



UNIVERSITÀ
DEGLI STUDI
DI TRIESTE

QUADRO LEGISLATIVO E FARMACOPEE: INTRODUZIONE

Ass. Prof. Massimiliano Pio di Cagno

24/02/2025



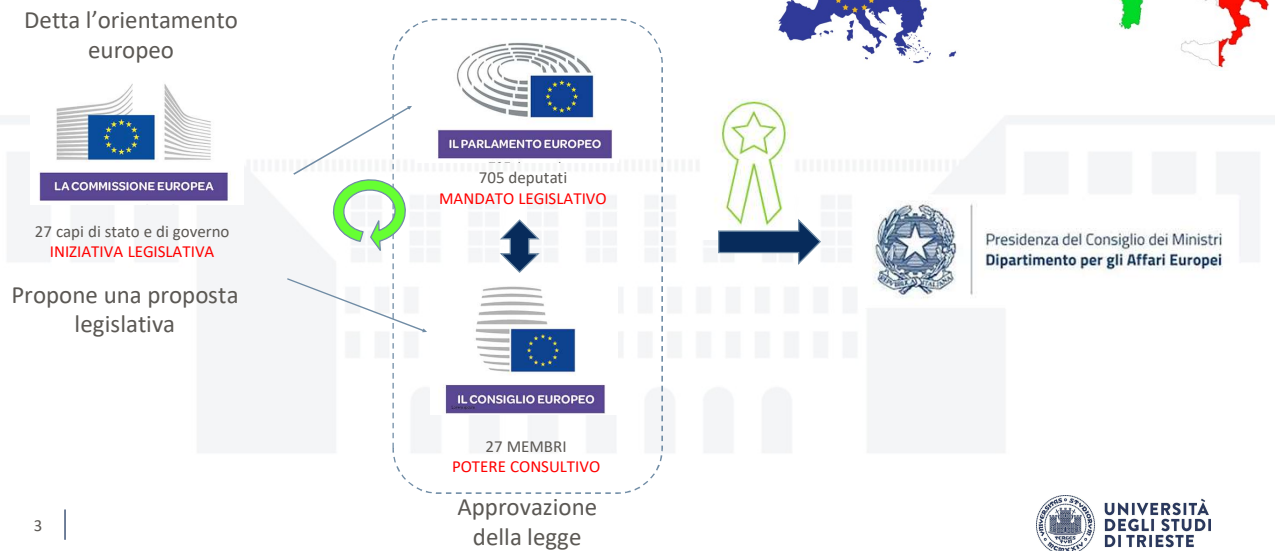
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OBBIETTIVI FORMATIVI

Al termine della lezione, lo studente deve essere in grado di:

- Descrivere il processi legislativi Europeo ed Italiano
- Elencare e descrivere le fonti di diritto italiano ed europea
- Ragionare sul sistema di recepimento ed armonizzazione delle leggi Europee in Italia
- Consultare autonomamente una Legge/Decreto Legge o qualsiasi atto pubblicato in Gazzetta Ufficiale
- Elencare e descrivere le differenze principali della farmacopea Europea e quella Italiana
- Essere in grado di consultare in autonomia Le Farmacopee Italiana ed Europea

SISTEMA LEGISLATIVO VIGENTE IN UE



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FONTI DI DIRITTO EUROPEE

REGOLAMENTI (LEGGE EUROPEA)

Di immediata attuazione in tutti gli stati membri dopo 18 mesi dalla pubblicazione in GUE. **Non ha bisogno di una legge Nazionale di implementazione. Giurisdizione in capo ai singoli Stati**

DIRETTIVE

Atti vincolanti per gli Stati membri. Ogni Stato deve emanare un atto di recepimento delle normativa intenzionalmente allo Stato entro 24 mesi dalla pubblicazione in Gazzetta Ufficiale Europea (GUE).

