

ISO/TS 20451:2026-04 (E)

Health informatics - Identification of medicinal products - Implementation for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

Contents		Page
Foreword		v
Introduction		vi
1 Scope		1
2 Normative references		1
3 Terms and definitions		2
4 Conformance		2
5 Concepts required for the unique identification of pharmaceutical products		2
5.1 General considerations for elements required for the unique identification of pharmaceutical products.....		2
5.2 Principles required for the unique identification of a pharmaceutical product.....		3
6 Identifying characteristics for the identification of pharmaceutical products		4
6.1 Pharmaceutical product identification strata and levels.....		4
6.2 PhPID specified substance.....		5
6.3 Pharmaceutical product specified substance identification (PhPID SpSub).....		6
6.4 Cardinality.....		6
6.5 Representation of strength concentration.....		7
6.6 Pharmaceutical product identifier (PhPID).....		7
6.7 PhPID identity.....		7
7 Ingredient, substance and strength		8
7.1 General considerations.....		8
7.2 Ingredient.....		10
7.2.1 Ingredient role.....		10
7.2.2 Substance.....		11
7.2.3 Specified substance.....		11
7.2.4 Specified substance group.....		11
7.2.5 Confidentiality indicator.....		12
7.2.6 Strength.....		12
7.2.7 Pharmaceutical product code concept for representing the normalised strength for liquid preparations.....		13
7.2.8 Strength (presentation).....		13
7.2.9 Strength (concentration).....		13
7.2.10 Measurement point.....		14
7.2.11 Country.....		14
7.2.12 Reference strength.....		14
7.2.13 Reference substance.....		15
7.2.14 Reference specified substance.....		15
7.2.15 Reference strength measurement point.....		15
7.2.16 Reference strength country.....		15
8 Pharmaceutical product: adjuvants and devices		16
8.1 General considerations.....		16
8.2 Detailed description of pharmaceutical product and device information.....		16
8.2.1 General.....		16
8.2.2 Pharmaceutical product.....		19
Annex A (informative) Messaging: ingredient, substance and strength		23

Annex B (informative) Messaging: pharmaceutical product and device	37
Annex C (informative) Examples representing the foundational data elements for the generation of pharmaceutical product identifiers (PhPIDs)	45
Annex D (informative) Examples of representation of strength	50
Annex E (informative) Requirements to facilitate global implementation	54
Bibliography	66