

**DECISION**  
**No. 8/29.02.2008**

**on approval of new and revised Romanian standard terms for  
pharmaceutical forms, administration routes and primary packaging, in  
line with those adopted by the European Pharmacopoeia Commission**

The Scientific Council of the National Medicines Agency,  
set up based on Minister of Public Health Order No. 485/09.05.2005, with  
further changes and completions, reunited on summons of the National  
Medicines Agency President in the ordinary meeting of 29.02.2008 in  
accordance with Article 10 of Government Ordinance No. 125/1998 related  
to the set up, organisation and functioning of the National Medicines  
Agency, approved as amended through Law No. 594/2002, as amended,  
agrees on the following

**DECISION**

**Art. 1.** - The new and revised Romanian Standard Terms for  
pharmaceutical forms, routes of administration and primary packages in  
accordance with those adopted by the Commission of the European  
Pharmacopoeia are approved, in accordance with the Annex, which is  
integral part of this decision.

**Art. 2.** - The present Decision shall be published in the next  
Supplement of the Romanian Pharmacopoeia the 10<sup>th</sup> edition.

**PRESIDENT**  
**of the Scientific Council**  
**of the National Medicines Agency**

**Acad. Prof. Dr. Victor Voicu**

**NEW AND REVISED**

**ROMANIAN STANDARD TERMS**

**for  
PHARMACEUTICAL FORMS  
ROUTES OF ADMINISTRATION  
PRIMARY PACKAGES  
in accordance with those adopted by  
the European Pharmacopoeia Commission**

New Romanian standard terms

Part 1: Pharmaceutical forms

Preparate oftalmice Eye preparation			
Normal terms		No.1) monogr. of Ph.Eur.	Observations
Romanian	English		
Picături oftalmice, emulsie	Eye drops, emulsion	no. 1163	-

Implanturi Implants			
Normal terms		No.1) monogr. of Ph. Eur.	Observations
Romanian	English		

Pulbere și solvent pentru pastă de implantare	Powder and solvent for implantation paste	no. 0520	Preparation used in parenteral implantation, in view of release of the active substance(s) during a certain period of time.
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Varia Miscellaneous			
Normal terms		Normal terms	Observations
Romanian	English		
Burete medicamentos	Medicated sponge	-	Sponge impregnated with one or several active substances. Various routes of administration are accepted.
Fir medicamentos	Medicated thread	-	-
Gel intestinal	Intestinal gel	-	Gel suitable for administration into bowel.

## Part 2: Routes of administration

Căile de administrare Routes of administration		
Romanian	English	Observations
Gastrică	Gastric use	The administration of a medicinal product into the stomach, using an adequate device.

Intestinală	Intestinal use	The administration of a medicinal product into the bowel, using an adequate device. Gastroenteral route is excluded.
Intraosoasă	Intraosseous use	The administration of a medicinal product into the bone marrow. Intrasternal route is excluded.

### Part 3: Primary packages, routes of administration

Ambalaje primare, sisteme de închidere și de administrare Containers		
Romanian	English	Observations
Inhalator	Inhaler	Device for the administration of an inhalation medicinal product. Nebulisers are excluded.

### Revised standard Romanian terms

#### Part 1: Pharmaceutical forms

Preparate parenterale Parenteral preparations			
Normal terms		No.1)	Observations
Romanian	English	monogr. of Ph. Eur.	
<del>Liofilizat</del> Pulbere pentru soluție injectabilă	<del>Lyophilisate</del> Powder for solution for injection	No. 520	The term “lyophilisate for suspension for injection” is accepted only for medicinal products for veterinary use.
<del>Liofilizat</del> Pulbere pentru suspensie injectabilă	<del>Lyophilisate</del> Powder for suspension for injection	No. 520	The term “lyophilisate for suspension for injection” is accepted only for medicinal products for veterinary use.

Liofilizat Pulbere pentru soluție perfuzabilă	Lyophilisate Powder for solution for infusion	No. 520	The term “lyophilisate for solution for infusion” is accepted only for medicinal products for veterinary use.
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Observation: the use of the term “oral lyophilisate” shall be maintained for medicinal products for human use.

Liofilizat oral/Oral lyophilisate = freeze-dried preparation, immediate release, administered lingually or dissolved in water prior to administration

Căile de administrare Routes of administration		
Romanian	English	Observations
Dentară	Dental use	The administration of a medicinal product on and within the teeth <u>or on and around the dental nerves.</u>
Gastro- enterală	Gastroenteral use	The administration of a medicinal product into <del>the stomach or duodenum</del> the gastrointestinal tract, using an adequate device. <u>To be used only when the terms “gastric” or “intestinal” are not applicable in case of routes of administration.</u>