

# DIN CEN ISO/TS 20451:2026-07 (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 (ISO/TS 20451:2026); English version  
CEN ISO/TS 20451:2026

---

## Contents

	Page
Foreword.....	v
Introduction.....	vi
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>2</b>
<b>4 Conformance.....</b>	<b>2</b>
<b>5 Concepts required for the unique identification of pharmaceutical products.....</b>	<b>2</b>
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
<b>6 Identifying characteristics for the identification of pharmaceutical products.....</b>	<b>4</b>
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
<b>7 Ingredient, substance and strength.....</b>	<b>8</b>
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
<b>Annex B (informative) Messaging: pharmaceutical product and device.....</b>	<b>37</b>
<b>Annex C (informative) Examples representing the foundational data elements for the generation of pharmaceutical product identifiers (PhPIDs).....</b>	<b>16</b>
8.1 General considerations.....	16
8.2 Detailed examples of representation of strength and device information.....	50
8.2.1 General.....	16
8.2.2 Pharmaceutical product.....	19
<b>Annex D (informative) Requirements to facilitate global implementation.....</b>	<b>54</b>
<b>Annex E (informative) Messaging: ingredient, substance and strength.....</b>	<b>23</b>

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



