SARTORIUS

Product Datasheet

PEIpro® Transfection Reagent

For Small- to Large-Scale Viral Vector Production

Product Information

PEIpro® is the leading PEI-based DNA transfection reagent that offers flexibility and scalability to develop a robust and sustainable viral vector manufacturing process. PEIpro® benefits from extensive research in PEI polymer chemistry and formulation to achieve the highest transfection efficiency in adherent and suspension cell culture systems. PEIpro® allows a smooth transition from initial process development to large-scale manufacturing of therapeutic viral vectors with three quality grades available: PEIpro®, PEIpro®-HQ, and PEIpro®-GMP. PEIpro®-GMP is the highest quality grade PEI-based reagent on the market and is provided with full regulatory documentation to support drug approvals.

Features and Benefits

- **Gold Standard:** Optimized PEI-based transfection reagent for scalable viral vector production
- **Reproducible:** Equivalent viral vector production guaranteed through three quality grades
- **GMP-Grade:** Manufactured in compliance with ICH Q7 guidelines
- **Residual Test:** Proprietary residual test to mitigate risks and ensure patient safety

Introduction

Relevant Applications

- Viral vector production (AAV | LVV | others)
- Cell and gene therapy

Relevant Process Steps

- Transfection (upstream process)

Three Quality Grades Support Seamless Transition From Process Development to Commercialization

The extensive research and development invested in PEIpro® and the Polyplus (now part of Sartorius) expertise in the manufacturing process has made PEIpro® the gold standard among commercially available PEIs for cell and gene therapy. Three quality grades are available to guarantee the level of process qualification, quality controls, traceability, and documentation required for each project stage, enabling a seamless transition from process development to commercialization (Table 1). Both PEIpro® and PEIpro®-HQ are produced in an ISO 9001 environment, ensuring robust quality control. The PEIpro®-GMP is produced in GMP-certified facilities following ICH Q7 guidelines that ensure a validated aseptic manufacturing process.

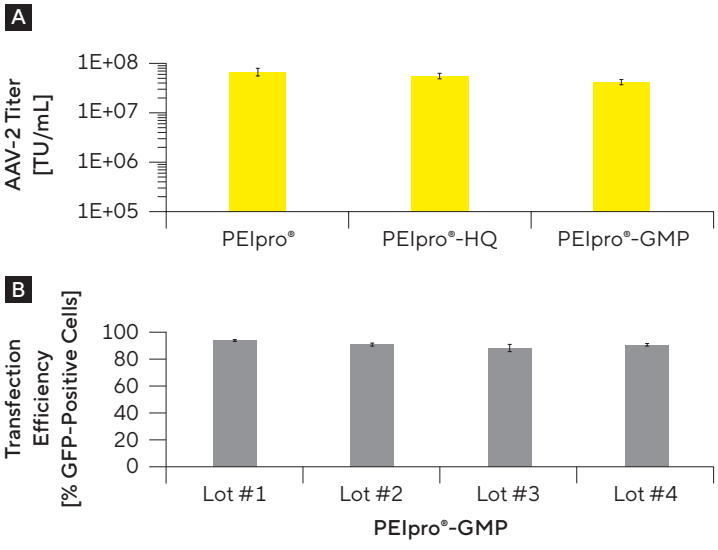
Table 1: *Comparison of Three Quality Grades of PEIpro® Transfection Reagent*

Characteristics	PEIpro®	PEIpro®-HQ	PEIpro®-GMP
Composition	Gold standard PEI-based transfection reagent for viral vector manufacturing used in cell and gene therapy. Ready-to-use, chemically-defined, and free of animal-derived components.		
Recommended use	Discovery to process development	Pre-clinical phase	Clinical trials and commercialization
Quality grade	Research use only	Highly qualified grade	cGMP grade
Packaging and size	▪ 1.5 mL vial ▪ 10 mL bottle ▪ 100 mL bottle ▪ 1 L bottle	▪ 100 mL bottle ▪ 1 L bottle	▪ 10 × 10 mL bottles ▪ 100 mL bottle ▪ 1 L bag (closed system)
Fill and finish manufacturing process	Filtration 0.22 µm	Filtration 0.22 µm	▪ Sterile filtration ▪ Validated aseptic process ▪ Simulations
Quality controls	Standard QCs	Extended QCs to assess identity, potency, purity and safety	Validated QCs according to European pharmacopeia assessing identity, potency, purity and safety
Product documentation	▪ Certificate of analysis ▪ Certificate of origin ▪ Non-hazardous product statement	▪ Certificate of analysis ▪ Certificate of origin ▪ Non-hazardous product statement	▪ Certificate of analysis ▪ Certificate of compliance ▪ Certificate of origin ▪ Non-hazardous product statement
Regulatory documentation	n/a	▪ Batch production documentation ▪ Quality agreement	▪ Drug master file (DMF) ▪ Chemistry, manufacturing and control (CMC) section ▪ Protocols for identity, concentration and activity testing ▪ Quality agreement
Audit	According to ISO 9001 2015	According to ISO 9001 2015	According to ICH Q7 Eudralex Volume 4 Part II and Annex I

A Scalable and Reproducible Transfection Reagent For a Robust Manufacturing Process

To ensure robust manufacturing, scaled-up or scaled-out therapeutic virus production with PEIpro®-HQ or PEIpro®-GMP is designed to maintain the production yields achieved with R&D grade PEIpro® during process development. PEIpro® is manufactured and formulated using a highly controlled and strict manufacturing process. By ensuring reproducibility from one run to the next, PEIpro® greatly facilitates process standardization, a key feature of reliable large-scale production. Moreover, PEIpro® is released using advanced quality controls, including a specification for transfection efficiency that supports excellent lot-to-lot consistency (Figure 1).

