

Clinical Drug (CD)

Definition of CD (precisely)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as presentation strength with unit of presentation or as concentration strength as appropriate, and 3) with its manufactured dose form (but in reconstituted oral liquid preparations, the administrable dose form - see below).

All Clinical Drugs that contain multiple *active* ingredient substances will have parent MPF and MP concepts that have the same set of active ingredient substances.

The limitation of the Clinical Drug class to the closed world view by the description of its precise active ingredient substances *only* precludes description of excipient substances such as flavours, preservatives, sweeteners etc as ingredients in a Clinical Drug. These substances can have significance for allergies etc. but can only be reliably described for individual authorised manufactured products, and as such are not within the scope of the international edition.

Similarly, by limiting the the Clinical Drug class in the international edition to expression of strength *either* as concentration strength *or* as presentation strength, medicinal product concepts that could usefully have *both* concentration and presentation strength (for example some liquid products such as liquid parenteral products or liquids for inhalation via a nebuliser) will have only concentration strength in the international edition. National extensions may author clinical drug concepts using the presentation strength(s) and unit(s) of presentation available in their jurisdiction if use case(s) require this. These concepts will be child concepts of the concentration clinical drug in the international edition. The diagrams below illustrate this:

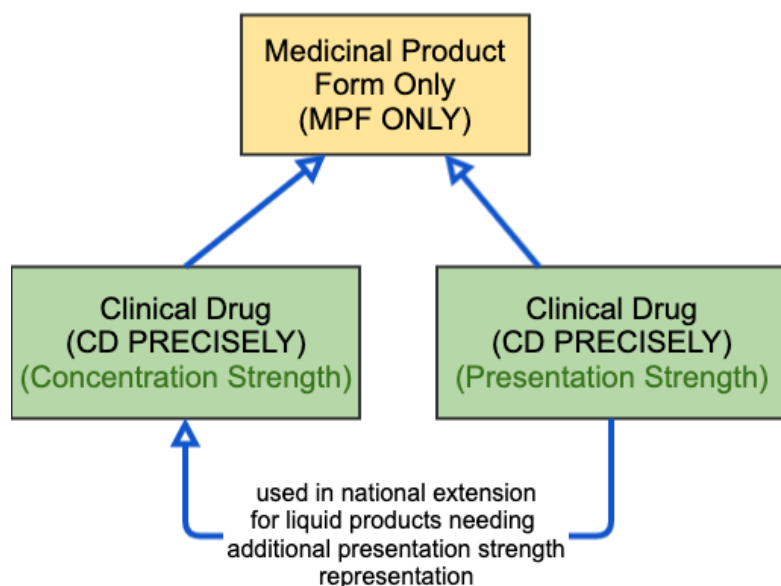


Figure 28: Clinical Drug concepts and their relationship together and to MPF only concepts

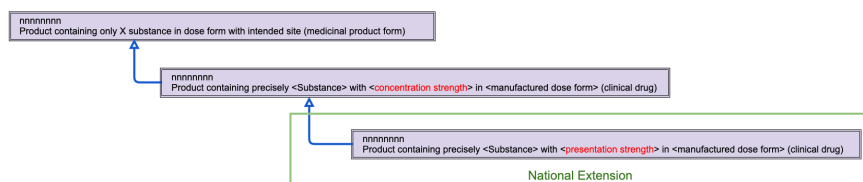


Figure 29: Clinical Drug concepts and their relationship together and to MPF only concepts in SNOMED notation, showing optional national extension concepts

Example:

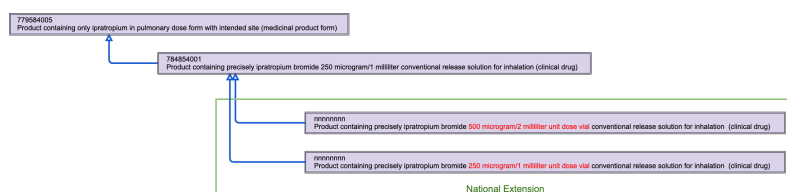


Figure 30: Clinical Drug example showing optional national extension concepts

Please also reference the National Extension specification for how to use additional model attributes to fully define concepts that can have both a concentration strength and a presentation strength such that they classify correctly.

Use cases supported by CD (precisely)

Use cases supported by the clinical drug concept include:

- As the abstract representation of products that are authorised, although without any sense of the excipient substances, the clinical drug concept is the source from which all other representation of medicinal product concepts flows; it acts as a clinically relevant grouper concept for medicinal products, and as such can support
 - international cross-border care delivery
 - International and national interoperability of patient medication information such as in patient summaries
- In national extensions, for many clinical purposes, such as product prescribing, adverse event reporting, formulary management, in recording medication history and in medication profiles
- Internationally and nationally in decision support and in protocols and treatment guidelines, when a more complete description of a product is required than MP or MPF
- In pharmacovigilance, especially for description of concomitant medication
- In analysis and research

Availability of CD concepts in the international edition

This class forms part of the medicinal product content provided in the international edition, although for liquid products, only concentration strength representation is provided.

Clinical Drug (precisely) (presentation strength)

Definition of Clinical Drug (precisely) (presentation strength)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as presentation strength with unit of presentation and 3) with its manufactured dose form.

This is used for product types such as tablets, capsules, pessaries, suppositories (Strength Pattern 1a in [Appendix A: Product Patterns](#)), sachets, ampoules or vials *containing* powders or granules etc. (solid dosage forms) and those presented with a metered dose valve such as inhalers and sprays.

Example diagrams for CD (precisely) presentation strength

Stated template view:

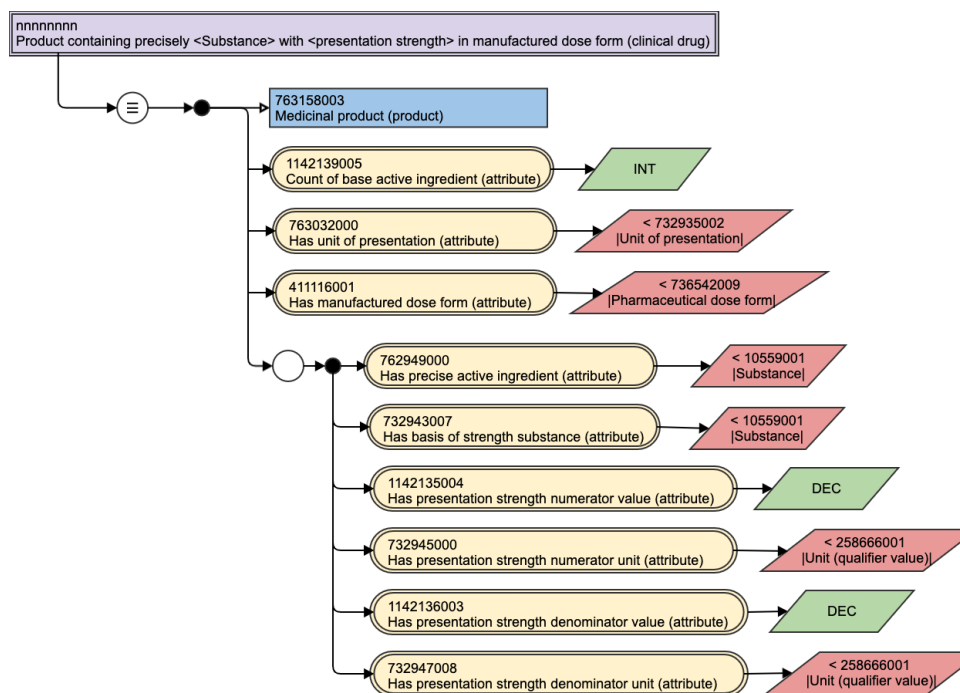


Figure 31: Clinical drug, presentation strength, stated template view

Examples: single active ingredient product: stated view followed by the inferred view that shows the proximal parent concepts associated with the product:

