

Ph. Eur. 10th Edition:

NEW MONOGRAPHS AND TEXTS

(COMPARED TO 9.0)



New substances
and finished products

7 finished products and

114 substances (active and excipients), including

17 patent-protected substances

New general chapters

12 texts adopted, including

8 methods of analysis

17 newly adopted Active Pharmaceutical Ingredients still
under patent for **therapeutically important** indications



ANTINEOPLASTIC AND
IMMUNOMODULATING AGENTS

5



ANTIINFECTIVES FOR
SYSTEMIC USE

3



NERVOUS SYSTEM

3



BLOOD AND BLOOD
FORMING ORGANS

2



RESPIRATORY SYSTEM

1



CARDIOVASCULAR SYSTEM

1

ALL OTHER
THERAPEUTIC
PRODUCTS
(IRON CHELATOR AND
CONTRAST MEDIA)

2



European Directorate
for the Quality
of Medicines
& HealthCare

Direction européenne
de la qualité
du médicament
& soins de santé



COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

7 finished product monographs to ensure the quality of generic medicines



NERVOUS SYSTEM

3

ALL OTHER THERAPEUTIC PRODUCTS (IRON CHELATOR)

2

ANTIINFECTIVES FOR SYSTEMIC USE

2

Newly adopted general chapters provide **modern** and **fit-for-purpose** analytical methods to **ensure the quality of medicines**, for instance:

The non-mandatory chapter on *Process analytical technology* (5.25) highlights the various modifications that have been made to the Ph. Eur. to support PAT* applications.

The chapter on *Chemical imaging* (5.24) is the first of its kind to be introduced in any pharmacopoeia worldwide. Elaborated by the Ph. Eur. Vibrational Spectroscopy and Analytical Data Modelling Working Party (VSADM), this non-mandatory chapter provides specific recommendations for assessing the performance of chemical imaging systems for the purpose of qualitative and quantitative investigations.

The chapter on *In vivo assay substitution with in vitro methods for quality control of vaccines* (5.2.14) was developed in accordance with the Council of Europe's European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes.



*Process Analytical Technology