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**