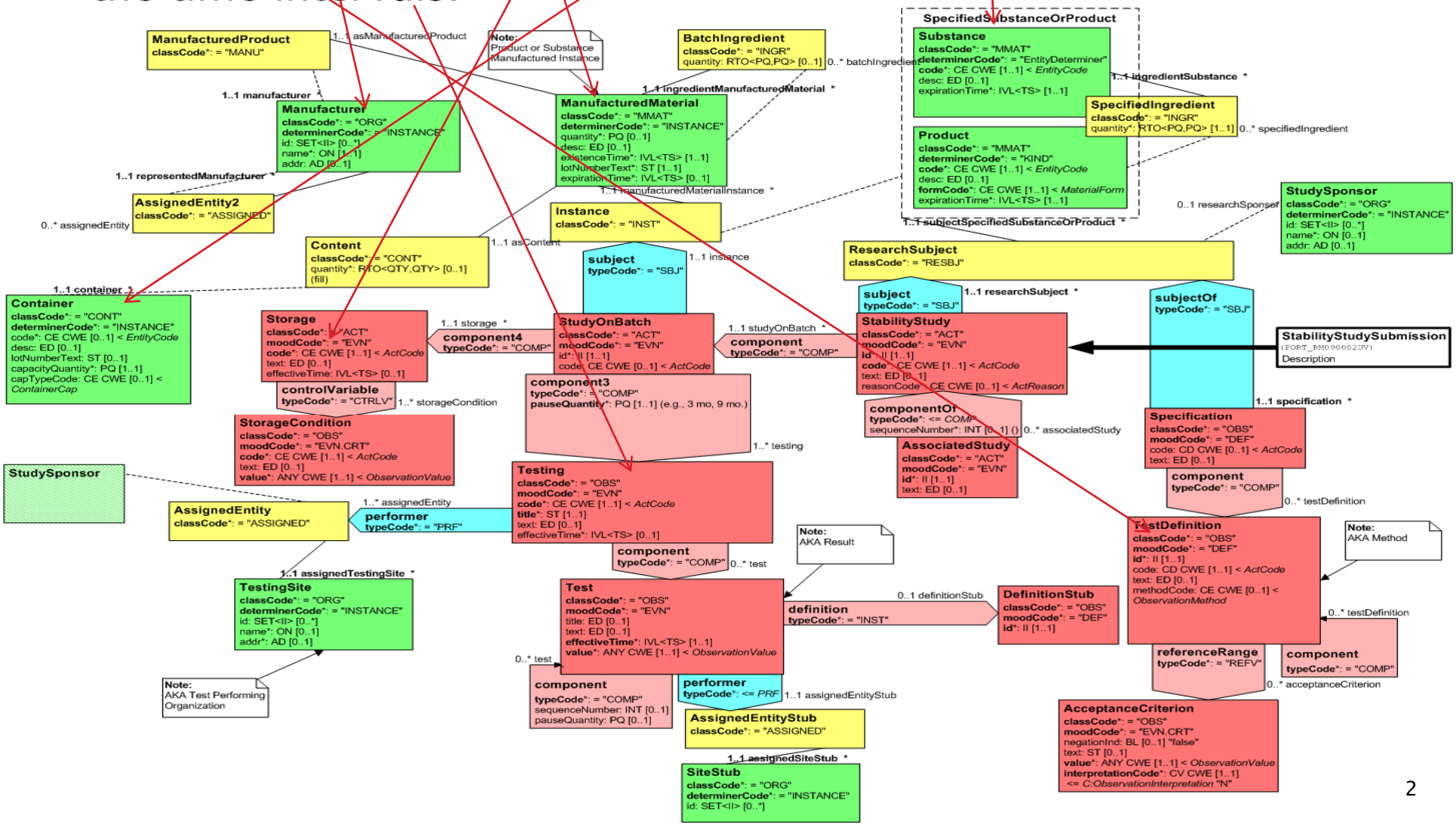
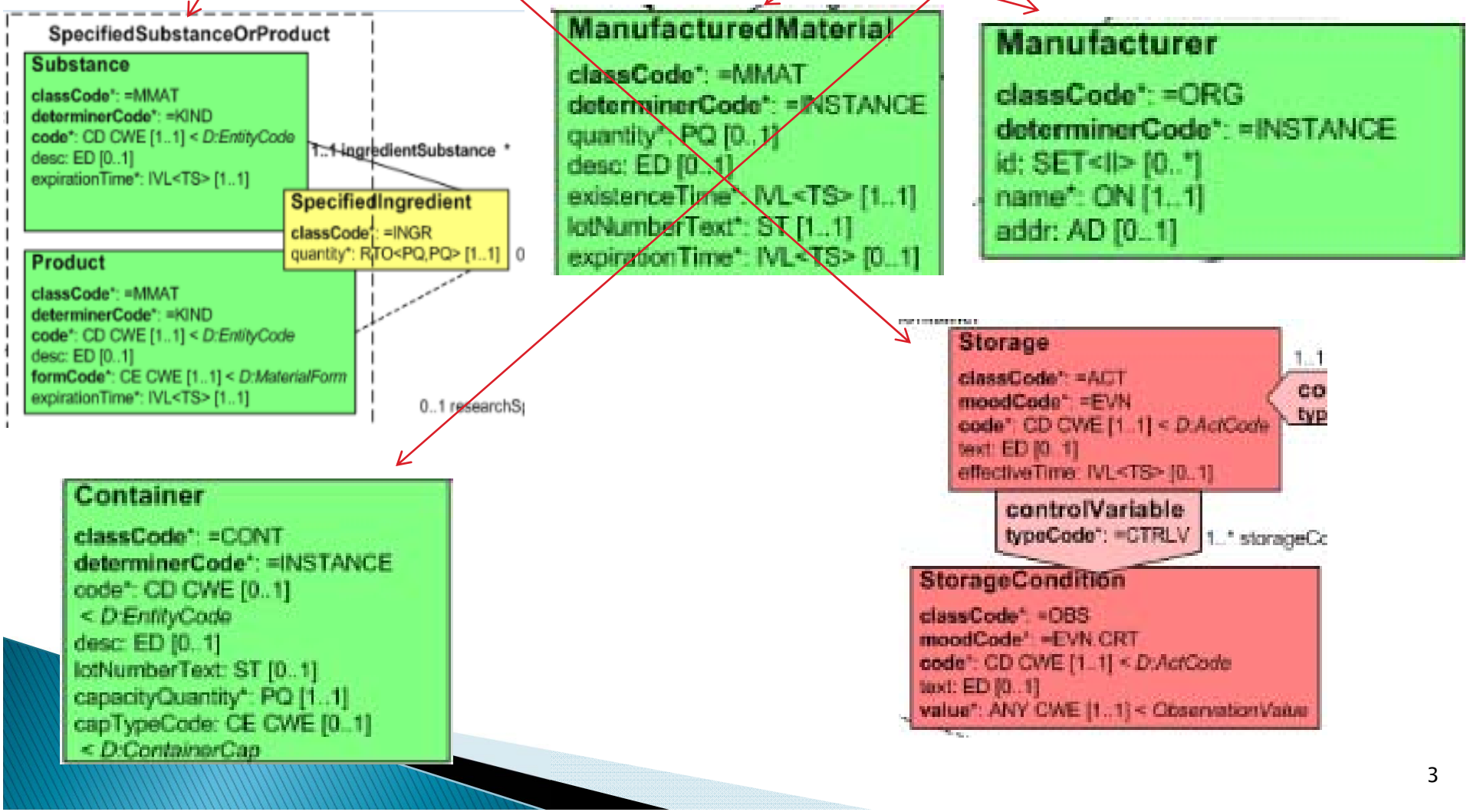
Modeled a stability study: Choose if substance or product, information about the specific lot of material, who manufactured it, the container/closure system, the testing and specifications, how it was stored, and the tests and results at the time intervals.



