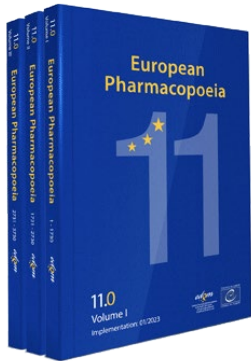
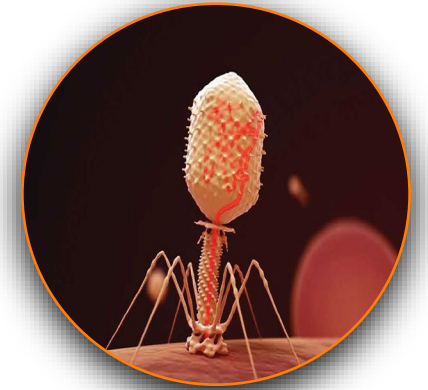


# THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



# Activities of the European Pharmacopoeia in the field of bacteriophages



*IABS*

*Avoiding Antimicrobial Resistance: Veterinary Use of Phages for Prevention, Therapy and Control of Bacterial Infections*

*19-20 November 2024*

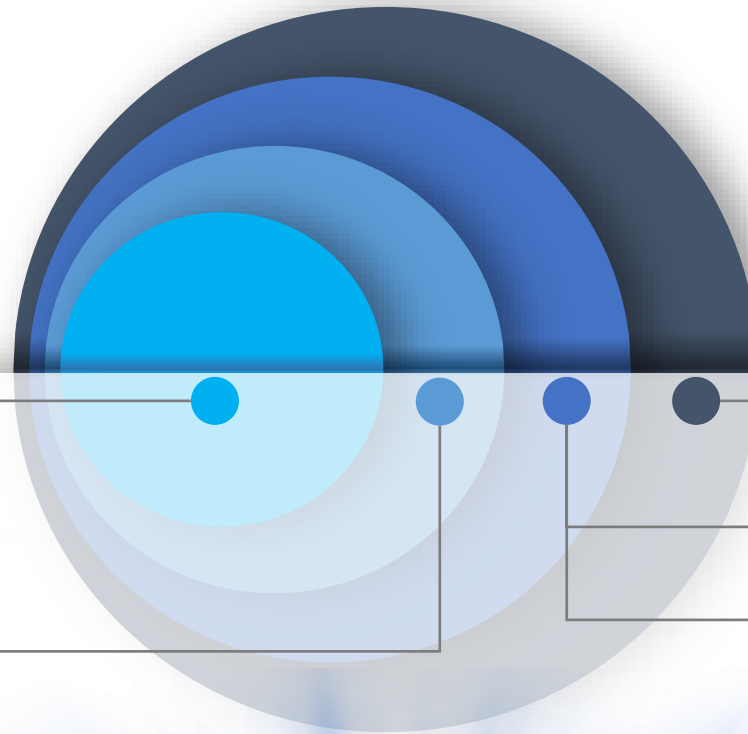
*Dr Olga Kolaj-Robin, EDQM*

## General chapters & general texts

- avoid repeating standard procedures or requirements in each monograph; aspects that cannot be treated in each monograph
- **become mandatory** when referred to in a monograph
- provide standard analytical procedures; guidance

## Individual monographs

- Specific but not stand alone
- Analytical procedures and acceptance criteria represent required quality standards
- Based on approved specifications backed up by batch data
- Reliance on manufacturers' feedback (public consultation)



## General notices

- **Essential reading**
- Apply to all texts
- Address general topics
- Provide basic information
- Include rules to understand texts, conventional expressions

## General monographs

### Dosage form monographs

- Classes of substances/medicinal products
- Mandatory for all substances/preparations within the scope of the definition
- Not cross-referenced in individual monographs (exceptions)



# Bacteriophages in the Ph. Eur.



- **Worldwide problem of antibiotic resistance**
- **Increased interest in phage therapy**
- **Phages – a promising alternative to antibiotics**

**CHALLENGE**

- **Currently one nationally authorised product in the EU**
- **Little manufacturing and clinical experience**
- **Limited regulatory guidance**
- **Off-the-shelf vs magistral preparations**
- **Veterinary & human products**
- **Diversity of targeted bacteria vs narrow spectrum of phages**
- **Phage adaptation**

