



भारतीय मानक ब्यूरो

उपभोक्ता मामले), एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार (**BUREAU OF INDIAN STANDARDS**
(Ministry of Consumer Affairs, Food & Public distribution, Govt. of India)

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व्यापक परिचलन मे मसौदा

संदर्भ	दिनांक
एम एच डी 17/टी - 61	20.02.2018

तकनीकी समिति एम एच डी 17

पाने वालो के नाम

- स्वास्थ्य सूचना विज्ञान विषय समिति, एम.एच.डी 17 के सभी सदस्यों को |
- चिकित्सा उपकरण एवम अस्पताल आयोजना विभाग परिषद |
- अन्य सभी रुचि रखने वाले |

प्रिय महोदय/महोदया,

निम्नलिखित प्रलेख सलग्न है :

प्रलेख सख्या : एम एच डी 17(12421)/आईएस/आईएसओ 11615 : 2017

शीर्षक : स्वास्थ्य सूचना विज्ञान — औषधीय उत्पादों की पहचान — औषधीय उत्पाद सूचना की विशिष्ट पहचान और आदान-प्रदान के लिए डेटा एलिमेंट्स और स्ट्रक्चर्स

प्रासंगिक आईएसओ विशिष्टताओं पर आधारित उपरोक्त दस्तावेज की तकनीकी सामग्री एमएचडी से अनुरोध पर प्राप्त किये जा सकते हैं |

कृपया उपरोक्त मानक मसौदे का अवलोकन करे और अपनी सम्मतिया यह बताते हुए भेजे कि अंततः यदि ये मानक राष्ट्रीय मानक के रूप में प्रकाशित हो जाये तो इन पर अमल करने में आपके व्यवसाय अथवा कारोबार में क्या कठिनाइयों आ सकती है |

सम्मतिया यदि कोई हो तो कृपया अगले पृष्ठ पर दिये गये पत्र में अधोहस्ताक्षरी को उपरिलिखित पते पर भेज दे |

सम्मतिया भेजने कि अंतिम तिथि : 22.03.2018

यदि कोई सम्मति प्राप्त नहीं होती है अथवा सम्मति में केवल भाषा संबंधी त्रुटि हुई तो उपरोक्त प्रलेख को यथावत अंतिम रूप दे दिया जायेगा। यदि कोई सम्मति तकनीकी प्रकृति की हुई तो विषय समिति के अध्यक्ष के परामर्श से अथवा उनकी इच्छा पर आगे की कार्यवाही के लिये विषय समिति को भेजे जाने के बाद प्रलेख को अंतिम रूप दे दिया जायेगा।

धन्यवाद,

भवदीय

(प्रकाश बचानी)

वैज्ञानिक 'ई' एवं प्रमुख (एम एच डी)
भारतीय मानक ब्यूरो
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भारतीय मानक ब्यूरो

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**DRAFTS IN
 WIDE CIRCULATION**

DOCUMENT DISPATCH ADVICE	
Ref.	Date
MHD 17/ T- 61	20.02.2018

TECHNICAL COMMITTEE: MHD 17

ADDRESSED TO:

1. All Members of Health Informatics Sectional Committee, MHD17
2. All Members of Medical Equipment and Hospital Planning Division Council (MHDC)
3. All others interested

Dear Sir/Madam(s),

Please find enclosed the following document:

Doc No.: MHD 17(12421)/ IS/ISO 11615 : 2017

TITLE : Health Informatics — Identification of Medicinal Products — Data Elements and Structures for the Unique Identification and Exchange of Regulated Medicinal Product Information

The technical contents of the above document corresponding to relevant ISO specification can be obtained from MHD on request.

Kindly examine the above draft standard and send your views stating any difficulties, which you are likely to experience in your business or profession, if these are finally adopted as National Standard.

Last date for comments: **22.03.2018**

Comments if any, may please be made in the format indicated and mailed to the undersigned at the above address. In case no comments are received or comments received are of editorial nature, you will kindly permit us to presume your approval for the above document as finalized. However, in case comments of technical nature are received then it may be finalized either in consultation with the Chairman, Sectional Committee or referred to the Sectional committee for further necessary action if so desired by the Chairman, Sectional Committee.

Thanking you,

Yours sincerely,

(Prakash Bachani)
Scientist 'E' & Head (MHD)
Bureau of Indian Standards
9, B. S. Zafar Marg
New Delhi - 110002

Encl: As above

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भारतीय मानक मसौदा

स्वास्थ्य सूचना विज्ञान — औषधीय उत्पादों की पहचान — औषधीय उत्पाद सूचना की विशिष्ट
पहचान और आदान-प्रदान के लिए डेटा एलिमेंट्स और स्ट्रक्चर्स

Draft Indian Standard

**Health Informatics — Identification of Medicinal Products — Data
Elements and Structures for the Unique Identification and Exchange of
Regulated Medicinal Product Information**

ICS 35.240.80

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Health Informatics Sectional Committee, MHD 17

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 11615 : 2017 ‘Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information’ issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Health Informatics Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 3166-1 ¹⁾ Codes for the representation of names of countries and their subdivisions — Part 1 : Country codes	IS 14836 (Part 1) : 2009 Codes for the representation of names of countries and their subdivisions : Part 1 Country codes (<i>first revision</i>)	Identical with ISO 3166-1 : 2006
ISO 8601 Data elements and interchange formats — Information interchange — Representation of dates and times	IS 7900 : 2007 Data elements and interchange formats — Information interchange — Representation of dates and times (<i>third revision</i>)	Identical with ISO 8601 : 2004
ISO 11238 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances	IS/ISO 11238 : 2012 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances (<i>under publication</i>)	Identical with ISO 11238 : 2012

¹⁾ Since revised in 2013.

ISO 11239 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging	IS/ISO 11239 : 2012 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (<i>under publication</i>)	Identical with ISO 11239 : 2012
ISO 11240 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement	IS/ISO 11240 : 2012 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement (<i>under publication</i>)	Identical with ISO 11240 : 2012
ISO 11616 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information	IS/ISO 11616 : 2017 Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (<i>under publication</i>)	Identical with ISO 11616 : 2017

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard/Other Publication</i>	<i>Title</i>
ISO 639-1	Codes for the representation of names of languages — Part 1: Alpha-2 code
ISO/TS 19844	Health informatics — Identification of Medicinal Products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances
ISO/TS 20440	Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
ISO/TS 20443	Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information
ISO/TS 20451	Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

ISO/IEC 5218

HL7 Version 3 Standard

Information technology — Codes for the representation of
human sexes
Structured Product Labelling

Note : This draft is the adoption of ISO 11615: 2017, which is available on the ISO website.

For the technical content of the above document, please contact :

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