Package, marking of drugs

Plan of the lecture:

1. Classification of finished drug products (FDP).
2. General requirements showed to quality of FDP.
3. Packages for FDP and requirements showed to them.
4. Marking of FDP package.

Classifying of finished drug products

- By pharmacological action
- By application method
- By kinds of containers and package
- By aggregative state
- By shelf-lives
- By storage conditions
- By toxicity

By aggregative state all drugs are classified as:

Parameters of drug quality

Consumer ones

- Dosage form
- Appearance
- Package

Organoleptic ones

- Color
- Smell
- Taste

Quality parameters of drugs to be inspected by a pharmacist while accepting them

Tablets

- Proper shape
- Unbroken edges without honeycombed areas
- The surface should be smooth and homogeneous

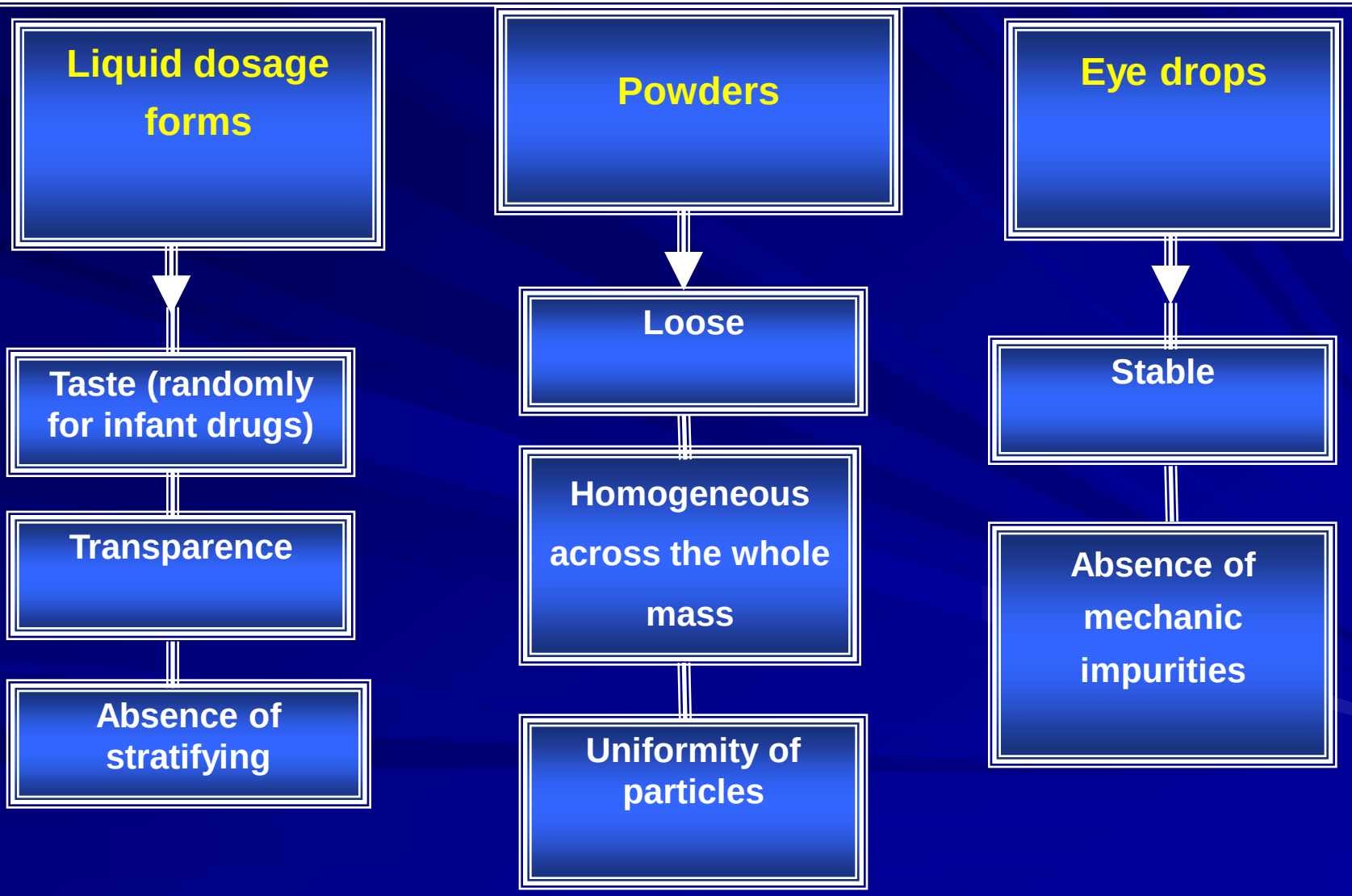
Dragee

- Proper spherical shape
- Homogeneous in colouring
- Equal and smooth

Granules

- Homogeneous in colouring
- Their size should be 0,2-3 mm
- Quantity of smaller and larger particles should not exceed 5 %

Quality parameters of drugs to be inspected by a pharmacist while accepting them



Quality parameters of drugs to be inspected by a pharmacist while accepting them

Solutions for injections

- Absence of mechanic impurities
- Colouring should correspond to those of the reference solution

Ointments and liniments

- Should have capability to smearing
- Plastic
- Homogeneous

Suppositories

- Homogeneous
- Proper shape stated in RD
- Sufficient hardness

Quality parameters of drugs to be inspected by a pharmacist while accepting them

Plasters

- Homogeneous
- The sticky layer should have necessary adhesion onto skin

Capsules

- **Proper shape**
- Transparent or painted
- Should not have air bubbles
- Should not have dust

Pressurized drugs

- Package should provide tightness (absence of signs of leakage)

Package of drugs

The purposes of drug package

To keep quality of contents during all roads from the manufacturer to the consumer

