

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

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

---

### Contents

Page

Foreword.....	iv
Introduction.....	v
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 Processing workflow.....</b>	<b>2</b>
<b>5 Phage isolation and purification from diverse environments.....</b>	<b>4</b>
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
<b>6 Quality control for phage or phage cocktail.....</b>	<b>5</b>
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
<b>Annex A (informative) Examples for sewage pre-treatment methods.....</b>	<b>8</b>
<b>Annex B (informative) Example of a method for obtaining a single bacterial colony.....</b>	<b>9</b>
<b>Annex C (informative) Examples for amplification methods.....</b>	<b>10</b>
<b>Annex D (informative) Example of a method for titre determination.....</b>	<b>11</b>
<b>Annex E (informative) Example of a method for phage concentration.....</b>	<b>12</b>
<b>Annex F (informative) Example of a method for phage screening.....</b>	<b>13</b>
<b>Annex G (informative) Example of a method for endotoxin removal.....</b>	<b>16</b>
<b>Bibliography.....</b>	<b>17</b>