DECISIONI

Sono unilaterali (verso uno Stato) e sono vincolanti per lo Stato a cui sono rivolte

RACCOMANDAZIONI E PARERI

Non sono vincolanti, hanno lo scopo di attirare l'attenzione su particolari problemi e di sensibilizzare i Paesi ad adottare provvedimenti

4

GERARCHIA DELLE FONTI DEL DIRITTO ITALIANO



5

CONSULTAZIONE DELLE LEGGI

6

FONTI DEL DIRITTO LEGISLAZIONE ITALIANA

- **LEGGE**: Di iniziativa Parlamentare (iter ordinario)
- **DECRETO LEGGE (DL)**: atto d'urgenza di iniziativa governativa, da recepirsi entro 60 giorni dal Parlamento con Legge (pena decadenza) (**approvazione «a valle» del Parlamento**)
- **DECRETO LEGISLATIVO (D.LGS.)**: Atto legislativo d'urgenza di iniziativa governativa emanato dal Parlamento (**approvazione «a monte» del Parlamento**) .

Iter standard per recepire normativa europea.

Non sempre le Leggi vengono abrogate, è pratica comune che L ma, più comunemente, DL e D.LGS. vengano usati come strumento per modificare leggi preesistenti

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ESEMPIO DI DL NON ABROGATIVO DI UNA LEGGE

DECRETO-LEGGE 24 gennaio 2012, n. 1 Disposizioni urgenti per la concorrenza, lo sviluppo delle infrastrutture e la competitività

Art1. «Fermo restando quanto previsto dall'articolo 3 del decreto-legge 13 agosto 2011, n. 138, convertito, con modificazioni, dalla legge 14 settembre 2011, n. 148, in attuazione del principio di libertà di iniziativa economica sancito dall'articolo 41 della Costituzione e del principio di concorrenza sancito dal Trattato dell'Unione europea, sono abrogate, dalla data di entrata in vigore dei decreti di cui al comma 3 del presente articolo e secondo le previsioni del presente articolo:



Il DL 138/2011 va a modificare una articolo (art 3) della legge 148/2011 che pur rimane valida. La modifica in questo caso e' la cancellazione di alcuni limiti

|



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ESEMPIO DI DL NON ABROGATIVO DI UNA LEGGE

«le norme che prevedono limiti numerici, autorizzazioni, licenze, nulla osta o preventivi atti di assenso dell'amministrazione comunque denominati per l'avvio di un'attività economica non giustificati da un interesse generale, costituzionalmente rilevante e compatibile con l'ordinamento comunitario nel rispetto del principio di proporzionalità»



Liberalizzazione delle catene di farmacie



REGOLAMENTI EU



REGOLAMENTI

Obbligatori in tutti i loro elementi. Emanati direttamente dal Consiglio o dalla Commissione

Regolamento (UE) 2015/478 del Parlamento europeo e del Consiglio, dell' 11 marzo 2015, relativo al regime comune applicabile alle importazioni (codificazione)



DIRETTIVE EU

DIRETTIVE

Vincolanti per quanto riguarda il fine da raggiungere. Ogni stato deve emanare un atto di recepimento delle normativa intentamente allo Stato.

Direttiva 2010/63/UE del Parlamento europeo e del Consiglio, del **22 settembre 2010**, sulla protezione degli animali utilizzati a fini scientifici Testo rilevante ai fini del SEE



GAZZETTA UFFICIALE

DECRETO LEGISLATIVO **4 marzo 2014**, n. 26 Attuazione della direttiva 2010/63/UE sulla protezione degli animali utilizzati a fini scientifici. (14G00036) (GU Serie Generale n.61 del 14-03-2014)