To protect from harmful influence of environment

To provide rational preparation of substances for transportation, moving, warehousing and consumption

In case of group package to form the block convenient for manipulation (moving)

Classifying of package

Initial (immediate) → is intended to provide necessary conditions for long safety of medical products therein

Secondary (outer) → is intended for protection of initial (immediate) packages and for more detailed complex of informative data

Group → Represents group of initial or secondary packages

Transport → It is package in transport containers in which production is delivered to destination points

General requirements to package of drugs

To keep quality of contents during the whole transit chain from manufacturer to consumer

To maintain convenience of transportation, storage and consumption of production

To be convenient for carrying and application

To contain all necessary information about drug product

To have attractive appearance

To provide opportunity for withdrawing of certain portions of contents preventing contamination of the remaining drug

To support cleanliness of a surface or sterility of a drug

Printed text should be precise and contrast

To prevent hide illegal opening of a package before application

To provide aesthetic influence on a consumer

To have high aesthetic and technological level of marking

To have proper color design for a certain pharmacotherapeutic group

Development of marking for drug package in Ukraine

The law of Ukraine about drugs 1996

Фрагмент

ЗАКОН УКРАЇНИ

Про лікарські засоби

Відомості Верховної Ради (ВВР), 1996, N 22, ст. 86)

(Вводиться в дію Постановою ВР N 124/96-ВР від 04.04.96, ВВР, 1996, N 22, ст. 87)

{ Із змінами, внесеними згідно із Законами
N 70/97-ВР від 14.02.97, ВВР, 1997, N 15, ст.115
N 783-XIV від 30.06.99, ВВР, 1999, N 34, ст.274
N 3370-IV від 19.01.2006, ВВР, 2006, N 22, ст.184
N 362-V від 16.11.2006, ВВР, 2007, N 3, ст.30
N 1034-V від 17.05.2007, ВВР, 2007, N 34, ст.446 }