Substance or product, information about the specific lot of material, who manufactured it, the container/closure system, and how it was stored



Substance or product, information about the specific lot of material, who manufactured it, the container/closure system, and how it was stored

Stability Study Data Message: 2.16.840.1.19927.1.12345.1.2010.5758.2.1

Study Code: Standard

Reason Code: Annual Report

Study Purpose: The purpose of this study EX 2010PRD5758 is to confirm the stability of BellaVie ™ (2 AMINOBUTYROLE ACID, DL) 2.0 mg, Pink Film Coated Extended Release Tablets (Product 54321) per the NDA post approval stability commitments.

Associated Messages are not displayed in the editor.

Study Number: 2.16.840.1.19927.1.12345.1.2010.5758	**Protocol Code:** Commercial	**Starting Date:** 27-Jul-2009	**Storage Condition and Sample Orientation:** 25 Deg C/60% RH Upright Orientation
Lot/Batch Number: EX-5758	**Product Code:** N54321-123; BellaVie ™	**Specification Code:** spec54321v01	**Manufacturer:** XYZ Pharmaceuticals, Inc. 84 Main Street, Utopia, CA, 90021, USA
Lot/Batch Size: 100000 tablet	**Product Manufacturing Date:** 26-Jul-2009	**Dosage Form:** Tablet, Film Coated, Extended Release	**Manufacturing Site:** Vandechemie Ruzettelaan 39234, Blankenberge, 8370, Belgium **Assignee:** Specialty Pharma 100 Spring St., Philadelphia, PA, 01972, USA
Expiration Dating: 14 Month 19-Oct-2010 (approved)	**Amount in Container:** 100 count	**Container/Closure Code:** Bottle Continuous Thread, Metal	**Container/Closure Description:** 100 tablets are contained in a 600 cc, white, HDPE bottle with a 28 mm continuous threading metal cap.
Drug Substance: 2 mg / 1 tablet 8306QPJ19P FDA Substance Registration System ,ALPHA-AMINOBUTYRIC ACID		**Drug Substance - Lot/Batch Numbers - Manufacturing Sites:** .ALPHA-AMINOBUTYRIC ACID 593421 Bervem Inc 3498 Northumberland Drive, Peabody, MA, 01520, USA Microcrystalline Cellulose MI3345-CEL Haorui Pharma-Chem Inc. 100 Menlo Park Drive, Edison, New Jersey, 08837, USA	