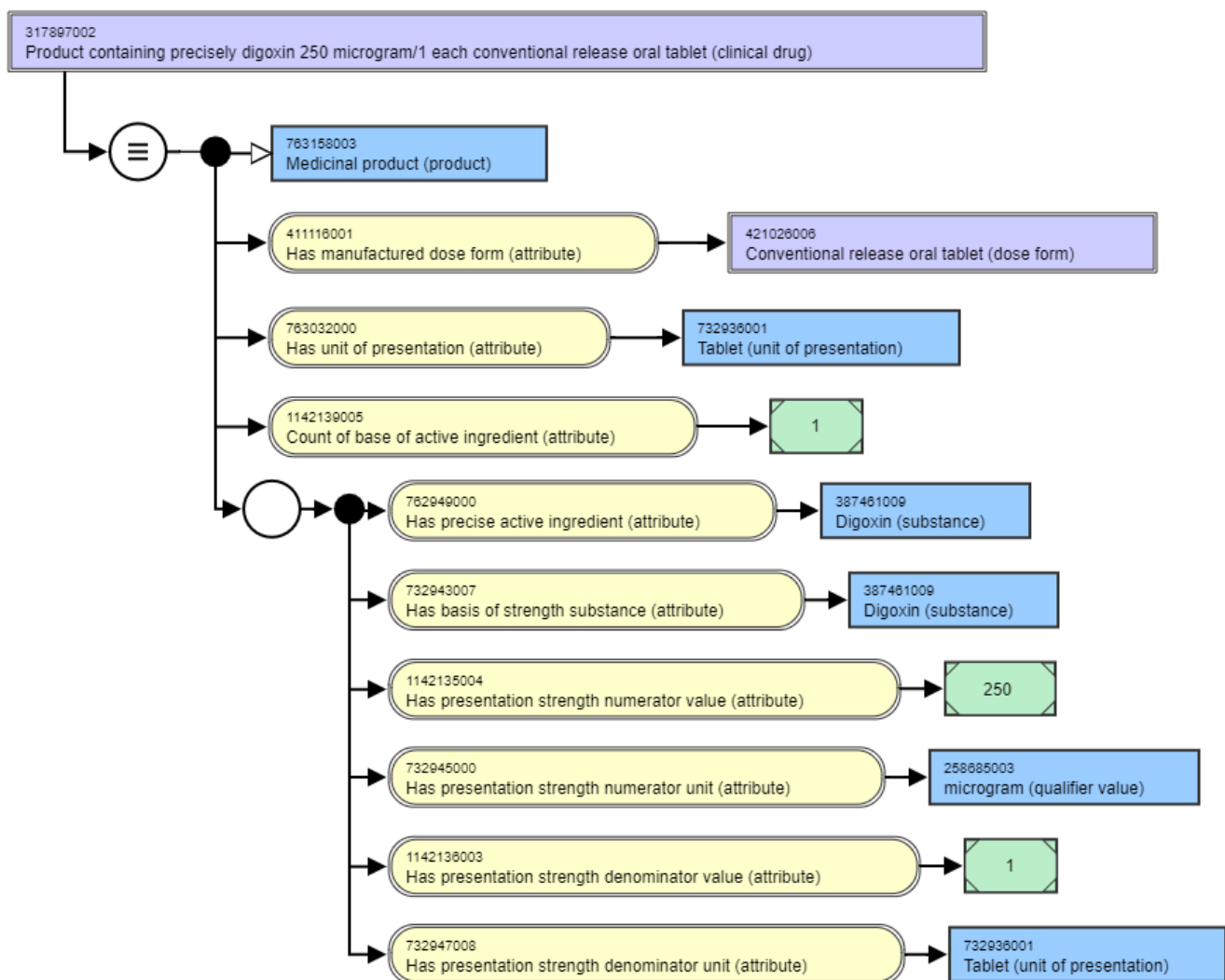


Figure 32: Clinical drug, presentation strength, example stated view

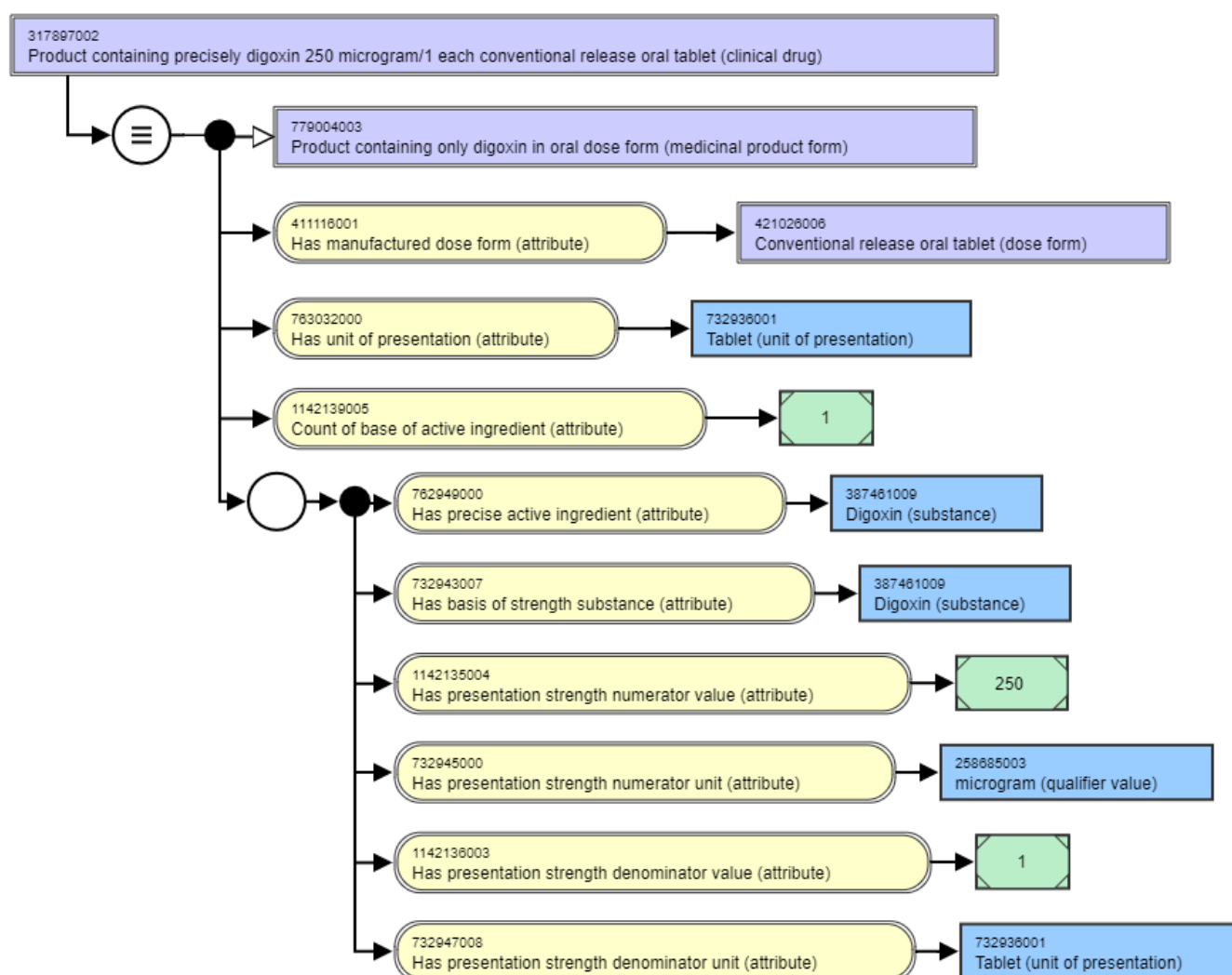


Figure 33: Clinical drug, presentation strength, example inferred view

Attributes of CD (precisely) (presentation strength)

The Clinical Drug (CD precisely) (presentation) concept is defined by three attributes and a set of substance/strength attributes:

Semantic tag	(clinical drug)
Definition status	<ul style="list-style-type: none"> 9000000000000073002 Sufficiently defined concept definition status
Exceptions	<ul style="list-style-type: none"> None identified

Attribute 411116001 Has manufactured dose form		<p>Range</p> <ul style="list-style-type: none"> < 736542009 Pharmaceutical dose form <p>Cardinality</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This attribute describes a grouping dose form concept for the medicinal product, where the grouping is the intended site for administration of the dose form of the product
Attribute 763032000 Has unit of presentation		<p>Range</p> <ul style="list-style-type: none"> < 732935002 Unit of presentation <p>Cardinality</p> <ul style="list-style-type: none"> 0..1 <p>Notes</p> <ul style="list-style-type: none"> This is the countable entity in which the clinical drug is presented See Appendix A: Product Patterns for the various patterns of use for the unit of presentation
Attribute 1142139005 Count of base of active ingredient		<p>Range</p> <ul style="list-style-type: none"> INT (integer) <p>Cardinality</p> <ul style="list-style-type: none"> 1..1 <p>Note</p> <ul style="list-style-type: none"> This attribute provides the number of base active ingredient substances present in the medicinal product
<p>Role Group [1..*]</p> <p>One role group is required for each precise active ingredient</p>	Attribute 762949000 Has precise active ingredient	<p>Range</p> <ul style="list-style-type: none"> < 105590001 Substance <p>Cardinality (within role group)</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This is a precise active ingredient substance that the concept contains. In each role group, only one precise active ingredient substance is stated
	Attribute 732943007 Has basis of strength substance	<p>Range</p> <ul style="list-style-type: none"> < 105590001 Substance <p>Cardinality (within role group)</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This is the basis of strength substance that the concept uses. In each role group, only one precise active ingredient substance is stated. The basis of strength substance is always stated explicitly, even when it is the same as the precise active ingredient substance

	Attribute 1142135004 Has presentation strength numerator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 732945000 Has presentation strength numerator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 1142136003 Has presentation strength denominator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 732947008 Has presentation strength denominator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1

For concepts that have two or more active ingredient substances that are modifications of the same base substance **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142141006 Count of base and modification pair	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
--	--

For concepts that have two or more active ingredient substances that are modifications of the same base active ingredient substance (i.e. parent ingredient substance) **and** where one is a further modification of the other (for example, a multi-ingredient product containing both dexamethasone phosphate and dexamethasone sodium phosphate, where the dexamethasone phosphate is a modification of dexamethasone (base) and dexamethasone sodium phosphate is a further modification of the dexamethasone phosphate) **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142140007 Count of active ingredient	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
---	--

As described in the MRCM rules, for practical and pragmatic reasons the additional ingredient count attributes have to be applied iteratively based on requirement.

