



NSAI
Standards

Standard Recommendation
S.R. CWA 15914-1:2009

Criteria, methodology and procedures
for creating an Ecodification
concerning substances used in
Pharmaceutical
compounding

S.R. CWA 15914-1:2009

Incorporating amendments/corrigenda issued since publication:

<i>This document replaces:</i>	<i>This document is based on:</i> CWA 15914-1:2009	<i>Published:</i>	
This document was published under the authority of the NSAI and comes into effect on: 27 February, 2009		ICS number: 35.240.80	
NSAI 1 Swift Square, Northwood, Santry Dublin 9	T +353 1 807 3800 F +353 1 807 3838 E standards@nsai.ie W NSAI.ie	Sales: T +353 1 857 6730 F +353 1 857 6729 W standards.ie	Price Code: K
Údarás um Chaighdeáin Náisiúnta na hÉireann			

CEN

CWA 15914-1

WORKSHOP

January 2009

AGREEMENT

ICS 35.240.80

English version

Criteria, methodology and procedures for creating an E-codification concerning substances used in Pharmaceutical compounding

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Contents	2
Foreword	4
1. Scope	5
2. Normative References	6
3. Definitions and abbreviations	7
3.1 Definitions	7
3.2 Abbreviations	9
4. The source of data	10
4.1 Supplier of substances	10
4.2 Pharmacopoeia	10
4.3 Reference books and reviews	10
4.4 Scientific committee	10
4.5 Maintenance	10
5. The Criteria of E-codification	11
5.1 Criteria of identicalness	11
5.2 Criteria of therapeutic similarity	11
5.3 Criteria of pharmacological properties	11
6. The structure of the database	13
6.1 The E-codification	13
6.1.1 The first key	13
6.1.2 The second key	13
6.1.3 The third key	13
6.2 Data structure of the basic pharmaceutical information on the substance	13
6.2.1 Preferred Name	13
6.2.2 Notes	14
6.2.3 CAS number	14
6.2.4 Group	14
6.2.5 Density	15
6.2.6 Melting point	15
6.2.7 Doping code	15
6.2.8 Substance and Supplier evaluation	15
6.2.9 Molecular weight	15
6.3 Substance record	15
6.4 Data structure of the Synonyms	16
6.4.1 Synonyms first key	16
6.4.2 Synonyms	16
6.4.3 Reference country code	16
6.4.4 Reference source	16
6.4.5 Language	16
6.5 Synonyms record	16
6.6 Data structure of the essential pharmacological information on the substance	16
6.6.1 Dose first key	16
6.6.2 ATC code	16
6.6.3 DDD	17
6.6.4 Average daily dose	17
6.6.5 Maximum daily dose	17
6.6.6 Minimum daily dose	17
6.6.7 Unit of measurement	17
6.6.8 Route of administration code / Application type	17
6.6.9 Route of administration description / Application type description	17
6.6.10 Patient target	18
6.6.11 Source of information	18
6.6.12 Note	18
6.6.13 MedDRA code	18
6.6.14 MedDRA description	18
6.7 Dose record	18
6.8 Data structure of the national information	19
6.8.1 National information first key	19

6.8.2	National notes	19
6.8.3	Reference country code.....	19
6.8.4	Country name	19
6.8.5	Language	19
6.8.6	Any field needs for specific national information	19
6.9	National information record.....	19
6.10	Data structure of the Supplier record.....	20
6.10.1	Supplier first key	20
6.10.2	Company name.....	20
6.10.3	Reference country code.....	20
6.10.4	Country name	20
6.10.5	Address of the registered office	20
6.10.6	Postal code of the registered office	20
6.10.7	City of the registered office	20
6.10.8	Province of the registered office	20
6.10.9	Address of operative seat	20
6.10.10	Postal code of the operative seat	20
6.10.11	City of operative seat	20
6.10.12	Province of operative seat	20
6.10.13	Tax number.....	20
6.10.14	Telephone number for orders	20
6.10.15	Fax number for orders	21
6.10.16	E-mail address for orders	21
6.10.17	Sales officer's name	21
6.10.18	Sales officer's telephone number	21
6.10.19	Sales officer's e-mail.....	21
6.10.20	Telephone number.....	21
6.10.21	Fax number.....	21
6.11	Supplier record.....	21
6.12	Chart of data structure	23
Annex A	: Part of plants	24
Annex B	: Production processes and general treatments for herbal preparations.....	29
Annex C	: Solvents for herbal, animal and mineral preparations	30
Annex D	: Physical form for substances with herbal and animal origin.....	31
Annex E	: Part of the animal.....	34