The 3 R's of Animal Research

Reduce



Reduce the number of animals used

RockStep

Refine



Refine tests to cause animals less stress

Replace



Replace animal studies with other methods

<https://www.rockstepsolutions.com/blog/the-3rs-of-humane-animal-research/>

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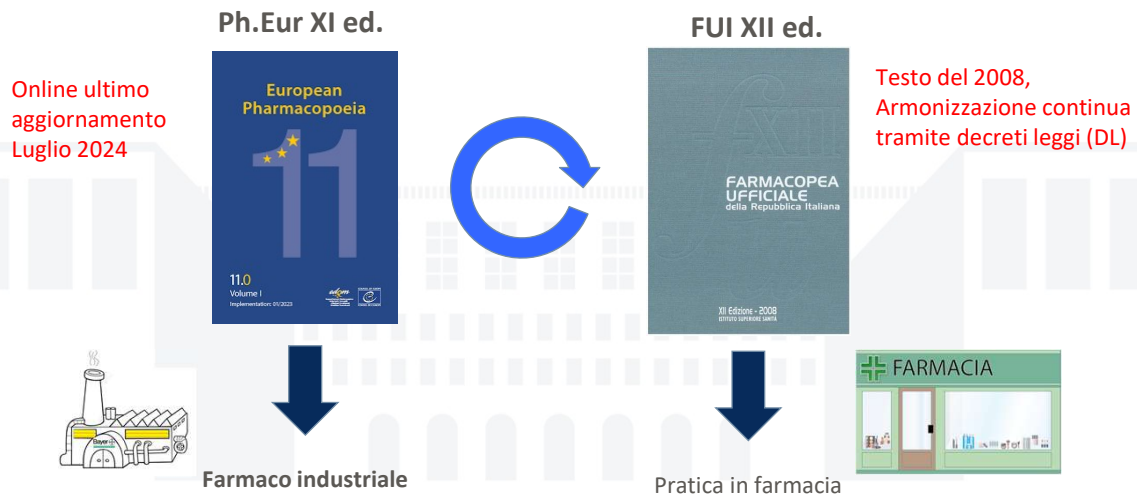
LEZIONE 1.1-QUESITO 1

INDICARE QUALE DELLE SEGUENTI AFFERMAZIONI È QUELLA CORRETTA:

- a) In caso di conflitto tra una legge Nazionale ed una Europea, La legge nazionale ha la precedenza in termini di applicabilità
- b) Le direttive europee sono immediatamente valide dal momento della pubblicazione in GUE su tutto il territorio comunitario europeo
- c) I decreti legge diventano validi senza conversione in legge da parte del parlamento
- d) I decreti legge devono essere convertiti in legge dal parlamento entro 60 giorni pena decadenza dell'atto

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PH.EUR. E FUI



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FARMACOEPA EUROPEA (XI ED.)

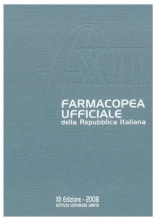


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4	REAGENTS	5379
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7	DOSAGE FORMS	965
8	VACCINES	1013
9	IMMUNOSERA	1233
10	RADIOPHARMACEUTICALS	5099
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Aggiornata
Luglio
2024

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FARMACOPEA UFFICIALE ITALIANA (XII ED.- 2008)



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Ph.Eur. = FUI

Ph.Eur. ≈ FUI

Ph.Eur. ≠ FUI

Presenti solo in FUI

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Le monografie si trovano in esteso solo sulla Ph.Eur.



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MONOGRAFIE GENERALI A CONFRONTO

Ph.Eur. Monografie generali
(07/2022:2902)

Non presenti in FUI XII-
2008

Ph.Eur. Monografie in ordine
alfabetico (07/2024:2619)

Ph. Eur. 11.5 (Luglio 2024)	
Allergen product	Monoclonal antibodies for human use
Chemical precursors for radiopharmaceutical preparations	Pharmaceutical preparations
Essential oils (Aetherolea)	Products of fermentation
Herbal drug extracts	Products with risk of transmitting agents of animal spongiform encephalopathies
Herbal drug preparations	Radiopharmaceutical preparation
Herbal drugs	Recombinant DNA technology, products of
Herbal teas	Substances for pharmaceutical use
Herbal teas, instant	Vaccines for human use
Immunosera for human use, animal	Vaccines for veterinary use
Immunosera for veterinary use	Vegetable fatty oils (olea herbaria)
Live biotherapeutic products for human use	

Ph.Eur. Monografie generali
(04/2019:3053;corrected 10.0)

Ph.Eur. Monografie in ordine
alfabetico (01/2024:2034)

(FUI-XII ed. (2008) Testo originale)

Monografie generali

Anticorpi monoclonali per uso umano	827	Prodotti allergenici	849
Droghe vegetali	831	Prodotti di fermentazione	852
Estratti	832	Prodotti ottenuti con la tecnologia del DNA ricombinante	854
Essenze	834	Sierimmuni di origine animale per uso umano	858
Oli grassi vegetali	837	Sierimmuni per uso veterinario	861
Piante per tisane	839	Sostanze per uso farmaceutico	866
Preparazioni a base di droghe vegetali	840	Vaccini per uso umano	869
Preparazioni radiofarmaceutiche	840	Vaccini per uso veterinario	874
Prodotti aventi il rischio di trasmettere gli agenti delle encefalopatie spongiformi animali	849		

