

ISO 11238:2018 (E)

Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Symbols and abbreviated terms
5	Description of the information modelling principles and practices
5.1	General considerations
5.2	Conceptual overview diagrams
5.3	Section high-level diagrams
5.4	Detailed diagrams
5.5	Relationships between classes
5.6	Notes
5.7	Attributes
5.8	Message exchange format
5.9	Conformance terminology and context as it relates to ISO 11238 and ISO/TS 19844
6	Requirements
6.1	General
6.2	Concepts required for the unique identification and description of substances
6.3	Concepts required for the description of specified substances
6.3.1	Relationship between Substances and Specified Substance Groups
6.4	Naming of substances
6.5	Requirements for unique identifiers
6.6	Existing identifiers and molecular structure representation
7	Types of substances
7.1	General
7.2	Element sets common to multiple types of substances
7.2.1	Structure
7.2.2	Isotope
7.2.3	Modification
7.2.4	Reference information
7.2.4.1	General
7.2.4.2	Substance classification
7.2.5	Source material
7.2.6	Taxonomy
7.2.7	Authentication of Herbal Drugs
7.2.8	Substance codes
7.3	Chemical substances
7.4	Protein substances
7.5	Nucleic acid substances
7.6	Polymer substances
7.7	Structurally diverse substances
7.8	Mixture

8 Defining specified substances

- 8.1 General**
- 8.2 Specified Substance Group 1**
- 8.3 Specified Substance Group 2**
- 8.4 Specified Substance Group 3**
- 8.5 Specified Substance Group 4**
 - 8.5.1 General**
 - 8.5.2 Specified Substance Group 4 Name**
 - 8.5.3 Grade**
 - 8.5.4 Use of analytical data**
 - 8.5.5 Manufacturing**
 - 8.5.6 Version and specification**
 - 8.5.6.1 General**
 - 8.5.6.2 Specification**
 - 8.5.6.3 Identity, Impurity and Potency**
 - 8.5.6.4 Amount**

Annex A (informative) Existing identifiers and molecular structure representations

- A.1 Identifiers**
 - A.1.1 General**
 - A.1.2 CAS Registry numbers**
 - A.1.3 InChI and InChIKey**
 - A.1.4 EC Number**
 - A.1.5 UNII**
 - A.1.6 ASK Number**
 - A.1.7 EV Code**
- A.2 Molecular structure representations**
 - A.2.1 General**
 - A.2.2 Molfile**
 - A.2.3 SMILES**
 - A.2.4 InChI**
 - A.2.5 CDX and CDXML file format**

Page count: 61