

Scalable viral vector production

PEIpro[®] product range



- + Gold standard transfection reagent for Gene and Cell therapy
- + Seamless transition from process development up to commercialization
- + Obtain high virus yields in both adherent and suspension cell systems
- + First GMP grade transfection reagent available worldwide
- + Customized regulatory support to meet compliance requirements
- + Validated GMP-compliant residual test service available

Process
development

Pre-clinical &
early phase clinical trial

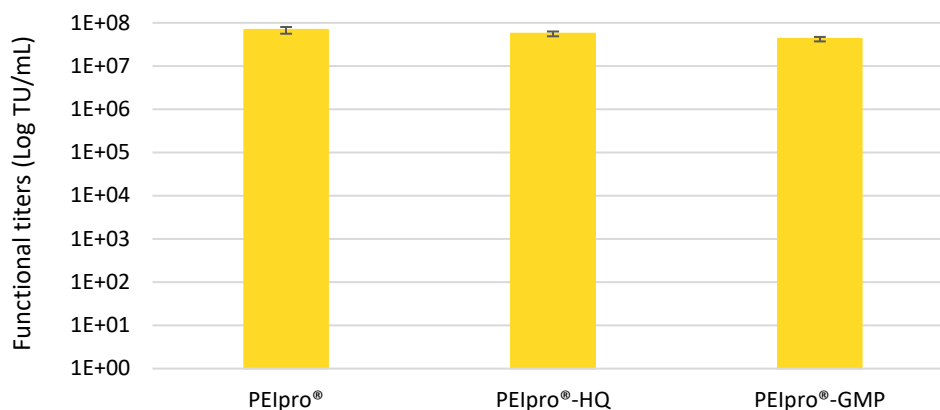
Clinical trials &
commercialization

Characteristics	PEIpro [®]	PEIpro [®] -HQ	PEIpro [®] -GMP
Quality Grade	R&D grade	Pre-clinical grade	GMP grade
Composition	Ready to use, chemically defined and animal derived component free		
Packaging	Bottles	Bottles	Bottles Bags (closed system)
Manufacturing site	Polyplus-transfection	Polyplus-transfection	Dual sourced from two GMP accredited facilities
Fill & finish manufacturing process	Sterile filtration	Sterile filtration	Sterile filtration Validated aseptic process
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
Audit	According to ISO 9001 2015	According to ISO 9001 2015	According to ICH Q7, GMP Part II and Annex I

Range of PEIpro[®] quality grade reagents for each step of nucleic acid-mediated viral vector-based manufacturing.



Three quality grades of PEIpro® with the same viral yield:



Transfection were performed on HEK-293T cells using standard protocols.

Polyplus-transfection® is the only supplier worldwide to offer a global solution:

- + 100% audit rate
- + PEIpro® residual test available
- + Several packaging sizes and conditioning
- + Dual sourced PEIpro®-GMP
- + Fully GMP-compliant PEIpro®-GMP:



Product	Part N°	Reagent size
PEIpro®	101000017	1,5 mL bottle
	101000033	10 mL bottle
	101000026	100 mL bottle
	101000029	1 L bottle

Product	Part N°	Reagent size
PEIpro®-HQ	101000052	100 mL bottle
	101000039	1 L bottle

Product	Part N°	Reagent size
PEIpro®-GMP	102000008 / 102000001	1 L bag
	102000005	300 mL bag
	102000002	100 mL bottle
	102000011	10 x 10 mL bottles



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