

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