Topic: NORMATIVE DOCUMENTATION for MEDICAL and PHARMACEUTICAL GOODS

The objective: to study kinds, structure, designations, scope of normative documents necessary for carrying out inspection analysis of medical and pharmaceutical goods.

Basic concepts and terms which should be acquired by students during their training and studying

Quality of product, standardization, level of standardization, normative document, standard, international standard, national standard, branch standard, standard of company, codex, qualifier, catalogue, register, specifications, regulation, analytical reference documentation, State Ukrainian Pharmacopoeia, European Pharmacopoeia, British Pharmacopoeia.

Questions for self-training

1. Quality of production and ways of its check.
2. Levels, purposes, tasks and principles of standardization.
3. Subjects and objects of standardization.
4. Kinds of normative documents (ND).
5. Kinds of standards.
6. Designations of normative documents.
7. The normative documents establishing requirements for quality of drugs and medicinal plant raw material.
8. The normative documents establishing requirements for products of medical purpose.
9. Structure of standards, specifications, analytical reference documentation (ARD). Basic, mandatory and optional parts of standards.
10. Validity terms of standards.

Maintenance of the class

1. Tests for control of student knowledge about the class topic.
2. Normative documents: standards (ДСТУ, ISO, GOST, ГСТУ, СТП), specifications, ARD, State Ukrainian Pharmacopoeia (SUPh), European Pharmacopoeia 3rd ed. (CD-version), British Pharmacopoeia 1999 (CD-version), catalogues, qualifiers, manuals.

Task N 1

To get acquainted with contents and structure of standards offered by the teacher and to make the conclusion about its conformity to corresponding national ND (e.g., DSTU 1.5:2003 for Ukrainian ND). To write out the sections necessary for inspection analysis:

- general technical requirements;
- labeling;
- packing;
- conditions of transportation and storage;

Write down results in table 1 using sample below.

Working Technique for Task N 1

For example, the DSTU ISO standard 780-2001 “Packing. Graphical Symbols for use in the Labelling of Transport Containers” is offered for the work.

Studying of the standard is performed in two stages.

Stage 1. To find designation of the standard, level of standardization, object of standardization, a kind of the standard, body accepted the standard; date of standard approval and a scope.

On the title page of the standard the following is specified: object of standardization – graphical symbols for use in the labelling of transport containers, designation of the standard – DSTU ISO 780-2001.

Developers of the standard, information about the state body accepting the standard, approval date and number of the report about approval are specified in the foreword.

We determine level of standardization. The given standard is national one.

Kind of the standard – basic.

The scope of the given standard specifies object of standardization (for symbols used to label transport containers).

Stage 2. We analyze structure of the standard offered, using the Annex 1.1. We judge about presence of the basic and obligatory sections in the standard.

The investigated standard contains all obligatory structural elements: title page, foreword, name, scope, requirements to object of standardization, bibliographic data. Besides it contains section "contents".

Results of the work are described in table 1.

Task N 2

To get acquainted with contents and structure of the analytical reference documentation offered by the teacher and to make the conclusion about its conformity to Order of MoH of Ukraine from 26.08.2005 № 426. To write out the

sections necessary for carrying out of inspection analysis:

- packing, labelling;
- transportation;
- storage.

Write down results of study into table 2 using sample below.

Table 1.

Results of studying DSTU ISO 780-2001 standard

Basic sections and elements of the standard	The investigated standard
1. Designation of the standard	DSTU ISO 780-2001
2. Level of standardization	National standard of Ukraine based on the international ND – ISO 780-2001
3. Object of standardization	Graphical symbols for use in the labelling of transport containers
4. Kind of the standard	Basic
5. The body which has accepted the standard	The state committee of Ukraine for problems of technical regulation and consumer policy
6. Date of standard approval	1.04.2002
7. Scope of the standard	Symbols used for labeling of transport containers
8. Presence of the basic and obligatory sections in the standard	The standard contains all obligatory sections: title page, foreword, name, scope, requirements to object of standardization, bibliographic data. Besides the standard contains section "contents".

Working Technique for Task N 2

For example, the ARD “Tabulettae Pyracetami 0,2 obductae № 10 in blister package” is offered.

Studying of the analytical reference documentation is performed in two stages.