Article 12. Marking of drugs

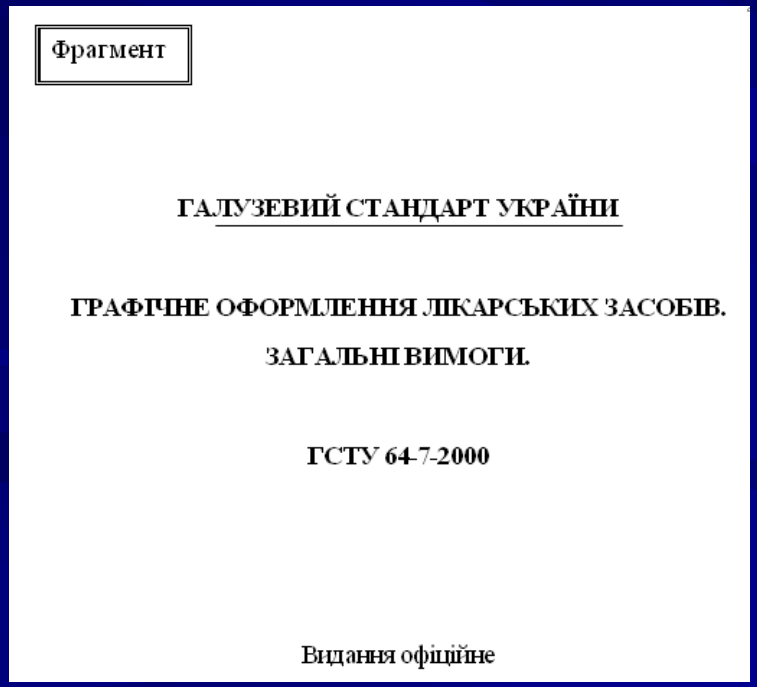
Marking printed onto a label, outer and initial package of drugs, must contain the following information:

- **name of a drug;**
- **name and address of its manufacturer;**
- **registration number;**
- **batch number;**
- **methods of application;**
- **dose of active ingredient in each unit and their amount in package;**
- **shelf-life;**
- **storage conditions;**
- **precautions.**

Development of marking for drug package in Ukraine

The Branch Standard of Ukraine. Graphic Design of Drugs. General requirements.

2000



Фрагмент

ГАЛУЗЕВИЙ СТАНДАРТ УКРАЇНИ

ГРАФІЧНЕ ОФОРМЛЕННЯ ЛІКАРСЬКИХ ЗАСОБІВ.
ЗАГАЛЬНІ ВИМОГИ.

ГСТУ 64-7-2000

Видання офіційне

Paragraph 2.1. Requirements for text

Text of drug marking must contain the following information in Ukrainian:

- **name of a country;**
- **name of a drug;**
- **name, trademark and address of manufacturer;**
- **indication of dosage form;**
- **quantity of a drug;**
- **dose of active ingredient(s) and list of necessary aids (for parenteral, ophthalmic and topical drugs - the full list of aids); in each unit and their amount in package;**
- **registration number;**
- **barcode;**
- **batch number;**
- **methods of application (optional);**
- **shelf-life;**
- **storage conditions;**
- **precaution “Keep away from children”.**

Development of marking for drug package in Ukraine

The Branch Standard of Ukraine.
Graphic Design of Drugs. General requirements.

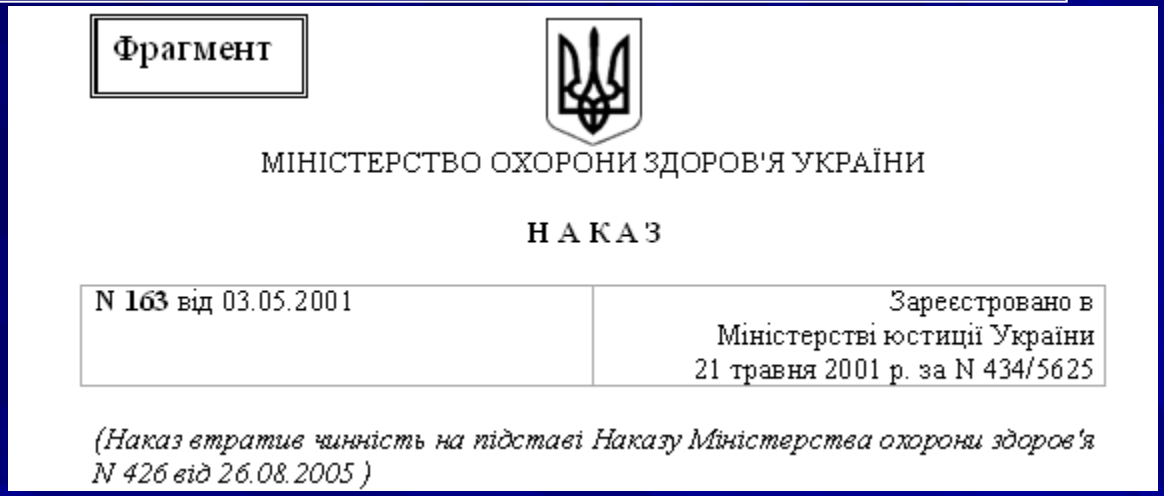
Dosage form	Type of package	Country	Enterprise Address	Trademark	Name of drug in Latin and Ukrainian language	Dosage, activity	Quantity in packing	Composition	Storage conditions	Registration number	Batch number	Shelf-life	Bar code	Precaution inscriptions	Sterility	Method of administration
1	2	3	4	5		7	8	9	10	11	12	13	14	15	16	17
Injection drugs	Retail container:															
	ampoule	-	- -	-	- +	+	+	-	-	-	+	-	-	-	-	-
	vial	+	+ +	+	- +	+	+	+	+	+	+	+	-	-	+	+
	syringe-tube	-	+ -	-	- +	+	+	-	-	-	+	+	-	-	-	-
	pack	+	+ +	+	+ +	+	+	+	+	+	+	+	+	+	+	+
	box	+	+ +	+	+ +	+	+	+	+	+	+	+	+	+	+	+
	group container	+	+ +	+	+ +	+	+	+	+	+	+	+	+	+	+	+

