Canadian Clinical Drug Data Set Technical Specification

The tables below provides the format and description of the attributes within each of the Canadian Clinical Drug Data Set (CCDD) files .  All strings are coded in UTF-8.

**The Non-proprietary Therapeutic Product; (ntp\_table)**

A representation of a brand independent and clinically oriented representation of a manufactured (therapeutic) drug product.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **ntp\_code** | String | 7 | Unique meaningless Non-proprietary Therapeutic Product identifier. |
| **ntp\_formal\_name** | String | 500 | The unambiguous description of the Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar products. |
| **ntp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **ntp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **ntp\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **ntp\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |
| **ntp\_type** | String | 8 | This attribute is used to differentiate combination products. Values = Combination product or Empty. |

**Therapeutic Moiety;** (**tm\_table)**

The representation of the functional and clinically significant part of the active ingredient substance(s) present in a medicinal product, and as such the TM class is an abstract representation of a medicinal product without reference to strength and dose form, focusing only on active ingredient substance(s).

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **tm\_code** | String | 7 | Unique meaningless Therapeutic Moiety identifier |
| **tm\_formal\_name** | String | 500 | The unambiguous description of the Therapeutic Moiety that includes details necessary to distinguish it from other similar products. |
| **tm\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **tm\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |

**Manufactured Product; (mp\_table)**

The representation of a brand specific drug that is available for prescribing and dispensing in Canada.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **mp\_code** | String | 8 | The unique Manufactured Product identifier, that may be a Health Canada assigned DIN or NPN, or an identifier specific to the CCDD. |
| **mp\_formal\_name** | String | 500 | The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar products. |
| **mp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **mp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **mp\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **mp\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |

**Manufactured Product, Non-proprietary Therapeutic Product, Therapeutic Product Relationship Table (mp\_ntp\_tm\_relationship\_table)**

Each row of this table represents the relationship between an MP (identified in the first two columns) and its NTP (identified in the second set of two columns), and if appropriate, its TM (identified in the third set of two columns).

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **mp\_code** | String | 8 | The unique Manufactured Product identifier, that may be a Health Canada assigned DIN or NPN, or an identifier specific to the CCDD. |
| **mp\_formal\_name** | String | 500 | The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar products. |
| **ntp\_code** | Numeric | 7 | Unique meaningless non-proprietary therapeutic product identifier assigned by Health Canada. |
| **ntp\_formal\_name** | String | 500 | The unambiguous description of the Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar products. |
| **tm\_code** | Numeric | 7 | Unique meaningless therapeutic moiety identifier assigned by Health Canada. |
| **tm\_formal\_name** | String | 500 | The unambiguous description of the therapeutic moiety that includes details necessary to distinguish it from other similar products. |

**Device Non-proprietary Therapeutic Product; (Device-ntp\_table)**

A brand independent and clinically oriented representation of a healthcare device. The scope to include devices that would be prescribed by primary care and dispensed by a pharmacy.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **device\_ntp\_code** | String | 7 | Unique meaningless Device Non-proprietary Therapeutic Product |
| **device\_ntp\_formal\_name** | String | 500 | The unambiguous description of the Device Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar products. |
| **device\_ntp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **device\_ntp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **device\_ntp\_status** | String | 8 | The lifecycle status for the concept in this file. Allowable values for status are “Active”, “Inactive”. |
| **device\_ntp\_status\_effective\_time** | String (Date) | 8 | The date of the status in this file. Format = YYYYMMDD. |

**Special Groupings Table (special\_groupings\_table)**

The following description will be added to the Editorial Guidelines and Gateway

This file identifies and provides relationships between concepts in the Canadian Clinical Drug Data Set (CCDD) and policies that apply to those products. The initial policy focus will be national and include opioid-containing products and controlled substances.

The file also provides information about the status of that relationship, so that historic information can be maintained (e.g. for a product whose policy information has changed over time).

In the future, this file may also contain information to identify groups of products that are subject to other types of special monitoring (e.g. antibiotics). Provincial policies may also be considered for addition in the future as well subject to the appropriate governance.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **ccdd\_code** | String | 8 | Unique meaningless identifier for a concept within the Canadian Clinical Drug Data Set. This may be a tm\_code, an ntp\_code or an mp\_code |
| **ccdd\_formal\_name** | String | 500 | The unambiguous description of the concept within the Canadian Clinical Drug Data Set. This may be a tm\_formal\_name, an ntp\_formal\_name or an mp\_formal\_name |
| **ccdd\_type** | String | 15 | The identification of the specific Canadian Clinical Drug Data Set concepttype (either MP, NTP or TM) |
| **policy\_type** | String | 250 | A code representing the policy that the concept described in ccdd\_code is controlled by.  The detail of the code can be found in the **coded\_attributes** table below. |
| **policy\_reference** | String | 250 | A reference to further information about the policy. This reference may be a url. |
| **special\_groupings\_status** | String | 8 | The lifecycle status of the relationship between the concept described in ccdd\_code and the policy described in policy\_type. Allowable values for this status are "active" and "inactive" |
| **special\_groupings\_status\_effective\_time** | String (Date) | 8 | The date of the relationship status described above. Format = YYYYMMDD |

**Manufactured Product to DIN or NPN Mapping (mp\_to\_DIN\_or NPN\_mapping\_table)**

The following description will be added to the Editorial Guidelines and Gateway

This file provides a mapping between all of the Manufactured Product (MP) concepts present in the Canadian Clinical Drug Data Set (CCDD) and medicinal products identified by a Health Canada DIN (Drug Identification Number) or Natural Product Number (NPN) in the Drug Product Database (DPD) or Licensed Natural Health Products Database (LNHPD).