Foreword

The present CWA sets forth criteria and methodologies, addressed to scientific editors, to be followed for the implementation of a databank concerning substances used by compounding pharmacists for preparing “Magistral Formula” and “Formula Officinalis”, as endorsed by the CEN/ISSS Workshop on Pharmaceutical Compounding E-codification Methodology (WS/PCEC), which was established on Oct 15th 2007

A list of the individuals and organizations which supported the technical consensus represented by this CEN Workshop Agreement is available to purchasers from the CEN/ISSS. The present CWA (CEN Workshop Agreement) has received the support of representatives of a variety of backgrounds: pharmacists, physicians, pharmacologists, representatives of European institutions in the pharmaceutical field, health informatics experts.

These specifications represent a first step into technical specifications concerning pharmaceutical compounding. The present CWA is a reference document for the competent working groups within the Joint Initiative ISO/CEN/HL7, for E-health and for regulatory agencies.

Within ISO TC 215 (Health Informatics) WG 6 work is ongoing on Identification of Medicinal Products - Product Information for Drug Dictionaries (MPID). ISO(-EN) standards is planned for the year 2010 - This CWA might need to be revised after the publication of the ISO(-EN) standard. The ISO/EN standard does not specifically address compounding pharmacy, the field of 'magistral formula' and “formula officinalis” as defined by Council Directive 83/2001, which is instead the focus of this CWA.

This CEN Workshop Agreement was endorsed electronically; the endorsement process ended on 20 September 2008. The Workshop was chaired by Alessandra Pastorino, consultant.

The following organizations have expressed support to the publication of the CWA

International Society of Pharmaceutical Compounding
Italian Society for Pharmacology
Pharmacy On Line Trade Sr.
SACCHI – Studio di Consulenza
Società Italiana Farmacisti Preparatori (SIFAP)

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN : AENOR, AFNOR, ASRO, BDS, BSI, CSNI, CYS, DIN, DS, ELOT, EVS, IBN, IPQ, IST, LVS, LST, MSA, MSZT, NEN, NSAI, ON, PKN, SEE, SIS, SIST, SFS, SN, SNV, SUTN and UNI.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN Management Centre.

1. Scope

The domain addressed by this CWA is the E-codification of substances used by compounding pharmacists in pharmaceutical compounding.

The present document specifies the technical requirements for creating the record structure and E-codification of the various substances supplied by commercial suppliers and used by the pharmacist in the pharmacy for preparing “Magistral Formula” and “Formula Officinalis” as defined by the European Directive 2001/83, Article 3, Paragraph 1) and 2).

The CWA includes a record of the supplier of substances.

“Magistral Formula” and “Formula Officinalis” are not themselves part of the present CWA

The users of the CWA are the editors of a databank. In this sense the CWA is not addressed to the final users of the databank but to the subjects which realize and implement the databank (the editors)

The purpose of the CWA is to define certain criteria the editors have to comply with, in realizing a databank in order to:

- (i) allow an unique identification of the single substance in order to avoid any possible misunderstanding;
- (ii) provides pharmacists and physicians with the basic information on each single substance and its administration (see paragraph 6.2, 6.4, 6.6, 6.8);
- (iii) provides pharmacists and physicians with indication on the availability of the substance on the European and international market;

The CWA aims at setting forth the basis for establishing a unique language for compounding pharmacists, physicians and providers to the pharmacy of substances.

The CWA proposes to fill a gap, in terms of harmonization, that characterizes the pharmaceutical compounding. This shall allow:

- (i) an increase in the sharing of scientific information concerning substances used in pharmaceutical compounding and basic pharmacological and administration information among physicians and pharmacists;
- (ii) a development of the pharmacy compounding;
- (iii) An increased in ADR reporting concerning substances used in pharmaceutical compounding by physicians, pharmacists and consumers.

Any authorized medicinal product is out of the scope of the present CWA.

The groups of substances which fall under the scope of the present document are the followings:

- **Synthetic substances**
- **Semi-synthetic substances**
- **Crude drug substances**

The above groups are listed with respect to origin.
See definitions on “substances” and “crude drug substances”.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-