Product

/stabilityStudy/subject/researchSubject/subjectProduct

Description:

Complex structure to describe a finished dosage form. This is for the product as a whole as it is at the time of this submission, not the specific lot of product contained in this report.

Simple Children:

Name	Type	Description	H	F
code	CE	An ACTCODE: ProductCode (i.e. a unique identifier of the product). For FDA implementation, only the "displayName" (i.e. the product name) is mandatory. If the NDC number exist for the product, is should be entered and prefix with "N". For NDA this is a new identifier. For ongoing studies the identifier must be identical to the already submitted code.	M	M
desc	ED	The product name must be put here and should be listed first. A description of the product provided by the submitter or an URI for additional external documentation. This is where the expirationTime can be specified as an expiration date and/or a dating period.	O	M
formCode	CE	An ACTCODE: Form type of this product.	M	M
expirationTime	IVL_TS	The "approved" or "proposed" expiration period (e.g. 24 Months expressed using the width tag, see example code below) for NDA, or the existing expiration period for ongoing studies. This value works in conjunction with the "expirationTime" in "ManufacturedMaterial".	R	M

Complex Children:

Name	Type	Description	H	F
specifiedIngredient	SpecifiedIngredient	The formulation of this product (many, if necessary).	O	R

Substance

/stabilityStudy/subject/researchSubject/subjectSubstance

Description:

When used as a child of "ResearchSubject" this element describes the substance on which the study is performed. This is for the substance as a whole as it is at the time of this submission, not the specific lot of substance contained in this report. The Preferred Substance Name must be used as listed at the FDA Substance Registration System - Unique Ingredient Identifier (UNII) web page, http://fdasis.nlm.nih.gov.

Simple Children:

Name	Type	Description	H	F
code	CE	An ACTCODE: code of the substance.	M	M
desc	ED	URI for additional documentation. This is where the expirationTime can be specified as a retest date, an expiration date and/or a dating period.	O	O
expirationTime	IVL_TS	The "approved" or "proposed" expiration period (e.g. 24 Months expressed using the width tag, see example code below) for the substance, or the existing expiration period for ongoing studies. This value works in conjunction with the "expirationTime" in "ManufacturedMaterial".	R	M

ManufacturedMaterial

/stabilityStudy/component/studyOnBatch/subjectInstance/manufacturedMaterialInstance

Description:

Describes the produced material used in the stability study. This is the specific lot of product or substance this report is about.

Simple Children:

Name	Type	Description	H	F
quantity	PQ	Total amount of material in the batch.	R	R
desc	ED	A textual Description or/and external reference to a PDF document describing details of this production. This is where the expirationTime can be specified as a retest date, an expiration date and/or a dating period.	O	O
existenceTime	IVL_TS	Date of production (use ISO 8601 format).	R	M
lotNumberText	ST	Company internal lot number.	R	M
expirationTime	IVL_TS	Date of expiration (based on the provided expirationCode of the "Product" element) or the proposed expiration date of the material. Interpretation for a product: In the XML code if a high value is provided the expiration date is approved (e.g., for an annual report or supplement), and if a low value is provide the expiration date is proposed (e.g., for a new drug application that has not been approved). Interpretation for "substances" (i.e. intermediates or APIs): In the XML code if a high value is provided the retest date is approved (e.g., for an annual update), and if a low value is provide the retest date is proposed (e.g., for a new drug master file). This value works in conjunction with the "expirationTime" in "Subject Product" or "Subject Substance".	R	M

Complex Children:

Name	Type	Description	H	F
asManufacturedProduct	Manufactured Product	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	M
AsContent	Content	A reference to the container/closure system.	M	M
BatchIngredient	BatchIngredient	A list of ingredients of type ManufacturedMaterial, so that a kind of "Batch Record" can be provided. Using this element leads to a recursive structure.	O	O

Manufacturer

/stabilityStudy/component/studyOnBatch/subject/Instance/manufacturedMaterialInstance/asManufacturedProduct/manufacturer

Description:

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

Simple Children:

Name	Type	Description	H	F
id	II	A set of identifiers that is used to uniquely identify the manufacturer or a manufacturing site. Use the DUNS number as the primary identifier. Other examples can be FEI number or a global unique identifier for the sponsoring organization assigned by IANA. For DUNS number, remove hyphens if present and prefix with "D" and if an FEI number prefix with an "F". Note: The assigningAuthorityName for a DUNS number is "Dun and Bradstreet D-U-N-S Number" and for a FEI number is "FDA FEI OID". A DUNS number and FEI number example are shown here. The assigning authority name is mandatory for all OIDs for organizations. Always list the DUNs number first if listing multiple numbers. It is the submitter's responsibility to ensure that the DUNS number id along with the firm's postal code (if any) and country match the DUNS number, postal code and country in the Dun and Bradstreet database. <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/>	O	M
name	ON	Name of the manufacturer (or manufacturing site).	R	M
addr	AD	Address.	O	M

Attributes

Root	ID	M	M
Extension		N	N
assigningAuthorityName		N	M
Displayable		N	N

Complex Children:

Name	Type	Description	H	F
assignedEntity	AssignedEntity2	One or many sub elements of "Manufacturer" type called "representedManufacturer" who produced this product on behalf of the "Manufacturer" given here or who partially produced the product.	O	M

Container

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

Description:

A simple structure to store the makeup of the container closure system.

Simple Children:

Name	Type	Description	H	F
Code	CE	Type of Container (e.g., bottle).	R	M
Desc	ED	A verbal Description of the container closure system or a reference to an external document which holds this Description.	O	O
lotNumberText	ST	The lot number of the production lot for this container.	O	O
capacityQuantity	PQ	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	CE	The code for the used closure system (e.g., plastic cap).	O	M

StorageCondition

/stabilityStudy/component/studyOnBatch/component2/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% R.H. upright).. Complex definitions can be made up of many controlVariables referencing simple storageConditions.

Simple Children:

Name	Type	Description	H	F
Code	CE	An ACTCODE: Storage condition code.	M	M
text	ED	A textual description or an external reference.	O	O
value	ANY	The condition, e.g. "25°" or "25°/60%" or "25°/60% upright."	M	M

Storage

/stabilityStudy/component/studyOnBatch/component2/storage

Description:

A list of one or many storage conditions (e.g., one reference to "25°/60%" and one to "upright" — or alternatively one reference to "25°/60% upright").

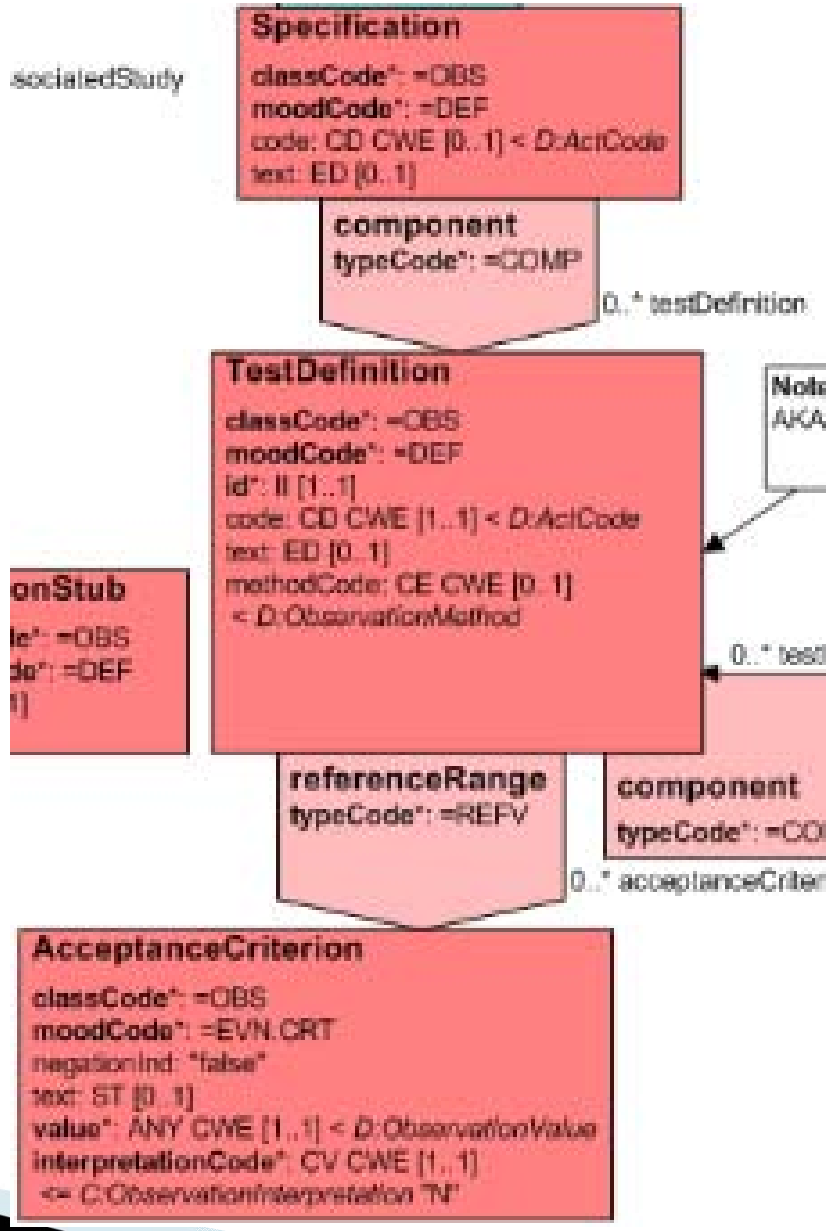
Simple Children:

Name	Type	Description	H	F
code	CE	An ACTCODE: fixed code value, may be used for other purposes in future versions.	M	M
text	ED	A textual description of this storage condition or an external reference to a PDF document to describe this storage condition.	O	O
effectiveTime	IVL_TS	The time the product is put on stability. The date the stability storage is started for this condition, (e.g. 20080412 for 12th of April 2008).	O	R

Complex Children:

Name	Type	Description	H	F
controlVariable	ControlVariable	Reference to the predefined storage conditions (one or many may be used).	M	M

Testing and specifications



Testing and specifications

Specification			
Test	Acceptance Criteria	Analytical Procedure	Component Tests
Sterility (Biological)	Passed	USP <71> Sterility (Compendial)	
Appearance (Physical)	Pink round, film-coated tablet scored 99 0T9 one side and plain on the other	NH401 General appearance method (Proprietary)	
Microbial Limits (Biological)	NA	USP <61> Microbial Limits (Compendial)	P. aeruginosa S. aureus Salmonella
Container Integrity (Physical)	Passed	NH401 General appearance method (Proprietary)	Closure Appearance Container Appearance
Total Viable Aerobic Count (Biological)	< 100 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count (Compendial)	
Assay (Chemical)	90.0% 110.0% of labeled claim (n=3) 90.0% 110.0% of labeled claim (n=3)	NH432 Assay (Proprietary)	
pH Measurement Average (Chemical)	3.3 to 4.5 3.3 to 4.5	USP <791> pH Measurement (Compendial)	pH Measurement
Dissolution Average (Physical)	1 hr: Average (n=6) is 26% - 34%; 4 hr: Average is 56% - 73%; 12 hr: Average is NLT 72%	NH772 Dissolution Profile (Proprietary)	
Dissolution (Physical)	1 hr: Each tablet is 20%-40%; 4 hr: Each tablet is 50%-75%; 12 hr: Each tablet is NLT 85%	NH772 Dissolution Profile (Proprietary)	Dissolution Hour
Impurity - Elemental (Chemical)	NA	NH740 Elemental Impurity Estimation (Proprietary)	Nickel Chromium Palladium
Permeation (Physical)	NA	USP <671> Containers Performance Testing (Compendial)	Water Weight Loss Light Transmission
Total Count of Failures (Chemical)	NMT 1 (n = 12)	NH432 Extractables (Proprietary)	Individual Alkali Oxide Extractables

Specification

/stabilityStudy/subject/researchSubject/subjectOf/specification

Description:

For this Element the "full" HL7 structure has to be provided for the specification.

Simple Children:

Name	Type	Description	H	F
code	CD	An ACTCODE: Specification identifier. i.e., the name and version of the specification (as displayName).	O	M
text	ED	URI for additional documentation.	O	R

Complex Children:

Name	Type	Description		
component	Component6	The testdefinition and acceptance criteria for these tests.	O	M

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.

Simple Children:

Name	Type	Description	H	F
text	ST	URI for additional documentation or free text.	O	O
value	ANY	The value of the criterion.	M	M
interpretationCode	CV	e.g., not more than (NMT), not less than (NLT), ...	M	M

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.

The assigning authority is understood to be the study sponsor.