Stage 1. We determine object of standardization, name of the manufacturer, the body ratified the ARD, date of its approval, presence of the basic sections and appendices.

On the title page there are: object of standardization – Tabulettae Pyracetami 0,2 obductae, name of the manufacturer, body ratified the ARD and date of its approval.

Stage 2. We investigate structure of the ARD, using Annex 1.1. We judge about presence of all basic sections in the ARD.

The ARD contains all basic sections: title page, structure, specification, quality control, packing, labeling, transportation, storage and main pharmacological action.

Sections "specification" and "quality control" include such subitems: description, identification, average weight, solubility, microbiological purity, quantitative determination.

The ARD contains also an original design for package of the drug.

Results of study of the ARD are submitted in table 2.

Table 2

Results of studying of ARD Tabulettae Pyracetami 0,2 obductae

The basic sections and elements of the ARD	The ARD for a drug
1. Object of standardization	"Tabulettae Pyracetami 0,2 obductae" – coated pyracetame tablets 0,2 g № 10 in blister package and box
2. Name of the manufacturer	Company "Halychpharm" Ltd.
3. The body ratifying the ARD	State pharmacological center of MoH of Ukraine
4. Date of approval	15.10.2004
5. Presence of basic sections	The ARD contains all basic sections: title page, structure, specification, quality control, packing, labelling, transportation, storage and main pharmacological action.
6. Presence of appendices	Original design for package of the drug

Task N 3

To get acquainted with the contents and structure of specifications offered by the teacher and to make a conclusion about its conformity to DSTU 1.3:2003. To write the sections necessary for carrying out of inspection analysis:

- technical requirements (parameters and sizes, basic indexes and characteristics, requirements to raw materials, purchased products, completeness, labelling, packing);
- acceptance procedures;
- transportation and storage;

To write down results of the study into table 3 using sample below.

Working Technique for Task N 3

For example, for analysis specifications 1811-002-45094918-97 “Гнучка упаковка у рулонах на основі алюмінієвої фольги для лікарських препаратів” are offered.

Study of the specifications is performed in two stages.

Stage 1. We determine designation of the specifications; object of standardization, the body (person) ratified the specifications, date of their approval and scope.

On the title page of the specifications there are: designation of the specifications ТУУ 1811-002-45094918-97; object of standardization – flexible packing in rolls on base of aluminum foil for drugs; body (person) who ratified the document - Prime director of the Company «Siberian aluminium» Ltd.; date of approval- 05.11.1997.

In section "scope" it is specified: for packing of drug products.

Stage 2. We investigate structure of specifications offered, using Annex 1.1. We judge about presence of the basic sections.

Specifications contain all basic sections: scope, technical requirements (parameters and sizes, the basic indexes and characteristics, requirements to raw materials, purchased products, completeness, labelling, packing), sanitary-and-hygienic requirements, acceptance procedures, quality control, transportation and storage, manufacturer's warranty, safety requirements.

Besides, the given specifications contain 2 appendices.

Results of studying are submitted in table 3.

Table 3

Results of studying of the specifications ТУУ 1811-002-45094918-97

The basic sections and elements of specifications	Investigated specifications
1. Designation of specifications	ТУУ 1811-002-45094918-97
2. Object of standardization	Flexible packing in rolls on base of aluminum foil for drugs
3. The body (person) which has ratified the specifications	Prime director of the Company «Siberian aluminium» Ltd.
4. Date of approval	05.11.1997
5. Scope of the specifications	For packing of drug products

6. Presence of the basic sections in specifications	Specifications contain all basic sections: scope, technical requirements (parameters and sizes, basic indexes and characteristics, requirements to raw materials, purchased products, completeness, labelling, packing), sanitary-and-hygienic requirements, acceptance procedures, quality monitoring, transportation and storage, manufacturer's warranty, safety requirements

Task N 4

To decode designations of normative documents offered by the teacher.

Working Technique for Task N 4

We decode designations of normative documents (examples):

1) DSTU 3763:2005

DSTU – index of the national standard of Ukraine;
3763 - registration number;
2005 - year of approval.

2) DSTU ISO 9591:2005

DSTU ISO – index of the national standard which authorizes the international standard in Ukraine;
9591 - registration number of the international standard;
2005 - year of approval in Ukraine.