Medicinal products with more granular (specific) representations are needed in the CCDD to meet its use cases. The types of products requiring more granular representation in the CCDD are primarily:

a) liquid injectable products, where several presentations of the product are identified by a single DIN (e.g. different sizes of pre-filled syringes), and

b) products presented in unit dose containers, where more than one amount is identified by a single DIN (e.g. 1 mL and 2 mL unit dose vials of a nebulizer solution)

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **mp\_code** | String | 8 | Unique identifier for a Manufactured Product in the Clinical Drug Data Set |
| **mp\_formal\_name** | String | 500 | Unambiguous description of a Manufactured Product in the Clinical Drug Data Set |
| **Health\_Canada\_identifier** | String | 8 | The DIN or NPN identifier assigned to an authorized medicinal product by Health Canada |
| **Health\_Canada\_product\_name** | String | 200 | The brand name (as present in the DPD or LNHPD) approved by Health Canada, under which the drug product may be marketed |
| **Health\_Canada\_description** | String | 150 | Optional text additional to the Product name used (as present in the DPD or LNHPD) to differentiate similar drug products on the basis of specific characteristics (e.g. single use syringe) |

**Coded attributes (coded\_attribute\_table)t**

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **attribute** | String | 8 | The name of the specific attribute from the CCDD file type the attribute value is present. |
| **attribute\_code** | String | 8 | Unique identifier for an attribute value within the Clinical Drug Data Set |
| **attribute\_value** | String | 50 | Unambiguous description of an attribute within Clinical Drug Data Set |
| **ccdd\_file\_type** | String | 200 | The name of the specific CCDD file type the attribute is from. |
| **attribute\_ status** | String | 8 | The lifecycle status for the concept in this file. Allowable values for status are “Active”, “Inactive”. |
| **attribute\_ status\_effective\_time** | String (Date) | 8 | The date of the status in this file. Format = YYYYMMDD. |

**The Non-proprietary Therapeutic Product Changes; (ntp\_change\_table)**

A representation of the changes from the previous released version of the ntp\_table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **ntp\_code** | String | 7 | Unique meaningless Non-proprietary Therapeutic Product identifier. |
| **ntp\_formal\_name** | String | 500 | The unambiguous description of the Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar products. |
| **ntp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **ntp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **ntp\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **ntp\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |
| **ntp\_type** | String | 8 | This attribute is used to differentiate combination products. Values = Combination product or Empty. |
| **change\_type** | String | 10 | This attribute provides the types of change applied to any aspect of the concept or applicable attributes. The types of change include “added” or “changed” |

**Therapeutic Moiety Changes;** (**tm\_change\_table)**

A representation of the changes from the previous released version of the tm\_table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **tm\_code** | String | 7 | Unique meaningless Therapeutic Moiety identifier assigned by Health Canada. |
| **tm\_formal\_name** | String | 500 | The unambiguous description of the Therapeutic Moiety that includes details necessary to distinguish it from other similar products. |
| **tm\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **tm\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |
| **change\_type** | String | 10 | This attribute provides the types of change applied to any aspect of the concept or applicable attributes. The types of change include “added” or “changed” |

**Manufactured Product Changes; (mp\_change\_table)**

A representation of the changes from the previous released version of the mp\_table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **mp\_code** | String | 8 | The unique Manufactured Product identifier, that may be a Health Canada assigned DIN or NPN, or an identifier specific to the CCDD. |
| **mp\_formal\_name** | String | 500 | The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar products. |
| **mp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **mp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **mp\_status** | String | 8 | The lifecycle state for the product. Allowable values for status are “Active”, “Inactive”. |
| **mp\_status\_effective\_time** | String (Date) | 8 | The date of the product status in this file. Format = YYYYMMDD. |
| **change\_type** | String | 10 | This attribute provides the types of change applied to any aspect of the concept or applicable attributes. The types of change include “added” or “changed” |

**Device Non-proprietary Therapeutic Product Changes; (Device-ntp\_change\_table)**

A representation of the changes from the previous released version of the Device-ntp\_table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Column** | **Data Type** | **Length** | **Description** |
| **device\_ntp\_code** | String | 7 | Unique meaningless Device Non-proprietary Therapeutic Product identifier |
| **device\_ntp\_formal\_name** | String | 500 | The unambiguous description of the Device Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar products. |
| **device\_ntp\_en\_description** | String | 500 | The user-friendly English description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **device\_ntp\_fr\_description** | String | 500 | The user-friendly French description that may be used for web applications or the user interface for any system. *NB: Not present in the files currently.* |
| **device\_ntp\_status** | String | 8 | The lifecycle status for the concept in this file. Allowable values for status are “Active”, “Inactive”. |
| **device\_ntp\_status\_effective\_time** | String (Date) | 8 | The date of the status in this file. Format = YYYYMMDD. |
| **change\_type** | String | 10 | This attribute provides the types of change applied to any aspect of the concept or applicable attributes. The types of change include “added” or “changed” |