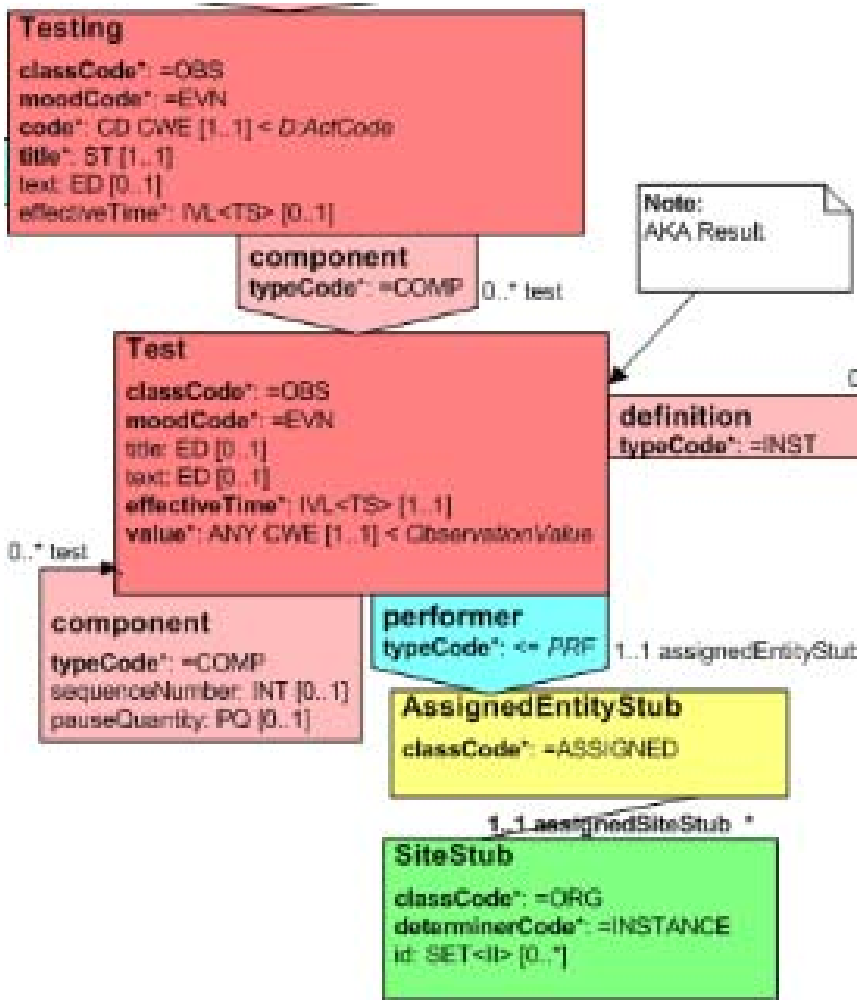
Simple Children:

Name	Type	Description	H	F
id	II	A global unique identifier for this TestDefinition **Attributes** Root: OID, M, M	M	M
text	ED	URI for additional documentation for this test, (e.g. SOP or Specification document for this method).	O	R

Complex Children:

Name	Type	Description	H	F
code	CD	An ACTCODE: Test code.	O	M
methodCode	CE	An ACTREASON: Method type.	O	M
referenceRange	ReferenceRange	The acceptance criterion for this parameter.	O	M
component	Component7	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 two additional levels may be provided.	O	M

Tests and results at the time intervals



Tests and results at the time intervals

Specification			Sampling Intervals: Months					
Test	Acceptance Criteria	Analytical Procedure	0	1	3	6	9	15
Sterility	Passed	USP <71> Sterility	Passed			Passed		Passed
Appearance	Passed	NH401 General appearance method	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)	P/F(5)
Microbial Limits	NA	USP <61> Microbial Limits	Passed			Passed		Passed
P. aeruginosa	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
S. aureus	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
Salmonella	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
Container Integrity	Passed	NH401 General appearance method	Passed	Passed	Passed	Passed	Passed	Passed
Closure Appearance	Passed	NH401 General appearance	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Container Appearance	Passed	NH401 General appearance method	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Total Viable Aerobic Count	NMT 200 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count	20			18		21
Assay	NLT 90 %_LC NMT 110 %_LC	NH432 Assay	102.19(3)	100.3(3)	102.0(3)	102.4(3)	103.3(3)	103.2(3)
pH Measurement Average	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13	4.12	4.1	4.12	4.09	4.07
pH Measurement	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13(3)	4.11(6)	4.10(6)	4.12(6)	4.08(6)	4.07(6)
Dissolution Average	NLT 26 %	NH772 Dissolution Profile	74.0(6)	74.4(6)	73.8(6)	74.9(6)	75.2(6)	75.6(6)
Dissolution	NA	NH772 Dissolution Profile	NA	NA	NA	NA	NA	NA
Dissolution Hour	NLT 20 %	NH772 Dissolution Profile	72.1(3)	77.3(3)	75.9(3)	74.6(3)	74.7(3)	77.1(3)
Impurity - Elemental	NA	NH740 Elemental Impurity Estimation	NA			NA		NA
Nickel	NMT 25 µg	NH740 Elemental Impurity Estimation	19.4			20.5		21.3
Chromium	NMT 25 µg	NH740 Elemental Impurity Estimation	12.5			19.8		19.8
Palladium	NMT 10 µg	NH740 Elemental Impurity Estimation	4.9			6.6		6.4
Permeation	Passed	USP <671> Containers Performance Testing	Passed	Passed	Passed	Passed	Passed	Passed
Water Weight Loss	NMT 2.5 %	USP <671> Containers Performance Testing	2.04(3)	2.01(3)	2.11(3)	2.01(3)	2.13(3)	2.01(3)
Light Transmission	NLT 290 nm NMT 450 nm	USP <671> Containers Performance Testing	358.(3)	353.(3)	360.(3)	376.(3)	368(3)	385(3)
Total Count of Failures	NMT 1 count	NH432 Extractables	0			0	0	1
Individual Alkali Oxide Extractables	Passed	NH432 Extractables	Passed(12)			Passed(12)	Passed(12)	P/F(12)

