

Canadian Clinical Drug Data Set

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1 Technical Specification; Version 20170919

Date	September 19, 2017
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1.1 About the Technical Specification

This technical specification identifies the data files for distributing the information contained in the Canadian Clinical Drug Data Set. The tables below provide the format and description of the attributes within each of the files. All strings are coded in UTF-8.

1.2 Technical Specification Release Notes 20170919

The Technical Specification has been modified since the July public review to include the following new file types:

- Special Groupings
- Coded Attribute
- Manufactured Product to DIN or NPN Mapping
- Delta Release files for each of the following; Non-proprietary Therapeutic Product, Manufactured Product, Therapeutic Moiety and Device Non-proprietary Therapeutic Product.

The existing Non-proprietary Therapeutic Product, Manufactured Product, Therapeutic Moiety and Device Non-proprietary Therapeutic Product files have been renamed to include the "Full Release" in the name of files.

There is no change to the Manufactured Product, Non-proprietary Therapeutic Product, Therapeutic Product Relationship file format.

1.3 Non-proprietary Therapeutic Product Full Release; (FILE NAME; ntp_full_release_yyyymmdd)

A representation of a brand independent and clinically oriented representation of a manufactured (therapeutic) drug product. The **'Full' release** contains every concept that has ever been released. This release provides a full historical record and can be used to obtain views of the state of any concept at any point in time since its first release. The 'Full' release includes inactive and active concepts.

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 concepts.
ntp_en_description	String	500	The user-friendly English description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
ntp_fr_description	String	500	The user-friendly French description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
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.

Column	Data Type	Length	Description
ntp_type	String	8	This attribute is used to differentiate combination products. Values = "Comb" (for Combination product) or "NA".

1.4 Therapeutic Moiety Full Release; (FILE NAME; tm_full_release_ yyyymmdd)

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). The **'Full' release** contains every concept that has ever been released. This release provides a full historical record and can be used to obtain views of the state of any concept at any point in time since its first release. The 'Full' release includes inactive and active concepts.

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 concepts.
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.

1.5 Manufactured Product Full Release; (FILE NAME; mp_full_release_ yyyymmdd)

The representation of a brand specific drug that is available for prescribing and dispensing in Canada. The '**Full**' release contains every concept that has ever been released. This release provides a full historical record and can be used to obtain views of the state of any concept at any point in time since its first release. The 'Full' release includes inactive and active concepts.

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 Canadian Clinical Drug Data Set.
mp_formal_name	String	500	The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar concepts.
mp_en_description	String	500	The user-friendly English description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
mp_fr_description	String	500	The user-friendly French description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
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.

1.6 Manufactured Product, Non-proprietary Therapeutic Product, Therapeutic Product Relationship; (FILE NAME; mp_ntp_tm_relationship_ yyyymmdd)

Each row represents the relationship between an MP and its NTP, and its TM (where one exists). It will include both active and inactive content from the full release files for the MP, NTP and TM.

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 Canadian Clinical Drug Data Set.
mp_formal_name	String	500	The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar concepts.
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 concepts.
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 concepts.

1.7 Device Non-proprietary Therapeutic Product Full Release; (FILE NAME; device-ntp_full_release_yyyymmdd)

A brand independent and clinically oriented representation of a healthcare device. The '**Full**' **release** contains every concept that has ever been released. This release provides a full historical record and can be used to obtain views of the state of any concept at any point in time since its first release. The 'Full' release includes inactive and active concepts.

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 concepts.
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. <i>NB: Not present in the files currently.</i>
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. <i>NB: Not present in the files currently.</i>
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.

1.8 Special Groupings; (FILE NAME; special_groupings_ yyyymmdd)

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).

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 concept type (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 file .

Column	Data Type	Length	Description
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.

1.9 Manufactured Product to DIN or NPN Mapping; (FILE NAME; mp_to_din_or_npn_mapping_YYYYMMDD)

This file provides a mapping between all of the Manufactured Product (MP) concepts present in the Canadian Clinical Drug Data Set (CCDD) and manufactured 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).

Manufactured products with more granular (specific) representations than what the DINs/NPNs provide are needed in the CCDD to meet clinical 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	The unique Manufactured Product identifier, that may be a Health Canada assigned DIN or NPN, or an identifier specific to the Canadian Clinical Drug Data Set.
mp_formal_name	String	500	The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar concepts.
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) primarily to differentiate similar drug products on the basis of specific characteristics (e.g. single use syringe).

1.10 Coded Attribute; (FILE NAME; coded_attribute_yyyymmdd)

This file provides the coded values used in an attribute field within the CCDD.

Column	Data Type	Length	Description
attribute	String	8	The name of the specific coded attribute from the CCDD file type .
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.

1.11 Non-proprietary Therapeutic Product Delta Release; (FILE NAME; ntp_delta_release_yyyymmdd)

A representation of the changes from the previous released version of the ntp_full_release. Only the NTP concepts that have changed will be provided in this file. The “**Delta' release**” contains only those concepts that have been added or changed since the previous release. The type of changes would include; inactivated and changes to any description.

Column	Data Type	Length	Description
ntp_code	String	7	Unique meaningless Non-proprietary Therapeutic Product identifier.
ntp_formal_name	String	500	

Column	Data Type	Length	Description
			The unambiguous description of the Non-proprietary Therapeutic Product that includes details necessary to distinguish it from other similar concepts.
ntp_en_description	String	500	The user-friendly English description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
ntp_fr_description	String	500	The user-friendly French description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
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 = "Comb" (for Combination product) or "NA".
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"

1.12 Therapeutic Moiety Delta Release; (FILE NAME ; tm_delta_release_ yyyymmdd)

A representation of the changes from the previous released version of the tm_full_release. Only the TM concepts that have changed will be provided in this file. The “**Delta' release**” contains only those concepts that have been added or changed since the previous release. The type of changes would include; inactivated and changes to any description.

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 concepts.
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”

1.13 Manufactured Product Delta Release; (FILE NAME; mp_delta_release_ yyyymmdd)

A representation of the changes from the previous released version of the mp_full_release. Only the MP concepts that have changed will be provided in this file. The “**Delta' release**” contains only those concepts that have been added or changed since the previous release. The type of changes would include; inactivated and changes to any description.

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 Canadian Clinical Drug Data Set.
mp_formal_name	String	500	The unambiguous description of the Manufactured Product that includes details necessary to distinguish it from other similar concepts.
mp_en_description	String	500	The user-friendly English description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
mp_fr_description	String	500	The user-friendly French description that may be used for web applications or the user interface for any system. <i>NB: Not present in the files currently.</i>
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”

1.14 Device Non-proprietary Therapeutic Product Delta Release; (FILE NAME; device- ntp_delta_release_ yyyymmdd)

A representation of the changes from the previous released version of the Device-ntp_full_release. Only the Device-NTP concepts that have changed will be provided in this file. The “**Delta**” release contains only those concepts that have been added or changed since the previous release. The type of changes would include; inactivated and changes to any description.

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 concepts.
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. <i>NB: Not present in the files currently.</i>
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. <i>NB: Not present in the files currently.</i>
device_ntp_status	String	8	The lifecycle status for the concept in this file. Allowable values for status are “Active”, “Inactive”.

Column	Data Type	Length	Description
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”