DECRETO 17 maggio 2018 : alla voce «Monografie generali» è aggiunta la monografia generale «Preparazioni farmaceutiche (no. 2619)»,
di cui all'allegato 4 al presente decreto;

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ACQUA DEPURATA (0008)

CAP.		PG.
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13	OMEOPATIA	1787
14-17	MONOGRAFIE IN ORDINE ALFABETICO	1853-6048

- La Ph. Eur accorpa tutte le monografie di tutti gli attivi e le "materie prime" (den. FUI) tra il cap. 14 e 17.
- La gran parte delle sostanze riportate in «materie prime» FUI non ci sono in Ph. Eur.

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EUROPEAN PHARMACOPOEIA 11.4

Water, purified

Reference solution. Mix 2 mL of aluminium standard solution (2 ppm Al), 10 mL of acetate buffer solution pH 6.0 R and 98 mL of distilled water R.

Blank solution. Mix 10 mL of acetate buffer solution pH 6.0 R and 100 mL of distilled water R.

Bacterial endotoxins (2.6.14 or 2.6.32): less than 0.25 IU/mL.



04/2019:0008

WATER, PURIFIED

Aqua purificata

H₂O

M, 18.02

Sterilised water for injections

DEFINITION

Water for injections in bulk that has been distributed into suitable containers, closed and sterilised by heat in conditions which ensure that the product still complies with the test for bacterial endotoxins. Sterilised water for injections is free from any added substances.

Examined in suitable conditions of visibility, it is clear and colourless.

Each container contains a sufficient quantity of water for injections to permit the nominal volume to be withdrawn.

TESTS

Conductivity: maximum 25 µS·cm⁻¹ for containers with a nominal volume of 10 mL or less; maximum 5 µS·cm⁻¹ for containers with a nominal volume greater than 10 mL.

Use equipment and the calibration procedure as defined under Water for injections in bulk, maintaining the sample temperature at 25 ± 1 °C.

Outflowable substance: For containers with a nominal volume less than 50 mL: heat 100 mL to boiling with 10 mL of dilute sulfuric acid R, add 0.4 mL of 0.02 M potassium permanganate and boil for 5 min; the solution remains faintly pink.

For containers with a nominal volume equal to or greater than 50 mL: heat 100 mL to boiling with 10 mL of dilute sulfuric acid R, add 0.2 mL of 0.02 M potassium permanganate and boil for 5 min; the solution remains faintly pink.

Aluminium (2.4.17): maximum 10 ppb, if intended for use in the manufacture of dialysis solutions.

Prescribed solution: To 400 mL of the water to be examined add 10 mL of acetate buffer solution pH 6.0 R and 100 mL of distilled water R.

Reference solution. Mix 2 mL of aluminium standard solution (2 ppm Al), 10 mL of acetate buffer solution pH 6.0 R and 98 mL of distilled water R.

Blank solution. Mix 10 mL of acetate buffer solution pH 6.0 R and 100 mL of distilled water R.

Residue on evaporation: maximum 4 mg (0.004 per cent) for containers with a nominal volume of 10 mL or less; maximum 3 mg (0.003 per cent) for containers with a nominal volume greater than 10 mL.

Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100–105 °C.

Particulate contamination: sub-visible particles (2.9.19). It complies with the requirements under Test A or Test B, as appropriate.

Sterility (2.6.1). It complies with the test.

Bacterial endotoxins (2.6.14 or 2.6.32): less than 0.25 IU/mL.

General Notices (1) apply to all monographs and other texts

DEFINITION

Water for the preparation of medicines other than those that are required to be both sterile and apyrogenic, unless otherwise justified and authorised.

Purified water in bulk

PRODUCTION

Purified water in bulk is prepared by distillation, by ion exchange, by reverse osmosis or by any other suitable method from water that complies with the regulations on water intended for human consumption laid down by the competent authority.

Purified water in bulk is moved and distributed in conditions designed to prevent growth of micro-organisms and to avoid any other contamination.