3) DSTU EN 12021:2004

DSTU EN – index of the national standard which authorizes the European standard in Ukraine;
12021 - registration number of the European standard;
2004 - year of approval in Ukraine.

4) DSTU GOST 30765:2003

DSTU GOST – index of the national standard which authorizes the interstate standard (GOST) in Ukraine;
30765 - registration number of the standard;
2003 - year of approval.

5) GOST 16427-93

GOST –index of interstate standard;

16427 - registration number;
1993 - year of approval.

6) ГСТУ (GSTU) 21-216-2002
ГСТУ –index of the branch standard of Ukraine;
21 - symbol of the ministry (department);
216 - registration number;
2002 - year of approval.

7) Specifications ТУ У 27.1-21987647-001:2005
ТУУ –index of specifications in Ukraine;
27.1 - code of the product according to State Classifier (first 3 digits);
21987647 - code of the organization – proprietor of specifications;
001 - registration number which manufacturer gives to specifications;
2005 - year of approval.

8) SOU (СОУ**) 64-21987647-001:2005**
СОУ –index of the standard of companies in Ukraine;
64 - symbol of the ministry;
21987647 - code of organization – proprietor of the standard;
001 - registration number which is given by proprietor of the standard;
2005 - year of approval.

9) STP СТП 64-01973118-005-2003
СТП –index of the enterprise standard;
64 - symbol of the ministry;
01973118 - code of organization - proprietor of the standard;
005 - registration number which is given by proprietor of the standard;
2003 - year of approval.

ANNEX 1

1.1. The basic sections of normative documents

Sections of standards (according to DSTU 1.5:2003)	Sections of specifications (according to DSTU 1.3:2003)	Sections of ARD (according to Order of MoH of Ukraine № 426 dated by 26.08.2005)
Elements of preface **1.title page*** **2.foreword*** 3.contents 4.introduction Elements of the basic part **5. name*** **6. scope*** 7. normative references, terms and definitions 8. designations and abbreviations **9. requirements to object of standardization*** 10. appendices **11. bibliographic data***	1. scope; 2. normative references; 3. technical requirements (parameters and sizes, basic indexes and characteristics, requirements to raw materials, auxiliary materials, purchased products, completeness, labeling, packing); 4. requirements for safety; 5. requirements for preservation of environment and recycling; 6. acceptance procedures; 7. quality control (tests, analysis, measurements); 8. transportation and storage; 9. requirements for operation, repair, manual for application; 10. warranties of manufacturer	1. title page; 2. composition of a drug with of quantitative and qualitative characteristics of active and additional substances; 3. specifications at release and during shelf-life with indication of quality parameters, their tolerances and reference on quality control technique; 4. quality control techniques for the drug; 5. package (the description of initial and outer package); conditions of storage; 7.shelf-life.

* - obligatory elements of the standard

1.2. Example of regional (European) standard EN 980:1996 (photocopy)

EUROPEAN STANDARD **EN 980**

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2003

ICS 01.080.20; 11.040.01; 11.120.01

Supersedes EN 980:1996

English version

Graphical symbols for use in the labelling of medical devices

Symboles graphiques utilisés pour l'étiquetage des dispositifs médicaux

Graphische Symbole zur Kennzeichnung von Medizinprodukten

This European Standard was approved by CEN on 9 January 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 980:2003 E

Contents

1 Scope

This European Standard specifies graphical symbols for use in the information supplied by the manufacturer with medical devices (including in vitro diagnostic medical devices).

NOTE This standard does not specify the circumstances under which particular symbols are used. Guidance on this is given in EN 1041.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 375:2001, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 376:2002, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

EN 556-1:2001, *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices.*

EN 28601:1992, *Data elements and interchange formats - Information interchange - Representation of dates and times (ISO 8601:1988 and its technical corrigendum 1:1991).*

3 General requirements

Graphical symbols used to convey the information given in 4.2 to 4.11 and 5.2 to 5.9 are given in this standard.

NOTE 1 Other symbols can be used to convey other information. Where graphical symbols are not taken from a Harmonized Standard, their meaning should be described in the documentation supplied with the device. Many other standards specify symbols for particular purposes and/or for particular kinds of device. The Bibliography lists some of these standards.

Enclosures shown in 4.2, 4.4, 4.7, 4.8.1, 4.8.2, 4.8.3, 4.10, 4.11, 5.3, 5.4, 5.6 and 5.8 shall be included as part of these symbols.