Clinical Drug (precisely) (concentration strength)

Definition of Clinical Drug (precisely) (concentration strength)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as concentration strength and 3) with its manufactured dose form (with the exception of reconstituted oral liquid preparations, where the administrable dose form is be used as it is the most clinically relevant),

This is used for product types such as cutaneous semi-solids (without metered actuation), bulk powders and granules, topical liquids (without metered actuation) including drops, oral liquids and drops, nebuliser liquids and liquid parenteral products.

Example diagrams for CD (precisely) concentration strength

Stated template view:

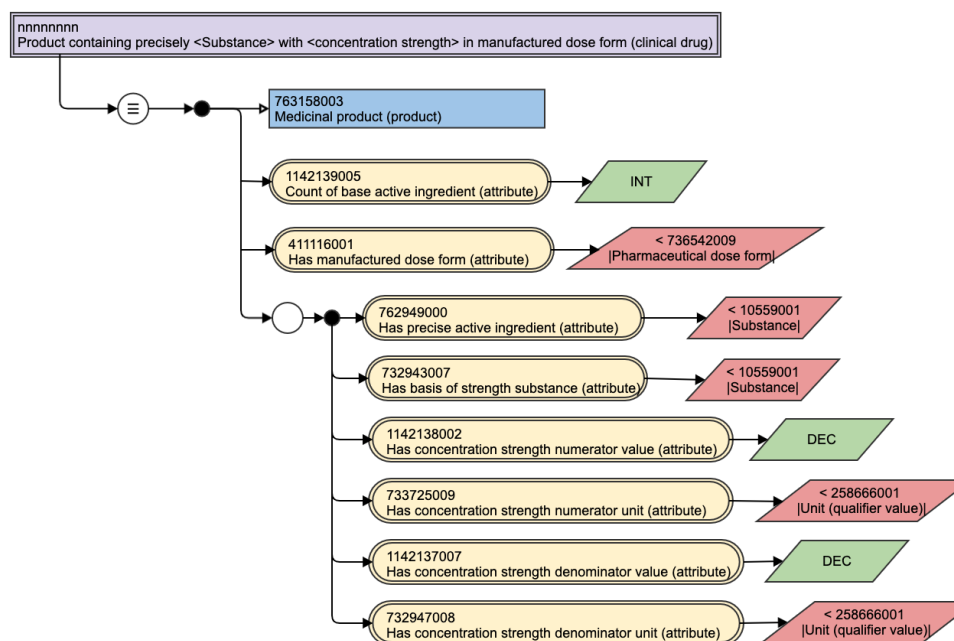


Figure 34: Clinical drug, concentration strength, stated template view

Examples: single active ingredient product: stated view followed by the inferred view that shows the proximal parent concepts associated with the product:

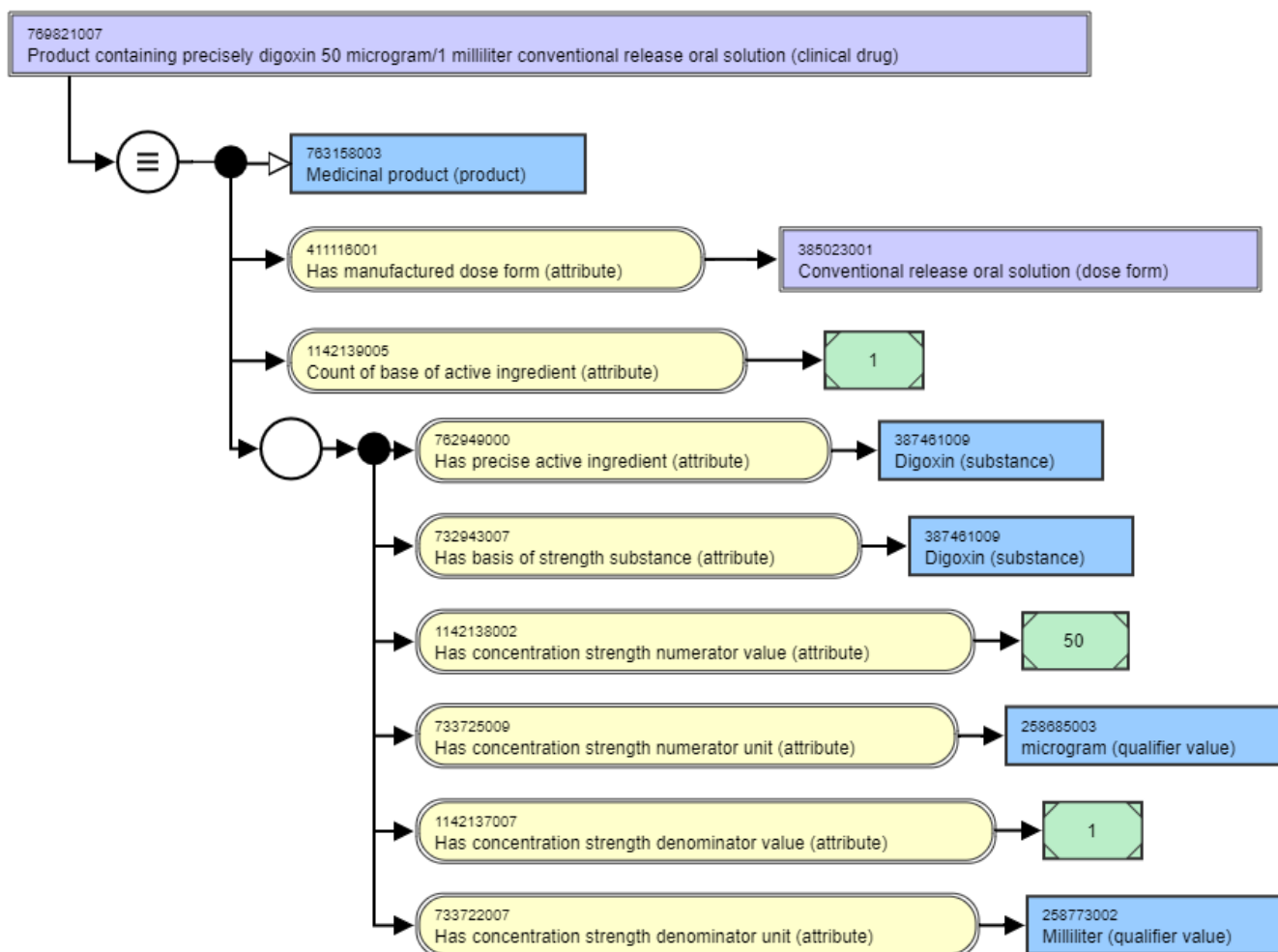


Figure 35: Clinical drug, concentration strength, example stated view

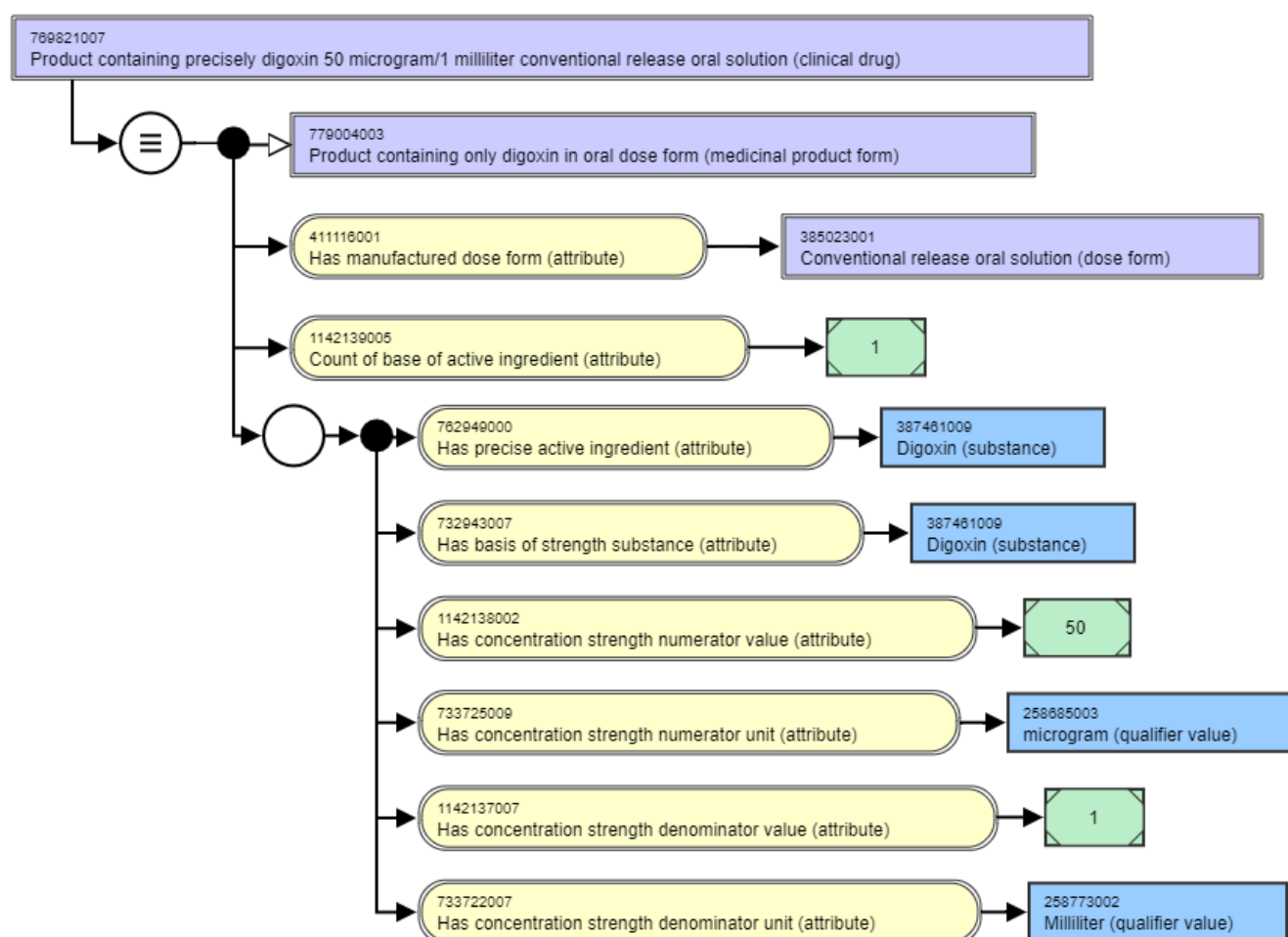


Figure 36: Clinical drug, concentration strength, example inferred view

Attributes of CD (precisely) (concentration strength)

The Clinical Drug (CD precisely) (concentration) concept is defined by two attributes and a set of substance/strength attributes; a Clinical Drug described only by concentration strength does not have a unit of presentation:

Semantic tag	(clinical drug)
Definition status	<ul style="list-style-type: none"> 9000000000000073002 Sufficiently defined concept definition status Exceptions <ul style="list-style-type: none"> None identified
Attribute 411116001 Has manufactured dose form	Range <ul style="list-style-type: none"> < 736542009 Pharmaceutical dose form Cardinality <ul style="list-style-type: none"> 1..1 Notes <ul style="list-style-type: none"> This is the finished dose form that a medicinal product is presented in by the manufacturer, before any transformation into an administrable dose form has taken place

Attribute 1142139005 Count of base of active ingredient		Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1 Note <ul style="list-style-type: none"> • This attribute provides the number of base active ingredient substances present in the medicinal product
Role Group [1..*] One role group is required for each precise active ingredient	Attribute 762949000 Has precise active ingredient	Range <ul style="list-style-type: none"> • < 105590001 Substance Cardinality (within role group) <ul style="list-style-type: none"> • 1..1 Notes <ul style="list-style-type: none"> • This is a precise active ingredient substance that the concept contains. • In each role group, only one precise active ingredient substance is stated
	Attribute 732943007 Has basis of strength substance	Range <ul style="list-style-type: none"> • < 105590001 Substance Cardinality (within role group) <ul style="list-style-type: none"> • 1..1 Notes <ul style="list-style-type: none"> • This is the basis of strength substance that the concept uses. • In each role group, only one precise active ingredient substance is stated. • The basis of strength substance is always stated explicitly, even when it is the same as the precise active ingredient substance
	Attribute 1142138002 Has concentration strength numerator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 733725009 Has concentration strength numerator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 1142137007 Has concentration strength denominator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1

	Attribute 733722007 Has concentration strength denominator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
--	---	---

For concepts that have two or more active ingredient substances that are modifications of the same base substance **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142141006 Count of base and modification pair	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
--	--

For concepts that have two or more active ingredient substances that are modifications of the same base active ingredient substance (i.e. parent ingredient substance) **and** where one is a further modification of the other (for example, a multi-ingredient product containing both dexamethasone phosphate and dexamethasone sodium phosphate, where the dexamethasone phosphate is a modification of dexamethasone (base) and dexamethasone sodium phosphate is a further modification of the dexamethasone phosphate) **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142140007 Count of active ingredient	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
---	--

As described in the MRCM rules, for practical and pragmatic reasons the additional ingredient count attributes have to be applied iteratively based on requirement.

Other Clinical Drug Grouping Concepts not present in this model or in the international edition

Clinical Drug concepts in the international release are defined by their precise active ingredient substance(s) and their basis of strength substance, as described above. A concept that grouped clinical drugs by their strength and basis of strength substance only (i.e. disregarding the precise active ingredient substance) may be appropriate in some contexts in national extensions (e.g. 'amlodipine 10mg conventional release oral tablet' as a concept with three child concepts 'amlodipine (as amlodipine besilate) 10mg conventional release oral tablet' and 'amlodipine (as amlodipine mesilate) 10mg conventional release oral tablet' 'amlodipine (as amlodipine maleate) 10mg conventional release oral tablet'. A Clinical Drug grouping concept of this nature would be a "Basis of Strength Substance Clinical Drug" concept as opposed to a "Clinical Drug containing Precisely" concept.

IDMP Compatibility

Although a Clinical Drug might look directly compatible with the IDMP concept of "Manufactured Item", in IDMP, a Manufactured Item is an "actual manufactured item (the tablet, liquid, cream contained within the package) as it is delivered from the manufacturer but before any transformation, if applicable, for administration to or use by the patient"; it is therefore a representation of a real entity, rather than an abstract entity. They are therefore not directly compatible classes of entities. A Manufactured Item is described by substances in a variety of roles, including excipient substances, not just its active substance(s) and their strengths. A Manufactured Item can be related to an appropriate Clinical Drug on the basis of its **active** ingredient substance(s) and relevant strength so that the Clinical Drug being an abstracted representation of the Manufactured Item, but they are not equivalent. The Manufactured Item concept in IDMP is equivalent to the Real Clinical Drug concept of the SNOMED national extension model.

On the basis that the IDMP concept of a Pharmaceutical Product could be defined by substance(s) playing only an active ingredient role, then the Clinical Drug concept is more directly compatible with the IDMP Pharmaceutical Product concept however if it is intended that the IDMP Pharmaceutical Product does include excipient substances, then there is no compatibility. Even then, the IDMP Pharmaceutical Product concept is clear that the dose form attribute is populated by the *administrable* dose form rather than the manufactured dose form, whereas, for everything other than products presented as reconstituted oral liquids, the Clinical Drug uses the *manufactured* dose form. Although for probably the majority of medicinal products the manufactured dose form is also the administrable dose form, for the minority for which this is not the case (for example, parenteral products presented as powders or granules that must be dissolved or dispersed prior to administration to the patient) this difference is significant. It is therefore not possible to state any direct class level equivalence between a Clinical Drug and an IDMP Pharmaceutical Product.

There is some compatibility between an IDMP PhP4 concept and a Clinical Drug. However, It is not (yet) clear as to how the "active substance - strength" description will be described in IDMP implementation. The SNOMED Clinical Drug is explicit in stating the basis of strength substance in its relevant granularity as required for patient care; IDMP is currently less clear as to how that will be done and what effect that will have on the description of a Pharmaceutical Product. In addition, IDMP allows for "active substance - strength" to be described by using either (and possibly even both) a Substance and Specified Substance. The distinction between Substance and Specified Substance in IDMP is thus: a substance is "any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical" whereas a Specified Substance is one that is "defined by groups of elements that describes multi-substance materials or specifies further information on substances relevant to the description of Medicinal Products". Specified substances are substances like simeticone, which are mixture substances, or substances that are defined by pharmacopoeial specification (like water for injection) or substance where a particular manufacturing process is specified (as for biosimilar products). For SNOMED CT, all such substances, with the possible exception of 'water for injection' could be present in the Substance hierarchy and are therefore candidate concepts to be used in the ingredient role attributes of concepts in the Medicinal Product hierarchy; as such the IDMP distinction between Substance and Specified Substance has no material effect.

Definition of CD (precisely)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as presentation strength with unit of presentation or as concentration strength as appropriate, and 3) with its manufactured dose form (but in reconstituted oral liquid preparations, the administrable dose form - see below).

All Clinical Drugs that contain multiple *active* ingredient substances will have parent MPF and MP concepts that have the same set of active ingredient substances.