Development of marking for drug package in Ukraine

The Order of MoH of Ukraine N 163

from 03.05.2001

became non-valid since 26.08.2005



Фрагмент

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ

НАКАЗ

N 163 від 03.05.2001	Зареєстровано в Міністерстві юстиції України 21 травня 2001 р. за N 434/5625

(Наказ втратив чинність на підставі Наказу Міністерства охорони здоров'я N 426 від 26.08.2005)

3.5.2. Onto primary package of small size (ampoule, tube-dropper, syringe-tube and others like that), which is placed into outer package that conforms to requirements of p. 3.4, the following data should be printed:

- name of a drug, and if necessary also its dose and way of administration;

- weight, volume, concentration or quantity of dosage units;

- number of production batch;

- shelf-life.

If area of a primary container is not enough the first three abovementioned subitems must be printed.

(Section 3 is amended with the paragraph 3.5 according to the Order of MoH N 442 from 01.11.2001)

Development of marking for drug package in Ukraine

Now in Ukraine marking of drug package is regulated by Order of MoH № 426 with amendments introduced by Orders of MoH №№ 536 and 543.

Order of the MoH of Ukraine N 426 from 26.08.2005

About claim of an order for examining documents to register drugs given for state registration (re-registering) and also examination of documents concerning changes in registration dossier during validity of registration certificate.

***(With amendments to Orders of MoH N95 from 01.03.2006, N536 from 11.09.2007 and N543 from 25.09.2008)*.**

Marking of finished drug products

- Name of the country
- Name of the enterprise - manufacturer, its trademark and address
- Name of a drug
- Indication of dosage form
- Quantity of a drug, dozage
- Qualitative and quantitative characteristics of active components
- Way of administration
- Conditions of storage
- Shelf- life
- Batch number
- Registration number
- Barcode

