EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Section 3: Pharmaceutical form

SmPC training presentation

Note: for full information refer to the European Commission's Guideline on summary of product characteristics (SmPC)

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I. General objectives of section 3

This section should state the pharmaceutical form according to the European Pharmacopoeia and a visual description of the product

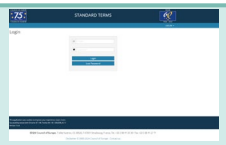
II.1 Term for pharmaceutical form

Should be described by **a full standard term of European Pharmacopoeia using SINGULAR FORM**
Term used in Section 1 should be the same as used in this section

Examples full standard term

If a **patient friendly term** (formerly **short term)** of the European Pharmacopoeia is used on **small immediate packaging material**, the **patient friendly term** should be **added in brackets in this section**

Examples short term



Standard Terms (edqm.eu)

(subscription only access)

Examples full standard term

A full term of European Pharmacopoeia using singular form

Prolonged-release tablet.

Solution for intraperitoneal use.

Powder for concentrate for solution for infusion.

Examples short term

A full term of European Pharmacopoeia using singular form

The patient friendly (formerly short) term should be added in brackets in this section

Film-coated tablet (tablet).

Eye drops, suspension (eye drops).

Concentrate for solution for infusion (sterile concentrate).

II.2 Description of pharmaceutical form

A **VISUAL DESCRIPTION** of the appearance of the product such as

COLOUR | markings | SIZE

For **tablets designed with a score line,** information should be given on whether or not the tablet can be divided into equal halves

Information on **pH** and **osmolarity**, as appropriate

Appearance before reconstitution should be stated in this section. *Appearance of the product **after reconstitution** should be stated in **sections 4.2 & 6.6***

SmPC example
description
description

score line

pH and osmolarity

appearance before reconstitution

Example-description

A **VISUAL DESCRIPTION** of the appearance of the product

COLOUR | markings | SIZE

7.0 mm, round, normal convex, white film-coated tablets debossed “OZ 2.5” on one side and “G” on the other side.

Example-pH and osmolarity

A **VISUAL DESCRIPTION** of the appearance of the product

COLOUR

Descripton, pH and osmolarity

Clear, colourless to pale yellow solution, with a pH of 6.0-7.5 and an osmolality of 260 – 320mOsm/kg.

Example–score line

For tablets designed with a score line, information should be given on whether or not reproducible dividing of the tablets has been shown

<The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The tablet can be divided into equal halves.>

(SmPC Guideline)

Example-appearance before reconstitution

Appearance before reconstitution should be stated in section 3.
Appearance after reconstitution should be stated in section 4.2 and 6.6

Active substance X 250 IU powder and solvent for solution for injection

Section 3
White to off-white cake/powder.
Clear, colourless solvent.

Section 4.2
For reconstitution instructions prior to administration, see section 6.6.

Section 6.6
The solution will be clear or slightly opalescent and colourless. The solution is to be discarded if visible particulate matter or discolouration is observed.

Thank you for consulting this training presentation

SmPC Advisory Group

Please note the presentation includes examples that may have been modified to best illustrate the related principle