

ISO 11616:2012-11 (E)

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviations	2
3.1 Terms and definitions	2
3.2 Abbreviations	7
4 Requirements	8
4.1 Elements required for the unique identification of pharmaceutical products	8
4.2 Exchange of pharmaceutical product information	9
5 Identifying characteristics for the identification of pharmaceutical products	9
5.1 Pharmaceutical product identification strata and levels	9
5.2 Cardinality	11
5.3 Representation of strength concentration	12
5.4 Pharmaceutical product identifier (PhPID)	12
5.5 Pharmaceutical product substance stratum elements (PhPID_SUB_Lx)	13
5.6 Pharmaceutical Product Specified Substance Stratum Elements (PhPID_SpSUB_Lx)	15
5.7 Identifying characteristics to express strength	17
6 Relationship between MPID and PhPID	19
6.1 Concepts required for the unique identification of a medicinal product and the association with PhPIDs	19
6.2 Pharmaceutical product identification criteria	21
7 Relationship between IMPID and PhPID	23
8 Conceptual model	25
Annex A (informative) Examples	27
Annex B (informative) Tabled examples	35
Bibliography	38