Microbiological monitoring: During production and subsequent storage, appropriate measures are taken to ensure that the microbial count is adequately controlled and monitored. Appropriate alert and action levels are set so as to detect adverse trends. Under normal conditions, an appropriate action level is a microbial count of 100 CFU/mL, determined by filtration through a membrane with a nominal pore size not greater than 0.45 µm, using R2A agar and incubating at 30–35 °C for not less than 5 days. The size of the sample is to be chosen in relation to the expected result.

R2A agar

Yeast extract

0.3 g

Peptone peptone

0.3 g

Casamino acids

0.3 g

Glucose

0.3 g

Starch

0.3 g

Dipotassium hydrogen phosphate

0.024 g

Magnesium sulfate, anhydrous

0.024 g

Sodium pyruvate

0.3 g

Agar

15.0 g

Purified water

1000 mL

Adjust the pH so that after sterilisation it is 7.2 ± 0.2. Sterilise by heating in an autoclave at 121 °C for 15 min.

Growth promotion of R2A agar

Preparation of test strains. Use standardised stable suspensions of test strains or prepare them as stated in Table 0008-1. Seed lot culture maintenance techniques (seed-lot systems) are used so that the viable micro-organisms used for inoculation are not more than 5 passages removed from the original master seed lot. Grow each of the bacterial strains separately as described in Table 0008-1. Use buffered sodium chloride-peptone solution pH 7.0 or phosphate buffer solution pH 7.2 to make test suspensions. Use the suspensions within 2 h, or within 24 h if stored at 2–8 °C. As an alternative to preparing and then diluting a fresh suspension of vegetative cells of *Bacillus subtilis*, a stable spore suspension is prepared and

Se dotata di codice identificativo, il testo in inglese della Ph.Eur. Corrisponde esattamente a quello in italiano su FUI



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PREPARAZIONI FARMACEUTICHE SPECIFICHE FUI

- Questo sottocapitolo non è presente in Ph.Eur.
- In questo capitolo sono riportate le preparazioni GALENICHE OFFICINALI, vale a dire le preparazioni che possono essere preparate nel laboratorio della farmacia e dispensate al pubblico
- Questo capitolo non ha rilevanza dal punto di vista regolatorio della produzione industriale di medicinali

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7. DOSAGE FORMS (SOTTOCAP. FORME FARMACEUTICHE FUI XII)

- Capsules
- Chewing gums, medicated
- Ear preparations
- Eye preparations
- Foams, medicated
- Granules
- Intramammary preparations for veterinary use
- Intraruminal delivery systems
- Intrauterine preparations for veterinary use
- Intravaginal preparations
- Liquid preparations for cutaneous application
- Liquid preparations for oral use
- Nasal preparations
- Oromucosal preparations
- Parenteral preparations
- Patches
- Plasters, medicated
- Powders for cutaneous application
- Powders, oral
- Premixes for medicated feeding stuffs for veterinary use
- Preparations for inhalation
- Preparations for irrigation
- Pressurized pharmaceutical preparations
- Rectal preparations
- Semi-solid preparations for cutaneous application
- Sticks
- Tablets
- Tampons, medicated
- Vaginal preparations
- Veterinary liquid preparations for cutaneous application
- Veterinary semi-solid preparations for oral

Forme farmaceutiche

Glossario	885	Preparazioni liquide per applicazione cutanea	906
Rastocchini	886	Preparazioni liquide per uso orale	908
Capsule	886	Preparazioni liquide veterinarie per applicazione cutanea	911
Cerotti transdermici	889	Preparazioni nasali	913
Compresse	890	Preparazioni oftalmiche	915
Dispositivi	894	Preparazioni oromucosali	918
Gomme da masticare medicate	895	Preparazioni parenterali	923
Granulati	895	Preparazioni per inalazione	926
Polveri per applicazione cutanea	897	Preparazioni per irrigazione	932
Polveri per uso orale	898	Preparazioni rettali	933
Premisce per mangimi medicati per uso veterinario	899	Preparazioni semisolidi per applicazione cutanea	935
Preparazioni auricolari	900	Preparazioni vaginali	938
Preparazioni farmaceutiche pressurizzate	902	Schiame medicate	941
Preparazioni intramammarie per uso veterinario	903	Tamponi medicati	942
Preparazioni intrauterine per uso veterinario	904		



ESEMPIO FORME DI DOSAGGIO («DOSAGE FORMDS» PH.EUR. XI)

FUI
Compresse,
0478, pp. 890

Tablets

EUROPEAN PHARMACOPOEIA 11.0

active substances, either alone or dissolved or dispersed in a suitable basis, and are usually intended to dissolve or melt at body temperature. They may be inserted into a body cavity or wound, or be applied externally.