Figure 1: *High Reproducibility with PEIpro® Regardless of (A) Quality Grade and (B) Production Lot*

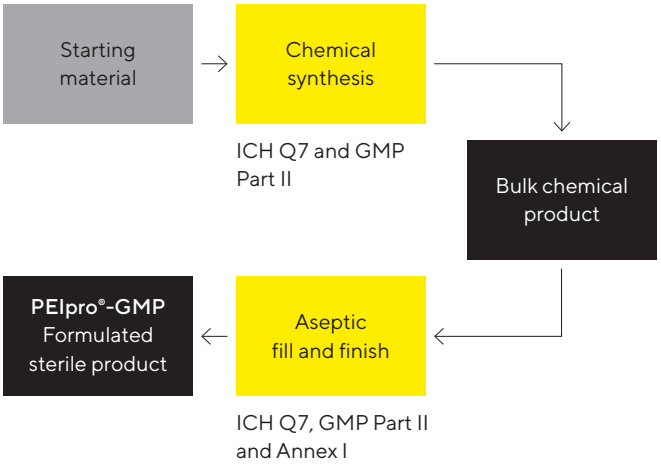


Note. (A) Suspension HEK-293T cells were seeded at 1×10^6 cells/mL in a commercial culture medium and transfected with either PEIpro®, PEIpro®-HQ or PEIpro®-GMP reagents following the same protocol for each product. AAV-2 titers were measured 72 hours after transfection using a GFP reporter gene expression. (B) Suspension HEK-293T cells were seeded at 1×10^6 cells/mL in a commercial culture medium and transfected with four different lots of PEIpro®-GMP with a GFP-expressing plasmid. Transfection efficiency was measured 48 hours post-transfection by flow cytometry.

Risk Mitigation With PEIpro®-GMP

Introducing any starting or raw | ancillary material in the manufacturing process of cell and gene therapies adds potential risk factors. Using PEIpro®-GMP as the transfection reagent to produce viral vectors increases confidence in the quality and safety of the process and product. PEIpro®-GMP is manufactured in compliance with international GMP guidelines ICH Q7 and correspondingly with EU "Guidelines for good manufacturing practices for medicinal products for human and veterinary use" (ICH Q7 and EudraLex Vol 4, Part II and Annex I: Manufacture of Sterile Medicinal Products). PEIpro®-GMP 1 L is provided in Flexsafe® bags with MPC connectors and weldable tubing suitable for closed systems to decrease contamination risks. A residual test to analyze the presence of the transfection reagent in the drug product is available through selected service providers.

Figure 2: *PEIpro®-GMP manufacturing process*



Note. PEIpro®-GMP is provided with a full set of tools to ensure traceability with dedicated regulatory documentation and analytics with different protocols to support both IND and BLA submissions.

Technical Specifications

PEIpro®

Attribute	PEIpro® 1.5 mL	PEIpro® 10 mL	PEIpro® 100 mL	PEIpro® 1 L
Quality grade	Research grade	Research grade	Research grade	Research grade
Type of container	Vial	Bottle	Bottle	Bottle
Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Neck diameter [mm]	n/a	13.7 ± 0.05	17.5 ± 0.05	27.4 ± 0.08
Height with closure [mm]	n/a	58.4 ± 1.5	100.8 ± 2.0	215.9 ± 2.5
Bottle diameter [mm]	n/a	24.9 ± 1.0	50.3 ± 1.5	91.4 ± 2.0

PEIpro®-HQ

Attribute	PEIpro®-HQ 100 mL	PEIpro®-HQ 1 L
Quality grade	Highly qualified	Highly qualified
Type of container	Bottle	Bottle
Material	Polypropylene	Polypropylene
Neck diameter [mm]	17.5 ± 0.05	27.4 ± 0.08
Height with closure [mm]	100.8 ± 2.0	215.9 ± 2.5
Bottle diameter [mm]	50.3 ± 1.5	91.4 ± 2.0

PEIpro®-GMP

Attribute	PEIpro®-GMP 10 × 10 mL	PEIpro®-GMP 100 mL	PEIpro®-GMP 1 L	PEIpro®-GMP Satellite Bag 100 mL
Quality grade	GMP	GMP	GMP	GMP (for ID test)
Type of container	Bottle (×10)	Bottle	Flexsafe® 2D Bag 1 L	Flexsafe® 2D Bag 1 L
Material	PETG (sterile)	PETG (sterile)	S80 Polyethylene film	S80 Polyethylene film
Neck diameter [mm]	14	28	n/a	n/a
Height [mm]	64	110	n/a	n/a
Bottle diameter [mm]	38	54	n/a	n/a
Bag dimension (W × H) [mm]	n/a	n/a	240 × 310	240 × 310
Connector	n/a	n/a	MPC (coupling male 1:4")	MPC (coupling male 1:4")
Other	n/a	n/a	Weldable tubing	Weldable tubing

Ordering Information

Item	Volume	Package	Order Number
PEIpro®	1.5 mL	Vial	101000017
PEIpro®	10 mL	Bottle	101000033
PEIpro®	100 mL	Bottle	101000026
PEIpro®	1 L	Bottle	101000029
PEIpro®-HQ	100 mL	Bottle	101000052
PEIpro®-HQ	1 L	Bottle	101000039
PEIpro®-GMP	10 × 10 mL	Bottle	102000131
PEIpro®-GMP	100 mL	Bottle	102000121
PEIpro®-GMP	1 L	Bag	102000008
PEIpro®-GMP satellite bag	100 mL	Bag	102000004

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