# ISO/TS 20853:2026-02 (E)

## Biotechnology - Bioprocessing - General requirements for bacteriophage preparation for therapeutic use

## Contents

Page


**Foreword** ... iv

**Introduction** ... v

**1 Scope** ... 1

**2 Normative references** ... 1

**3 Terms and definitions** ... 1

**4 Processing workflow** ... 2

**5 Phage isolation and purification from diverse environments** ... 4
5.1 Preliminary preparations ... 4
5.2 Phage enrichment ... 4
5.3 Phage isolation ... 4
5.4 Phage amplification ... 4
5.5 Phage suspension titration ... 4
5.6 Phage storage ... 4
5.7 Genome sequencing ... 5
5.8 Bioinformatic analysis ... 5
5.9 Phage selection ... 5

**6 Quality control for phage or phage cocktail** ... 5
6.1 Removal of harmful bacterial toxins ... 5
6.1.1 Endotoxin removal ... 5
6.1.2 Exotoxin removal ... 5
6.2 PFU titration ... 5
6.3 Endotoxin quantification ... 6
6.4 Sterility testing ... 6
6.5 Bacterial proteins checking ... 6
6.6 Residual bacterial DNA detection ... 6
6.7 pH determination ... 6

**Annex A** (informative) **Examples for sewage pre-treatment methods** ... 8

**Annex B** (informative) **Example of a method for obtaining a single bacterial colony** ... 9

**Annex C** (informative) **Examples for amplification methods** ... 10

**Annex D** (informative) **Example of a method for titre determination** ... 11

**Annex E** (informative) **Example of a method for phage concentration** ... 12

**Annex F** (informative) **Example of a method for phage screening** ... 13

**Annex G** (informative) **Example of a method for endotoxin removal** ... 16

**Bibliography** ... 17