The limitation of the Clinical Drug class to the closed world view by the description of its precise active ingredient substances *only* precludes description of excipient substances such as flavours, preservatives, sweeteners etc as ingredients in a Clinical Drug. These substances can have significance for allergies etc. but can only be reliably described for individual authorised manufactured products, and as such are not within the scope of the international edition.

Similarly, by limiting the the Clinical Drug class in the international edition to expression of strength *either* as concentration strength *or* as presentation strength, medicinal product concepts that could usefully have *both* concentration and presentation strength (for example some liquid products such as liquid parenteral products or liquids for inhalation via a nebuliser) will have only concentration strength in the international edition. National extensions may author clinical drug concepts using the presentation strength(s) and unit(s) of presentation available in their jurisdiction if use case(s) require this. These concepts will be child concepts of the concentration clinical drug in the international edition. The diagrams below illustrate this:

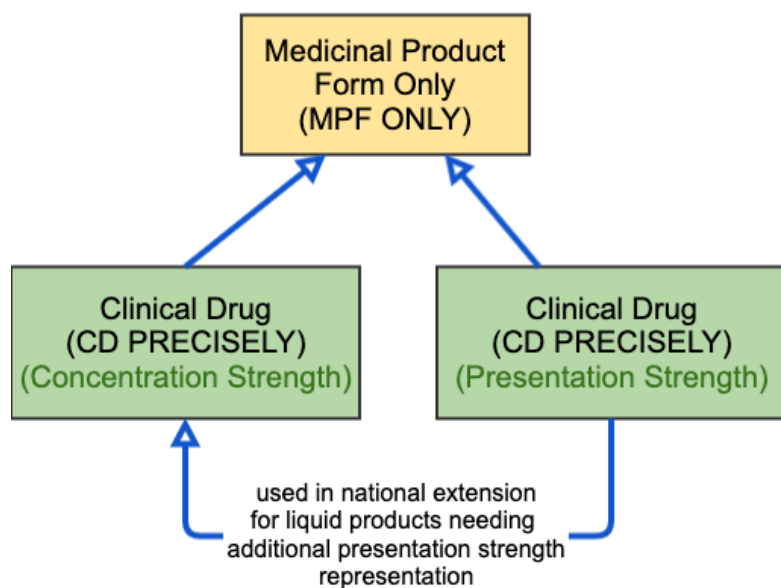


Figure 37: Clinical Drug concepts and their relationship together and to MPF only concepts

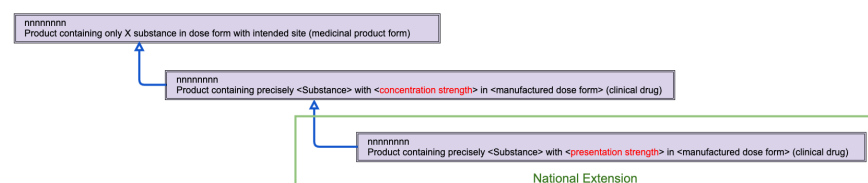


Figure 38: Clinical Drug concepts and their relationship together and to MPF only concepts in SNOMED notation, showing optional national extension concepts

Example:

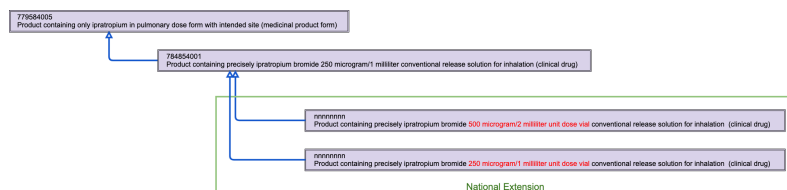


Figure 39: Clinical Drug example showing optional national extension concepts

Please also reference the National Extension specification for how to use additional model attributes to fully define concepts that can have both a concentration strength and a presentation strength such that they classify correctly.

Use cases supported by CD (precisely)

Use cases supported by the clinical drug concept include:

- As the abstract representation of products that are authorised, although without any sense of the excipient substances, the clinical drug concept is the source from which all other representation of medicinal product concepts flows; it acts as a clinically relevant grouper concept for medicinal products, and as such can support
 - international cross-border care delivery
 - International and national interoperability of patient medication information such as in patient summaries
- In national extensions, for many clinical purposes, such as product prescribing, adverse event reporting, formulary management, in recording medication history and in medication profiles
- Internationally and nationally in decision support and in protocols and treatment guidelines, when a more complete description of a product is required than MP or MPF
- In pharmacovigilance, especially for description of concomitant medication
- In analysis and research

Availability of CD concepts in the international edition

This class forms part of the medicinal product content provided in the international edition, although for liquid products, only concentration strength representation is provided.

Clinical Drug (precisely) (presentation strength)

Definition of Clinical Drug (precisely) (presentation strength)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as presentation strength with unit of presentation and 3) with its manufactured dose form.

This is used for product types such as tablets, capsules, pessaries, suppositories (Strength Pattern 1a in [Appendix A: Product Patterns](#)), sachets, ampoules or vials *containing* powders or granules etc. (solid dosage forms) and those presented with a metered dose valve such as inhalers and sprays.

Example diagrams for CD (precisely) presentation strength

Stated template view:

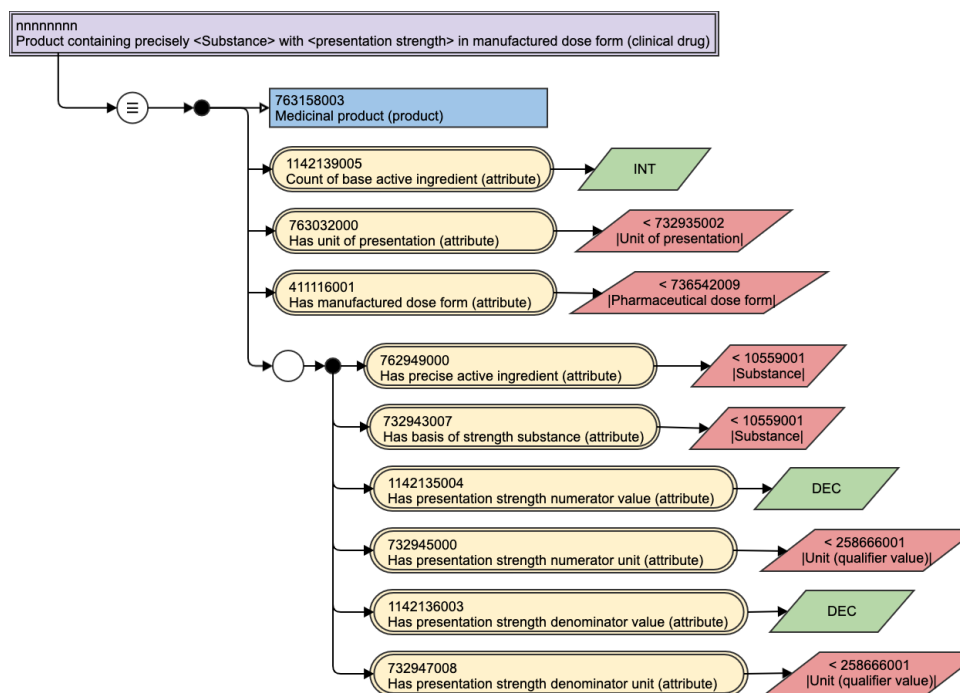


Figure 40: Clinical drug, presentation strength, stated template view

Examples: single active ingredient product: stated view followed by the inferred view that shows the proximal parent concepts associated with the product:

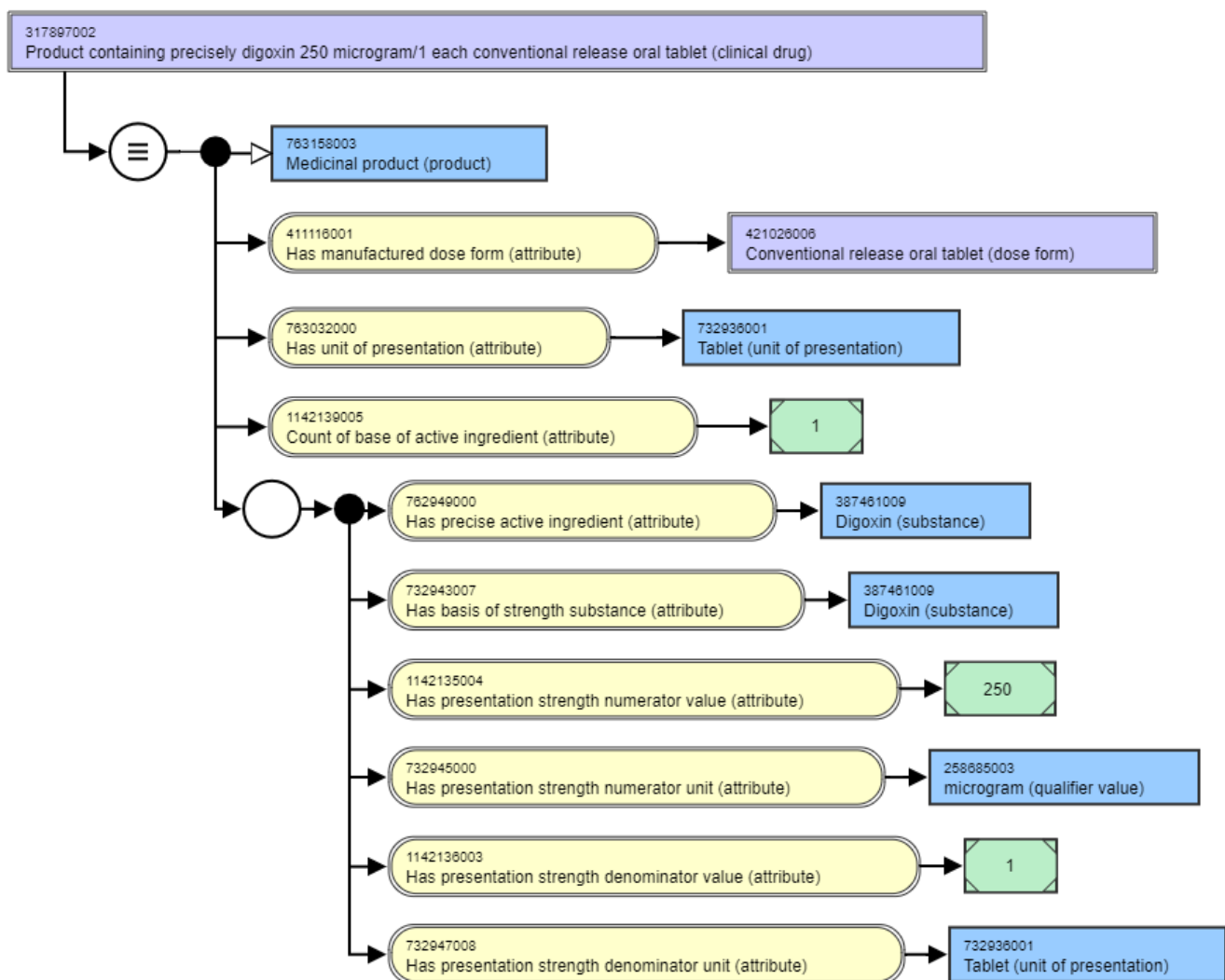


Figure 41: Clinical drug, presentation strength, example stated view

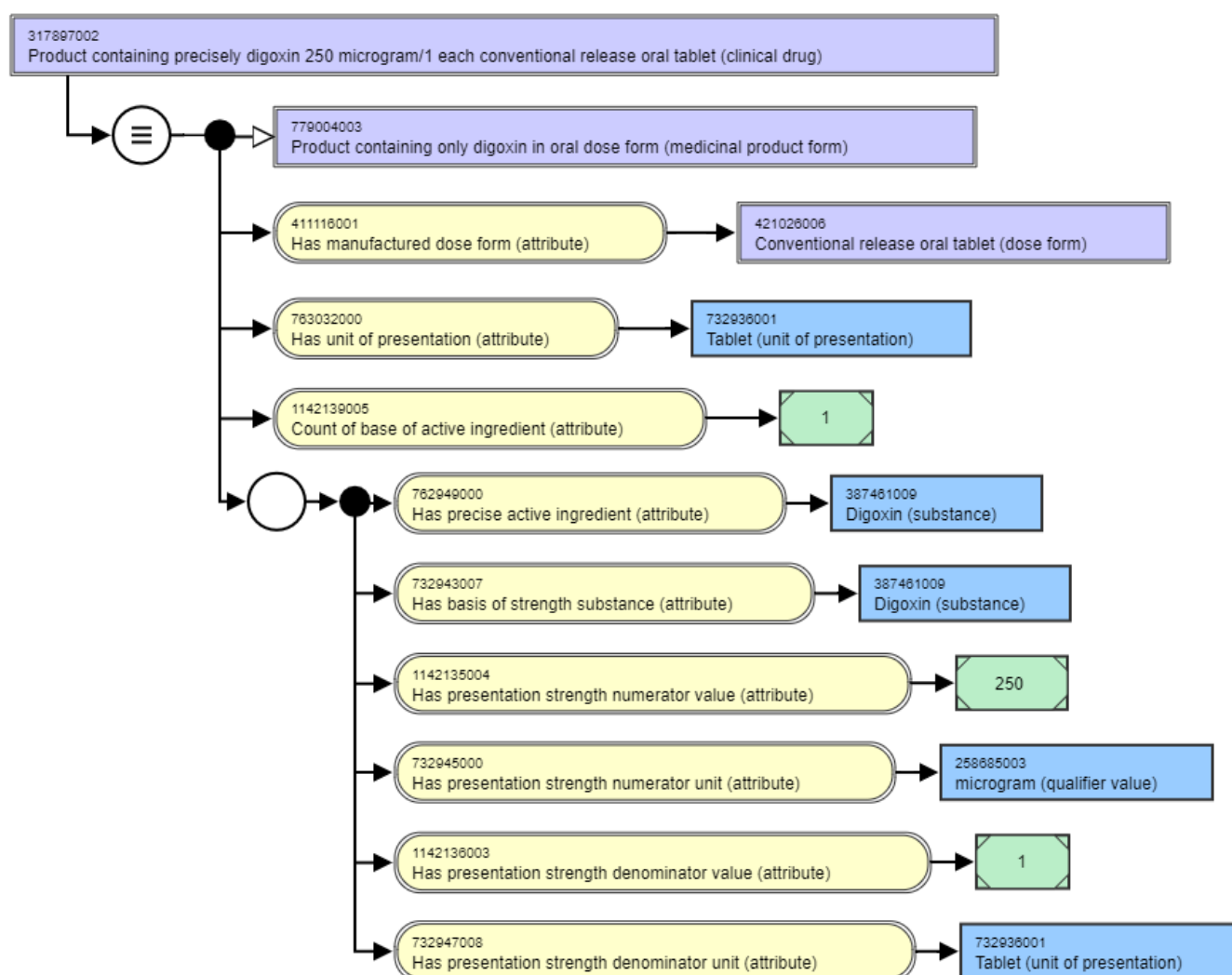


Figure 42: Clinical drug, presentation strength, example inferred view

Attributes of CD (precisely) (presentation strength)

The Clinical Drug (CD precisely) (presentation) concept is defined by three attributes and a set of substance/strength attributes:

Semantic tag	(clinical drug)
Definition status	<ul style="list-style-type: none"> 9000000000000073002 Sufficiently defined concept definition status
Exceptions	<ul style="list-style-type: none"> None identified

Attribute 411116001 Has manufactured dose form		<p>Range</p> <ul style="list-style-type: none"> < 736542009 Pharmaceutical dose form <p>Cardinality</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This attribute describes a grouping dose form concept for the medicinal product, where the grouping is the intended site for administration of the dose form of the product
Attribute 763032000 Has unit of presentation		<p>Range</p> <ul style="list-style-type: none"> < 732935002 Unit of presentation <p>Cardinality</p> <ul style="list-style-type: none"> 0..1 <p>Notes</p> <ul style="list-style-type: none"> This is the countable entity in which the clinical drug is presented See Appendix A: Product Patterns for the various patterns of use for the unit of presentation
Attribute 1142139005 Count of base of active ingredient		<p>Range</p> <ul style="list-style-type: none"> INT (integer) <p>Cardinality</p> <ul style="list-style-type: none"> 1..1 <p>Note</p> <ul style="list-style-type: none"> This attribute provides the number of base active ingredient substances present in the medicinal product
<p>Role Group [1..*]</p> <p>One role group is required for each precise active ingredient</p>	Attribute 762949000 Has precise active ingredient	<p>Range</p> <ul style="list-style-type: none"> < 105590001 Substance <p>Cardinality (within role group)</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This is a precise active ingredient substance that the concept contains. In each role group, only one precise active ingredient substance is stated
	Attribute 732943007 Has basis of strength substance	<p>Range</p> <ul style="list-style-type: none"> < 105590001 Substance <p>Cardinality (within role group)</p> <ul style="list-style-type: none"> 1..1 <p>Notes</p> <ul style="list-style-type: none"> This is the basis of strength substance that the concept uses. In each role group, only one precise active ingredient substance is stated. The basis of strength substance is always stated explicitly, even when it is the same as the precise active ingredient substance

	Attribute 1142135004 Has presentation strength numerator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 732945000 Has presentation strength numerator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 1142136003 Has presentation strength denominator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 732947008 Has presentation strength denominator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1

For concepts that have two or more active ingredient substances that are modifications of the same base substance **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142141006 Count of base and modification pair	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
--	--

For concepts that have two or more active ingredient substances that are modifications of the same base active ingredient substance (i.e. parent ingredient substance) **and** where one is a further modification of the other (for example, a multi-ingredient product containing both dexamethasone phosphate and dexamethasone sodium phosphate, where the dexamethasone phosphate is a modification of dexamethasone (base) and dexamethasone sodium phosphate is a further modification of the dexamethasone phosphate) **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142140007 Count of active ingredient	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
---	--

As described in the MRCM rules, for practical and pragmatic reasons the additional ingredient count attributes have to be applied iteratively based on requirement.