NOTE 2 The use of similar enclosures around other symbols is not precluded (e.g. 4.5 and 4.9).

All symbols and accompanying information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary, at a distance which takes into account the specifics and size of the individual medical device.

NOTE 3 Colours and minimum dimensions are not specified in this standard.

4 Symbols already in use

4.1 General

This clause presents symbols that are well-understood and already in use and are recognised to be suitable without need for further explanation.

1.3. Example of national (Australian / New Zealand) standard

AUSTRALIAN / NEW ZEALAND STANDARD 4179:1997
ISO 10282:1994

SINGLE-USE STERILE SURGICAL RUBBER GLOVES — SPECIFICATION

Originated in Australia as AS 4179 —1994. Jointly revised and designated AS/NZS 4179:1997.

PUBLISHED JOINTLY BY: STANDARDS AUSTRALIA 1 The Crescent, Homebush NSW2140 Australia

STANDARDS NEW ZEALAND Level 10, Radio New Zealand House, 155 The Terrace, Wellington 6001 New Zealand

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/14 on Surgical Apparel, to supersede AS 4179—1994, *Single use (sterile) rubber surgical gloves.* It is technically equivalent to, and reproduced from ISO 10282, *Single-use sterile surgical rubber gloves—Specification.*

The objective of this Standard is to achieve an acceptable level of safety to protect the patient and the user from cross-contamination.

In some parts of this Standard, the Australian/New Zealand requirements differ from the ISO Standard. To accommodate these differences, a marginal bar is placed alongside the ISO text, and Appendices XX and YY detail the Australian/New Zealand specifications for the deviations.

At the request of the Therapeutic Goods Administration in Australia and the Ministry of Health in New Zealand, the sampling and conformance requirements from ISO 10282 have been retained for use by the regulatory authorities when they conduct testing.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

As this Standard is reproduced from an International Standard, the following applies:

(a) The number appears on the cover and title page while the International Standard number appears only on the cover.

(b) In the source text, 'this International Standard' should read 'this Australian/New Zealand Standard'.

(c) A full point substitutes for a comma when referring to a decimal

marker.

(d) The reference to International Standards should be replaced by the equivalent Australian Standards, as follows:

Reference to International Standard

ISO

37 Rubber, vulcanized or thermoplastic— Determination of tensile stress-strain properties

188 Rubber, vulcanized—Accelerated ageing or heat-resistance tests

2859-1 Sampling procedures for inspection by attributes. Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

4648 Rubber, vulcanized or thermoplastic — Determination of dimensions of test pieces and products for test purposes

7000 Graphical symbols for use on equipment — Index and synopsis

Australian Standard

AS 1683.11 Methods of test for elastomers. Method 11: Tension testing of vulcanized rubber

1683.26 Methods of test for elastomers. Method 26: Rubber, vulcanized— Accelerated ageing or heat-resistance tests

1199 Sampling procedures and tables for inspection by attributes

CONTENTS

AUSTRALIAN/NEW ZEALAND STANDARD

Single-use sterile surgical rubber gloves Specification

1 Scope

This International Standard specifies requirements for packaged sterile

gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination. It is applicable to single-use gloves that are worn once and then discarded. It does not apply to examination or procedure gloves.

This standard is intended as a reference for the performance and safety of rubber surgical gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling and storage procedures are outside the scope of this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subjectto revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 37:1994, *Rubber; vulcanized or thermoplastic — Determination of tensile stress-strain properties.*

ISO 188:1982, *Rubber; vulcanized — Accelerated ageing or heat-resistance tests.*

ISO 2859-1:1989, *Sampling procedures for inspection by attributes — Part 7: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 4648:1991, *Rubber, vulcanized or thermoplastic — Determination of dimensions of test pieces and products for test purposes.*

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

3 Classification

Gloves are classified by type, design and finish as follows:

3.1 Type

Two types are classified:

type 1: gloves made primarily from natural rubber latex;

type 2: gloves made primarily from synthetic rubber latex or from a solution of rubber.

3.2 Design

Two designs are classified:

design R: gloves with straight fingers;

design C: gloves with fingers curved in the palmar direction.

3.3 Finish

Two finishes are classified:

finish T: textured surface over part or all of the glove;

finish P: smooth surface.