Testing

/stabilityStudy/component/studyOnBatch/component1/testing

Description:

This is a representation of "pulling a sample from the climatic chamber".

Simple Children:

Name	Type	Description	H	F
code	CE	An ACTCODE: pauseDescription. Something done with the sample, e.g., freeze sample.	M	M
title	ST	A title that labels a collection of related tests across pauseQuantities.	M	M
text	ED	A textual description or an external reference.	O	O
effectiveTime	IVL_TS	The date the sample was scheduled to be pulled from the chamber and tested (use ISO 8601 notation).	R	M

Complex Children:

Name	Type	Description	H	F
component	Component1	A reference to the tests performed with this sample.	M	M
performer	Performer1	A list of all testing sites involved in this testing.	M	M

Test

/stabilityStudy/component/studyOnBatch/component1/testing/component/test
or
/stabilityStudy/component/studyOnBatch/component1/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 "Component2" reference.

Simple Children:

Name	Type	Description	H	F
title	ED	Alternative name of the measured result. An example use is to identify "specified unknowns", since all of these results point to the same specification (i.e., "definition"). This attribute can be used to identify "specified unknowns", since all of these results point to the same specification (i.e., "definition").	O	R
text	ED	A textual description or an external reference. This is where lab comments and/or notebook reference can be specified.	O	O
effectiveTime	IVL_TS	A testing date that is mandatory on the first level. On the second level, a nullFlavour has to be provided where no actual result is available.	M	M
value	ANY	For PQ data type, eStability supports the following nullFlavor terms when appropriate: ¶ NI – No Information¶ NA – Not Applicable (see example)¶ NAV – Temporarily Unavailable¶ TRC – Trace¶ UNK - unknown¶ ¶ To report PQ data that is less than the limit of detection (LOD) or limit of quantitation (LOQ), eStability supports the method of reporting it as a ST data in the format of '<0.02' where 0.02 is the LOD or LOQ. It is recommended that the LOD value is reported in the <text> tag as a data comment (see example below).¶ ¶ When the submitter elects to report a face value of this type of data, the data can be reported normally. Reporting as such, it is essential to document that the nature of data in the <text> tag (see example below).¶	M	M

Complex Children:

Name	Type	Description	H	F
performer	Performer2	A reference to a testing site.	M	M
definition	Definition	Reference to a specification for this test.	O	M
component	Component2	Recursive reference to a "Test".	R	R

Use the NCI Thesaurus code list posted at http://evs.nci.nih.gov/ftp1/FDA/Stability