Name of the country

Name of the enterprise - manufacturer, its address

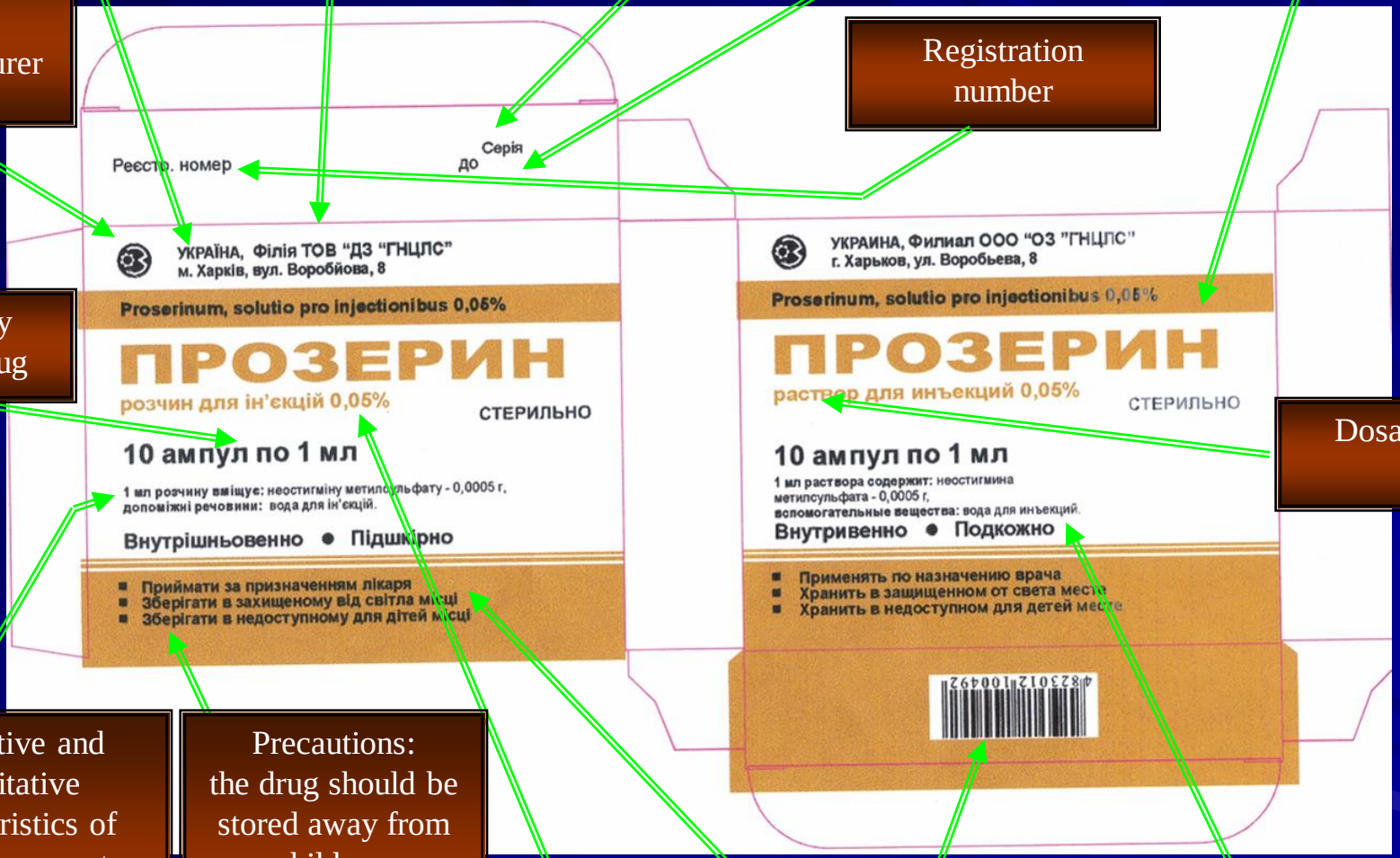
Batch number

Shelf-life

Name of the drug

Trademark of the manufacturer

Registration number



Quantity of the drug

Dosage form

Qualitative and quantitative characteristics of active components, the list of auxiliary substances

Precautions: the drug should be stored away from children; protected from light; should be used only by prescription of a physisian

Conditions of storage

Barcode

Way of administration

Concentration (activity) or dozage

Onto initial package such as blisters, initial package of suppositories, tubes the following information should be printed:

- Name of a drug
- Dozage, concentration, activity of a drug
- Batch number
- Shelf-life
- Proprietor of the registration certificate

Onto initial package of small size (ampoule, tube - droppers, syringe - tubes, etc.) the following data should be pronted:

- Name of a drug
- Concentration or activity
- Quantity of a drug
- Batch number
- Shelf - life

Registration number

Before 08.2003

Р.04.00/00453 or П.04.02/00105
04.00 - date of registration (year - 2000, month - 04)
04.02 - date of a re-registration (year - 2002, month - 04)
00453 and 00105 - list numbers of registration in the State registry of drugs and medical products of Ukraine

Since 08.2003. Order of MoH of Ukraine № 358

№ UA/0981/01/01, № UA/0981/01/02
Diclac (tablets by 50 and 75 mg)
№ UA/1838/01/01 (Tonzipret tablets)
№ UA/1838/02/01 (Tonzipret drops)
UA - Ukraine,
0981, 1838 - list numbers of drugs in State registry
01, 02... (the first ones) - digital designating of dosage forms
01, 02... (the second ones) - digital designating of dosage

Batch number of drugs

Example: 1390205
139 - manufacturing number
02 - month of manufacturing, 2005 – year of manufacturing