## One of Ph. Eur. Commission priorities for 2023-2025

<https://www.edqm.eu/en/the-european-pharmacopoeia-commission>



## Drafting by the Ph. Eur. **Bacteriophage Working Party**

- **Regulators, Industry, Hospitals, Experimental & Governmental Institutions**
- **Human and veterinary fields**
- **EMA liaison for alignment with the EMA guideline on veterinary phage therapy**



  
EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 27 January 2023  
2 EMA/CVMP/NTWP/32862/2022  
3 Committee for Veterinary Medicinal Products (CVMP)  
4

5 Guideline on quality, safety and efficacy of veterinary  
6 medicinal products specifically designed for phage  
7 therapy

# Bacteriophages in the Ph. Eur.




- Worldwide problem of antibiotic resistance
- Increased interest in phage therapy
- Phages – a promising alternative to antibiotics



## Phage therapy medicinal products (5.31)



**RESULT**

- General chapter **INFO**
- Provides framework of requirements with built-in flexibility 
- Covers naturally occurring or genetically modified, single phages or their mixtures administered by various routes for human and veterinary use
- Covers unlicensed pharmaceutical preparations as per general monograph 2619
- Purified harvest contains a **single** phage therapy active substance
- Potency (infectious titre) of **each** phage in the final lot to be determined
- Phage adaptation of a clinical isolate for an individual patient addressed;

**CHALLENGE**

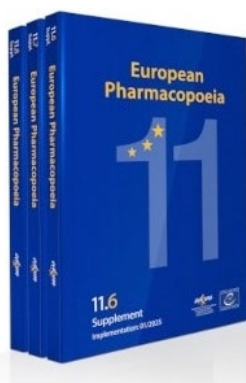
- Currently one nationally authorised product in the EU
- Little manufacturing and clinical experience
- Limited regulatory guidance
- Off-the-shelf *vs* magistral preparations
- Veterinary & human products
- Diversity of targeted bacteria *vs* narrow spectrum of phages
- Phage adaptation

# Bacteriophages in the Ph. Eur. – next step



## Phage therapy medicinal products (5.31)

- **General chapter** adopted at 178<sup>th</sup> EPC Session (March 2024)
- Pre-published on the EDQM website due to exceptionally high interest in the context of antimicrobial resistance and since published in **Supplement 11.6**



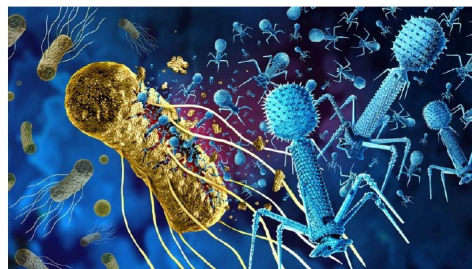
European Directorate for the Quality of Medicines & HealthCare

[You are here: European Directorate for the Quality of Medicines & HealthCare > Newsroom > New general chapter on phage therapy medicinal products \(5.31\) adopted and pre-published on the EDQM website](#)

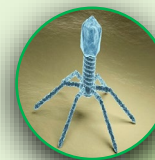
### Newsroom

New general chapter on Phage therapy medicinal products (5.31) adopted and pre-published on the EDQM website

EDQM | STRASBOURG, FRANCE | 10/04/2024



Rising levels of [antimicrobial resistance](#), in recent years, identified as one of the leading threats to global public health and development, have prompted renewed interest in the use of phage therapy for the treatment of bacterial infections. This led the [European Pharmacopoeia Commission \(EPC\)](#) to make the elaboration of European Pharmacopoeia (Ph. Eur.) texts standardising requirements for phage therapy one of its [top priorities for the years 2023-2025](#).



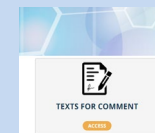
## Bacteriophage potency determination (2.7.38)



- **General chapter** added to the Work Programme at 176<sup>th</sup> EPC Session (June 2023)
- Aiming at standardisation of potency testing of single phage preparations and providing guidance for potency testing of multicomponent mixtures of phages



**! Tentative !**  
**Public consultation**



**Pharmeuropa 37.2**  
*Public deadline: 30/06/25*  
*NPA deadline: 31/08/25*

# Thank you for your attention

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