Uncoated sticks and sticks for insertion into wounds are sterile.

PRODUCTION

In the manufacture, packaging, storage and distribution of sticks, suitable measures are taken to ensure their microbial quality. Recommendations in this aspect are provided in general chapter 3.1.4. Microbiological quality of non-sterile pharmaceutical preparations and solutions for pharmaceutical use.

Uncoated sticks and other sterile sticks are prepared using materials and methods designed to ensure sterility and to avoid the introduction of contaminants, and the growth of micro-organisms; recommendations in this aspect are provided in general chapter 3.1.1. Methods of preparation of sterile products.

TESTS

Uniformity of dosage units (2.9.6). Single-dose sticks comply with the test ex. where justified and authorized, with the test for uniformity of content and/or uniformity of mass shown below. Herbal drugs and herbal drug preparations present in the dosage form are not subject to the provisions of this paragraph.

Uniformity of content (2.9.6). Unless otherwise prescribed or justified and authorized, tablets with a content of active substance less than 2 mg or less than 2 per cent of the total mass comply with test B. If the preparation contains more than one active substance, the requirement applies only to those substances that correspond to the above conditions.

Uniformity of mass (2.9.6). Single-dose sticks comply with the test. If the test for uniformity of content is prescribed for all active substances, the test for uniformity of mass is not required.

Stability (2.9.1). Uncoated sticks and sticks for insertion into wounds comply with the test for sterility.

LABELLING

The label state, for uncoated sticks and sticks to be inserted into wounds, that they are sterile.

Tablets

Compressi

The requirements of this monograph do not necessarily apply to preparations that are presented as tablets intended for use other than by oral administration. Requirements for such preparations may be found, where appropriate, in other general monographs, for example Rectal preparations (1145), Vaginal preparations (1146) and Oromucosal preparations (1147). This monograph does not apply to sticks, oral paste and gums. Where justified and authorized, the requirements of this monograph do not apply to sticks for veterinary use. Tablets for use in the mouth comply with the requirements of the monograph Oromucosal preparations (1145).

DEFINITION

Tablets are solid preparations containing a single dose of one or more active substances. They are obtained by compressing active substances of particles or by another suitable manufacturing technique, such as extrusion, moulding or freeze-drying (lyophilization). Tablets are intended for oral administration. Some are evaluated while, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is absorbed or absorbed.

The particles consist of one or more active substances with or without excipients such as fillers, binders, disintegrating agents, lubricants, diluents, substances capable of modifying the behaviour of the preparation in the digestive tract, colouring matter authorized by the competent authority and flavouring substances.

Tablets are usually single, solid cylinders, the end surfaces of which are flat or convex and the edges of which may be bevelled. They may have break marks and may bear a symbol or other markings. Tablets may be coated.

Where applicable, containers for tablets comply with the requirements for materials used for the manufacture of containers (3.1) and subcontainers and containers (3.2) and subcontainers.

PRODUCTION

of particles or particles appropriate produced by granulation methods. In the manufacture of tablets, measures are taken to ensure that they possess a suitable mechanical strength to avoid crumbling or breaking on handling or subsequent processing. This may be demonstrated using the test described in general chapter 2.9.7. Testing of compressed tablets and 2.9.8. Resistance to crushing of tablets.

In the manufacture, packaging, storage and distribution of tablets, suitable measures are taken to ensure that they possess a suitable mechanical strength to avoid crumbling or breaking on handling or subsequent processing. This may be demonstrated using the test described in general chapter 2.9.7. Testing of compressed tablets and 2.9.8. Resistance to crushing of tablets.

Take 30 tablets at random, break them by hand and, from all the parts obtained from 1 tablet, take 1 part for the test and reject the other parts. Weigh each of the 30 parts individually and calculate the average mass. The weight for each part must not be more than 1 individual mass is outside the limits of 80 per cent to 120 per cent of the average mass. The tablets fail to comply with the test if more than 1 individual mass is outside these limits, or if 1 individual mass is outside the limits of 75 per cent to 125 per cent of the average mass.