1	NCIt Su	NCIt Subset Preferred Term	NCIt Co	NCIt Preferred Term	NCIt De	Stability Preferred Term	Stability Definition
110	C96074	Stability Product Form Terminology	C42888	Aerosol Foam Dosage Form	A foam tha	Aerosol, Foam	
111	C96074	Stability Product Form Terminology	C42889	Aerosol Spray Dosage Form	A spray th	Aerosol, Spray	
112	C96074	Stability Product Form Terminology	C60897	Augmented Cream Dosage Form	A cream th	Cream, Augmented	
113	C96074	Stability Product Form Terminology	C60957	Augmented Lotion Dosage Form	A lotion th	Lotion, Augmented	
114	C96074	Stability Product Form Terminology	C60984	Augmented Ointment Dosage Form	An ointmer	Ointment, Augmented	
115	C96074	Stability Product Form Terminology	C42890	Bead Dosage Form	A solid in t	Bead	
116	C96074	Stability Product Form Terminology	C42891	Block Dosage Form	A solid or s	Block	
117	C96074	Stability Product Form Terminology	C25158	Capsule Dosage Form	A solid cor	Capsule	
118	C96074	Stability Product Form Terminology	C45414	Cement Dosage Form	A base cor	Cement	
119	C96074	Stability Product Form Terminology	C42892	Chewable Bar Dosage Form	A bar desig	Bar, Chewable	
120	C96074	Stability Product Form Terminology	C42893	Chewable Tablet Dosage Form	A tablet de	Tablet, Chewable	
121	C96074	Stability Product Form Terminology	C42894	Chewing Gum Dosage Form	A semi-sol	Gum, Chewing	
122	C96074	Stability Product Form Terminology	C42678	Cigarette Dosage Form	A solid cor	Cigarette	
123	C96074	Stability Product Form Terminology	C60884	Cloth Dosage Form	A solid cor	Cloth	
124	C96074	Stability Product Form Terminology	C42895	Coated Capsule Dosage Form	A capsule	Capsule, Coated	
125	C96074	Stability Product Form Terminology	C42896	Coated Pellet in Capsule Dosage Form	A capsule	Capsule, Coated Pellets	
126	C96074	Stability Product Form Terminology	C42897	Coated Tablet Dosage Form	A tablet wh	Tablet, Coated	
127	C96074	Stability Product Form Terminology	C60891	Concentrated Dosage Form	A solution	Concentrate	
128	C96074	Stability Product Form Terminology	C42899	Concentrated Injectable Solution Dosage Form	A concentr	Injection, Solution, Concentrate	
129	C96074	Stability Product Form Terminology	C42898	Concentrated Solution Dosage Form	A concentr	Solution, Concentrate	
130	C96074	Stability Product Form Terminology	C42900	Cone Dosage Form	A solid wit	Cone	
131	C96074	Stability Product Form Terminology	C28944	Cream Dosage Form	A semi-sol	Cream	
132	C96074	Stability Product Form Terminology	C42901	Crystal Dosage Form	A solid tha	Crystal	
133	C96074	Stability Product Form Terminology	C42902	Delayed Release Capsule Dosage Form	A capsule	Capsule, Delayed Release	
134	C96074	Stability Product Form Terminology	C42903	Delayed Release Granule Dosage Form	A solid cor	Granule, Delayed Release	
135	C96074	Stability Product Form Terminology	C87540	Delayed Release Granule for Suspension Dosage	A pharmac	Granule for Suspension, Delayed Release	
136	C96074	Stability Product Form Terminology	C42997	Delayed Release Particle Tablet Dosage Form	A tablet co	Tablet, Delayed Release Particles	
137	C96074	Stability Product Form Terminology	C42904	Delayed Release Pellet in Capsule Dosage Form	A capsule	Capsule, Delayed Release Pellets	
138	C96074	Stability Product Form Terminology	C42905	Delayed Release Tablet Dosage Form	A tablet th	Tablet, Delayed Release	
139	C96074	Stability Product Form Terminology	C45413	Dental Liner Dosage Form	A resinous	Liner, Dental	
140	C96074	Stability Product Form Terminology	C42906	Dentifrice Gel Dosage Form	A gel inten	Gel, Dentifrice	
141	C96074	Stability Product Form Terminology	C42907	Dentifrice Paste Dosage Form	A paste of	Paste, Dentifrice	
142	C96074	Stability Product Form Terminology	C42908	Dentifrice Powder Dosage Form	A powder c	Powder, Dentifrice	
143	C96074	Stability Product Form Terminology	C43525	Disc Dosage Form	A flat, circu	Disc	
144	C96074	Stability Product Form Terminology	C60927	Dosage Form for Solution	A substanc	For Solution	
145	C96074	Stability Product Form Terminology	C60928	Dosage Form for Suspension	A substanc	For Suspension	
146	C96074	Stability Product Form Terminology	C48624	Dosage Form Not Applicable	An indicati	Not Applicable	
147	C96074	Stability Product Form Terminology	C42679	Douche Dosage Form	A substanc	Douch	
148	C96074	Stability Product Form Terminology	C42763	Dressing Dosage Form	A substanc	Dressing	
149	C96074	Stability Product Form Terminology	C60992	Drop Solution Dosage Form	A solution	Solution/Drops	
150	C96074	Stability Product Form Terminology	C60995	Drop Suspension Dosage Form	A suspens	Suspension/Drops	
151	C96074	Stability Product Form Terminology	C17423	Drug Delivery System	Modern tec	Drug Delivery System	
152	C96074	Stability Product Form Terminology	C42909	Effervescent Granule Dosage Form	A granule c	Granule, Effervescent	
153	C96074	Stability Product Form Terminology	C64884	Effervescent Powder Dosage Form	A powder c	Powder, Effervescent	
154	C96074	Stability Product Form Terminology	C42910	Effervescent Tablet Dosage Form	A tablet co	Tablet, Effervescent	
155	C96074	Stability Product Form Terminology	C42911	Electrically Controlled Extended Release Patch D	A patch th	Patch, Extended Release, Electrically Controlled	
156	C96074	Stability Product Form Terminology	C42912	Elixir Dosage Form	A solution	Elixir	
157	C96074	Stability Product Form Terminology	C42913	Emulsion Dosage Form	A semi-sol	Emulsion	