Clinical Drug (precisely) (concentration strength)

Definition of Clinical Drug (precisely) (concentration strength)

An abstract representation of a medicinal product based on description of 1) its precise active ingredient substances only and explicitly, 2) the stated basis of strength substance(s) with strength, expressed as concentration strength and 3) with its manufactured dose form (with the exception of reconstituted oral liquid preparations, where the administrable dose form is be used as it is the most clinically relevant),

This is used for product types such as cutaneous semi-solids (without metered actuation), bulk powders and granules, topical liquids (without metered actuation) including drops, oral liquids and drops, nebuliser liquids and liquid parenteral products.

Example diagrams for CD (precisely) concentration strength

Stated template view:

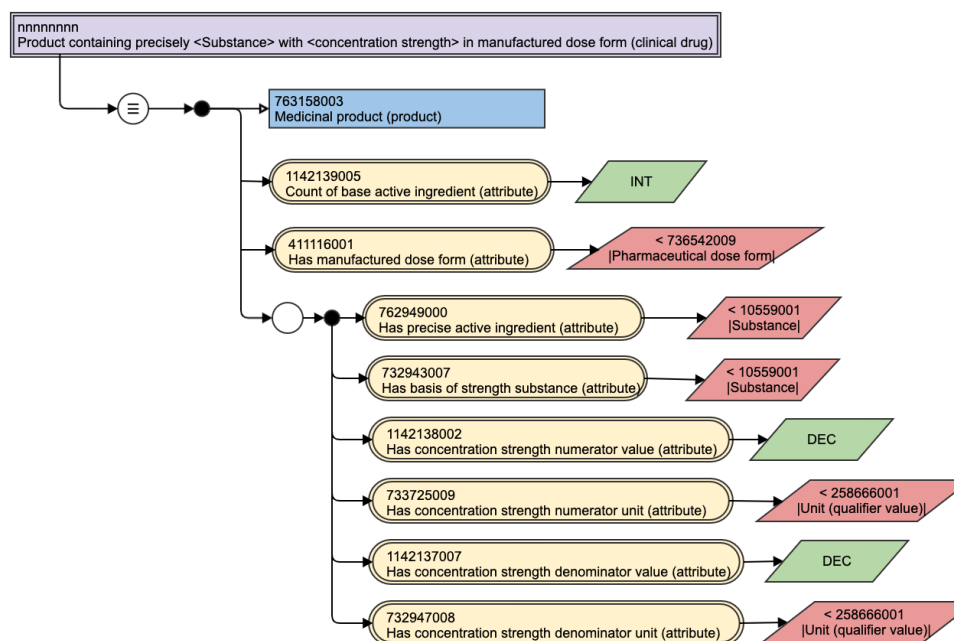


Figure 43: Clinical drug, concentration strength, stated template view

Examples: single active ingredient product: stated view followed by the inferred view that shows the proximal parent concepts associated with the product:

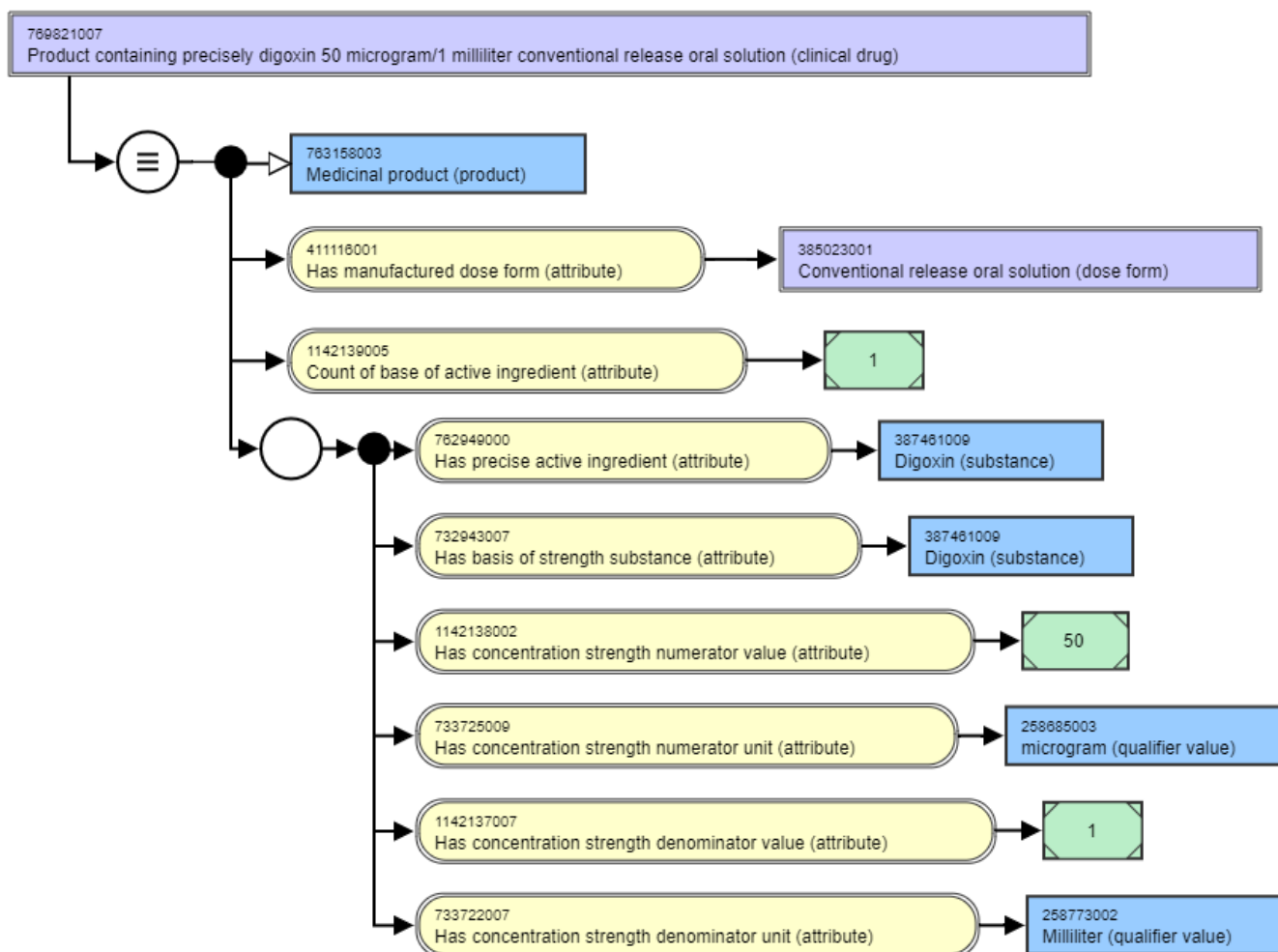


Figure 44: Clinical drug, concentration strength, example stated view

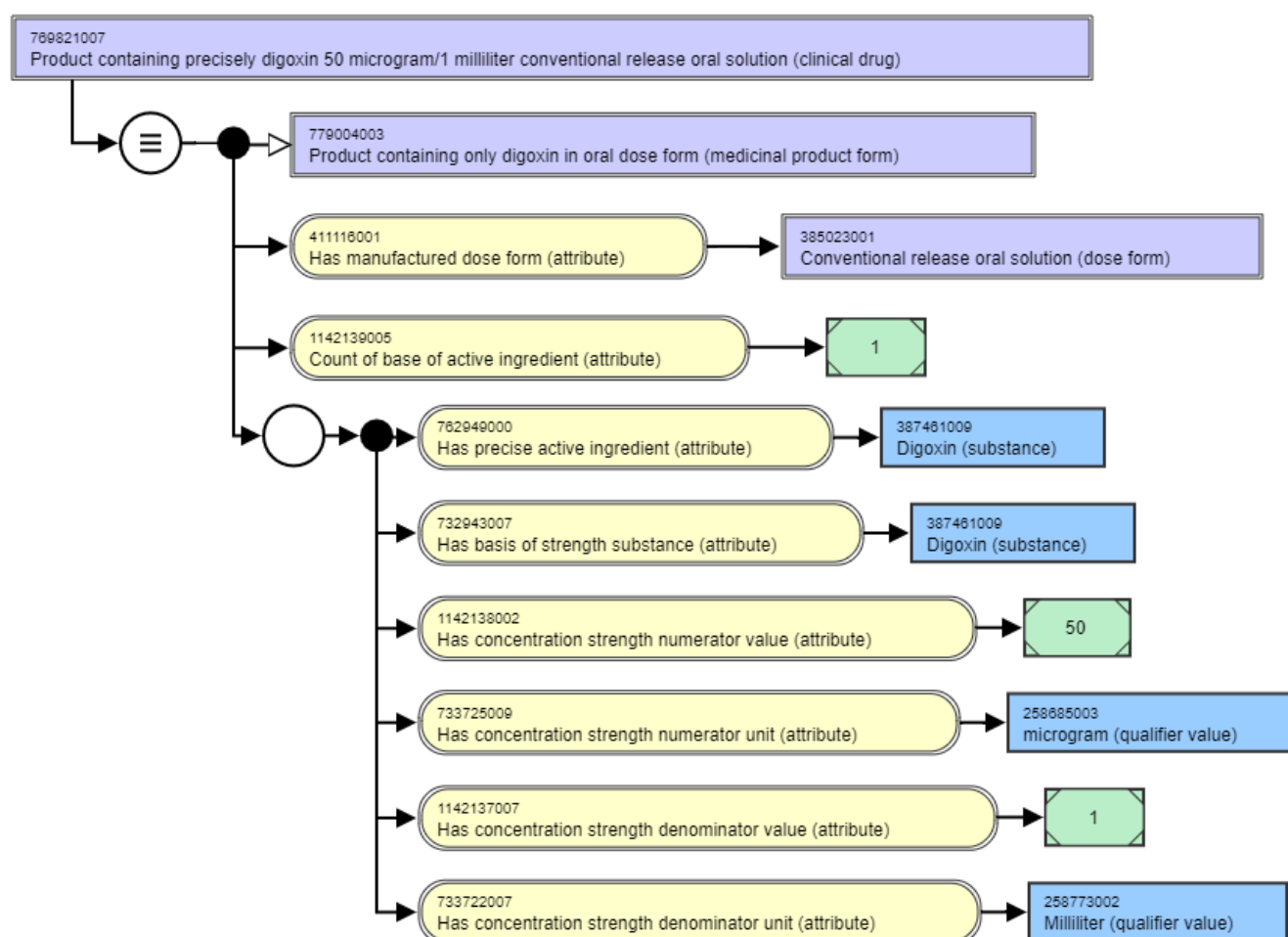


Figure 45: Clinical drug, concentration strength, example inferred view

Attributes of CD (precisely) (concentration strength)

The Clinical Drug (CD precisely) (concentration) concept is defined by two attributes and a set of substance/strength attributes; a Clinical Drug described only by concentration strength does not have a unit of presentation:

Semantic tag	(clinical drug)
Definition status	<ul style="list-style-type: none"> 9000000000000073002 Sufficiently defined concept definition status Exceptions <ul style="list-style-type: none"> None identified
Attribute 411116001 Has manufactured dose form	Range <ul style="list-style-type: none"> < 736542009 Pharmaceutical dose form Cardinality <ul style="list-style-type: none"> 1..1 Notes <ul style="list-style-type: none"> This is the finished dose form that a medicinal product is presented in by the manufacturer, before any transformation into an administrable dose form has taken place

Attribute 1142139005 Count of base of active ingredient		Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1 Note <ul style="list-style-type: none"> • This attribute provides the number of base active ingredient substances present in the medicinal product
Role Group [1..*] One role group is required for each precise active ingredient	Attribute 762949000 Has precise active ingredient	Range <ul style="list-style-type: none"> • < 105590001 Substance Cardinality (within role group) <ul style="list-style-type: none"> • 1..1 Notes <ul style="list-style-type: none"> • This is a precise active ingredient substance that the concept contains. • In each role group, only one precise active ingredient substance is stated
	Attribute 732943007 Has basis of strength substance	Range <ul style="list-style-type: none"> • < 105590001 Substance Cardinality (within role group) <ul style="list-style-type: none"> • 1..1 Notes <ul style="list-style-type: none"> • This is the basis of strength substance that the concept uses. • In each role group, only one precise active ingredient substance is stated. • The basis of strength substance is always stated explicitly, even when it is the same as the precise active ingredient substance
	Attribute 1142138002 Has concentration strength numerator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 733725009 Has concentration strength numerator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
	Attribute 1142137007 Has concentration strength denominator value	Range <ul style="list-style-type: none"> • DEC (decimal) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1

	Attribute 733722007 Has concentration strength denominator unit	Range <ul style="list-style-type: none"> • < 767524001 Unit of measure (qualifier value) Cardinality (within role group) <ul style="list-style-type: none"> • 1..1
--	---	---

For concepts that have two or more active ingredient substances that are modifications of the same base substance **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142141006 Count of base and modification pair	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
--	--

For concepts that have two or more active ingredient substances that are modifications of the same base active ingredient substance (i.e. parent ingredient substance) **and** where one is a further modification of the other (for example, a multi-ingredient product containing both dexamethasone phosphate and dexamethasone sodium phosphate, where the dexamethasone phosphate is a modification of dexamethasone (base) and dexamethasone sodium phosphate is a further modification of the dexamethasone phosphate) **and where** MP precisely concepts are required, and for single ingredient product concepts where the active substance is an ingredient in these multiple modification multi-ingredient products, the following extra ingredient count attribute will be required in order to support correct relationships generated by the MRCM:

Attribute 1142140007 Count of active ingredient	Range <ul style="list-style-type: none"> • INT (integer) Cardinality <ul style="list-style-type: none"> • 1..1
---	--

As described in the MRCM rules, for practical and pragmatic reasons the additional ingredient count attributes have to be applied iteratively based on requirement.

Other Clinical Drug Grouping Concepts not present in this model or in the international edition

Clinical Drug concepts in the international release are defined by their precise active ingredient substance(s) and their basis of strength substance, as described above. A concept that grouped clinical drugs by their strength and basis of strength substance only (i.e. disregarding the precise active ingredient substance) may be appropriate in some contexts in national extensions (e.g. 'amlodipine 10mg conventional release oral tablet' as a concept with three child concepts 'amlodipine (as amlodipine besilate) 10mg conventional release oral tablet' and 'amlodipine (as amlodipine mesilate) 10mg conventional release oral tablet' 'amlodipine (as amlodipine maleate) 10mg conventional release oral tablet'. A Clinical Drug grouping concept of this nature would be a "Basis of Strength Substance Clinical Drug" concept as opposed to a "Clinical Drug containing Precisely" concept.

IDMP Compatibility

Although a Clinical Drug might look directly compatible with the IDMP concept of "Manufactured Item", in IDMP, a Manufactured Item is an "actual manufactured item (the tablet, liquid, cream contained within the package) as it is delivered from the manufacturer but before any transformation, if applicable, for administration to or use by the patient"; it is therefore a representation of a real entity, rather than an abstract entity. They are therefore not directly compatible classes of entities. A Manufactured Item is described by substances in a variety of roles, including excipient substances, not just its active substance(s) and their strengths. A Manufactured Item can be related to an appropriate Clinical Drug on the basis of its **active** ingredient substance(s) and relevant strength so that the Clinical Drug being an abstracted representation of the Manufactured Item, but they are not equivalent. The Manufactured Item concept in IDMP is equivalent to the Real Clinical Drug concept of the SNOMED national extension model.

On the basis that the IDMP concept of a Pharmaceutical Product could be defined by substance(s) playing only an active ingredient role, then the Clinical Drug concept is more directly compatible with the IDMP Pharmaceutical Product concept however if it is intended that the IDMP Pharmaceutical Product does include excipient substances, then there is no compatibility. Even then, the IDMP Pharmaceutical Product concept is clear that the dose form attribute is populated by the *administrable* dose form rather than the manufactured dose form, whereas, for everything other than products presented as reconstituted oral liquids, the Clinical Drug uses the *manufactured* dose form. Although for probably the majority of medicinal products the manufactured dose form is also the administrable dose form, for the minority for which this is not the case (for example, parenteral products presented as powders or granules that must be dissolved or dispersed prior to administration to the patient) this difference is significant. It is therefore not possible to state any direct class level equivalence between a Clinical Drug and an IDMP Pharmaceutical Product.

There is some compatibility between an IDMP PhP4 concept and a Clinical Drug. However, It is not (yet) clear as to how the "active substance - strength" description will be described in IDMP implementation. The SNOMED Clinical Drug is explicit in stating the basis of strength substance in its relevant granularity as required for patient care; IDMP is currently less clear as to how that will be done and what effect that will have on the description of a Pharmaceutical Product. In addition, IDMP allows for "active substance - strength" to be described by using either (and possibly even both) a Substance and Specified Substance. The distinction between Substance and Specified Substance in IDMP is thus: a substance is "any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical" whereas a Specified Substance is one that is "defined by groups of elements that describes multi-substance materials or specifies further information on substances relevant to the description of Medicinal Products". Specified substances are substances like simeticone, which are mixture substances, or substances that are defined by pharmacopoeial specification (like water for injection) or substance where a particular manufacturing process is specified (as for biosimilar products). For SNOMED CT, all such substances, with the possible exception of 'water for injection') could be present in the Substance hierarchy and are therefore candidate concepts to be used in the ingredient role attributes of concepts in the Medicinal Product hierarchy; as such the IDMP distinction between Substance and Specified Substance has no material effect.