Tablets

EUROPEAN PHARMACOPOEIA 11.0

TESTS

Uniformity of dosage units (2.9.6). Tablets comply with the test ex. where justified and authorized, with the test for uniformity of content and/or uniformity of mass shown below. Herbal drugs and herbal drug preparations present in the dosage form are not subject to the provisions of this paragraph.

Uniformity of content (2.9.6). Unless otherwise prescribed or justified and authorized, tablets with a content of active substance less than 2 mg or less than 2 per cent of the total mass comply with test B. If the preparation contains more than one active substance, the requirement applies only to those substances that correspond to the above conditions.

Unless otherwise justified and authorized, coated tablets other than film-coated tablets comply with test A. Inspection of their content of active substance(s).

Uniformity of mass (2.9.6). Uncoated tablets and, unless otherwise justified and authorized, film-coated tablets comply with the test. If the test for uniformity of content is prescribed or justified and authorized for all the active substances, the test for uniformity of mass is not required.

Disintegration. Unless otherwise justified and authorized, a suitable test is carried out, for example one of the tests described in general chapter 2.9.3. Disintegration test for solid dosage forms.

Where a disintegration test is prescribed, a disintegration test is performed.

Uncoated tablets

DEFINITION

Uncoated tablets include single-layer tablets resulting from a single compression of particles and multi-layer tablets, consisting of concentric or parallel layers obtained by successive compression of particles of different composition. The excipients used are not specifically intended to modify the release of the active substance in the digestive fluids.

Uncoated tablets conform to the general definition of tablets. A broken tablet, when examined under a lens, shows either a relatively uniform section (single-layer tablets) or a stratified texture (multi-layer tablets) but no signs of cracking.

TESTS

Disintegration (2.9.3). Uncoated tablets comply with the test using water R at the liquid medium. Add a disc to each tablet. Operate the apparatus for 15 min, unless otherwise justified and authorized, and examine the state of the tablets. If the tablets fail to comply because of adherence to the discs, the results are invalid. Repeat the test on a further 6 tablets, omitting the discs.

Coated tablets

DEFINITION

Coated tablets are tablets covered with one or more layers of various substances such as natural or synthetic resins, gums, gelatins, inorganic and insoluble fillers, waxes, plasticizers, pigments, colouring matter authorized by the competent authority and substances used as coatings are usually applied as a solution or suspension in conditions in which evaporation of the vehicle occurs. When the coating is a very thin polymeric coating, the tablets are known as film-coated tablets.

Coated tablets have a smooth surface, which is often coloured and may be printed, a broken section, when examined under a lens, shows a core surrounded by one or more continuous layers with a different texture.

Modified-release tablets

DEFINITION

Modified-release tablets are coated or uncoated tablets that contain special excipients or are prepared by special procedures, or both, designed to modify the rate, the place or the time at which the active substance(s) are released. Modified-release tablets include prolonged-release tablets, delayed-release tablets and pulsatile-release tablets.

Effervescent tablets

DEFINITION

Effervescent tablets are uncoated tablets generally containing active substances and carbonates or bicarbonates of sodium or potassium which react rapidly in the presence of water to release carbon dioxide. They are intended to be dissolved or dispersed in water before administration.

Saggi da condurre per legge in fase di controllo qualità

Descrizione sottoclassi estesa

0478



LEZIONE 1.1-QUESITO 2

INDICARE QUALE DELLE SEGUENTI AFFERMAZIONI È QUELLA CORRETTA:

- a) La farmacopea Ufficiale Italiana è l'unico testo vigente sul territorio nazionale in materia di produzione di medicinali, sia galenici che industriali
- b) La Ph.Eur. è il testo di riferimento da utilizzare per il controllo qualità dei prodotti galenici
- c) La FUI contiene preparazioni farmaceutiche specifiche non previste dalla normativa europea, che possono essere preparate nelle farmacie presenti sul territorio nazionale
- d) Se un medicinale è descritto in FUI sotto forma di monografia, questo può essere venduto e commercializzato in tutto i paesi del Sistema Economico Europeo (SEE)

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«TAKE HOME MESSAGES»

- _____
- _____
- _____
- _____
- _____

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