



for Antibody & Viral **Vector Production** 





## MAXgene® GMP

### Our premier GMP grade transfection PEI for accelerated clinical therapies.

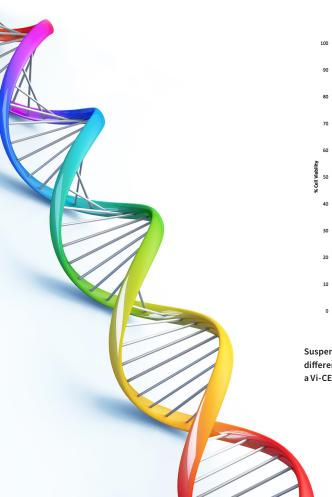


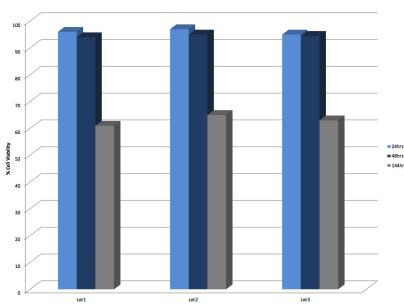
### **HIGHLIGHTS**

- Clinical trials and commercialization
- High transfection efficiency
- cGMP solution manufactured under ISO 13485:2016
- Validated manufacturing processes
- Fully synthetic, animal-origin-free
- Cost-effective
- Reproducible, scalable, versatile

MAXgene GMP (cat# 26406/ solution and cat# 26435/ powder) is a cGMP transfection reagent for the development and manufacturing of viral vectors for cell- and gene-based therapies. It is an ideal reagent for the manufacture of clinical grade AAVs, LVs and recombinant proteins. MAXgene GMP capitalizes on the efficiency and scalability of Polysciences' research grade (PEI MAX or Transporter 5) while adding the validation process and regulatory components necessary for its use as a raw material in clinical trials and commercial manufacturing. Our stringent formulation, manufacturing and QC processes ensure each batch meets established specifications for identity, potency, purity, traceability and safety.

With MAXgene GMP, Transporter 5, and PEI MAX, Polysciences offers a complete range of products (solid and liquid forms) for use through all phases of bioprocessing.





Suspension HEK-293T cells were seeded at a density of  $1 \times 10^6$  cells/mL and transfected with three different lots of MAXgene GMP. Cell proliferation was measured 24hr, 48hr and 144hr post-transfection by a Vi-CELL® XR counter.

### **Bioprocess Manufacturing Scale-up Sequence**

PEI MAX® cat# 24765	Transporter 5® cat# 26008	MAXgene® GMP, Powder cat# 26435	MAXgene® GMP cat# 26406
1g, 100mg sizes	5mL, 50mL sizes	1g size	1L size
Research Grade Solid	Research Grade Solution	Commercial Grade Powder	Commercial Grade Solution
Standard QC	Standard QC	Validated QC	Validated QC

#### **TRANSPORTER 5®**

### Non-GMP, Research Grade Solution

Transporter 5 (cat# 26008) is a non-GMP, research grade ready-to-use solution for initial process development and scale-up prior to GMP validation and production batches. As every transfection is a major investment, we have formulated Transporter 5 to offer reliable performance in any process across expression systems.

### PEI MAX®

# Linear Polyethylenimine Hydrochloride (MW 40,000), Non-GMP, Research Grade Solid

PEI MAX 40K (cat# 24765) is a non-GMP research grade solid transfection reagent popular for academic and early stage research.

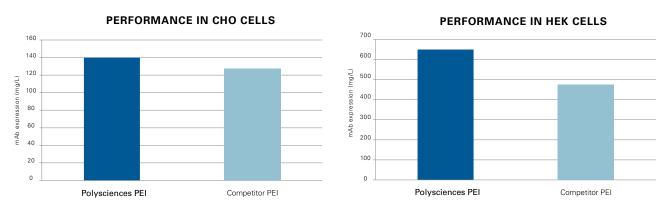
#### **HIGHLIGHTS**

- Non-GMP, research grade solution
- For pre-cGMP pilot studies
- Provides seamless transition to MAXgene for cGMP batches
- High transfection efficiency
- Predictable and scalable performance
- Used for process development, preclinical and early phase clinical trials

### **HIGHLIGHTS**

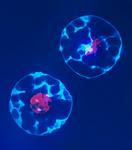
- Non-GMP, research grade solid
- Used in process development and pre-clinical studies

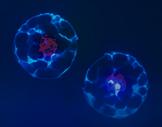
Combined with appropriate quality controls, as well as lot-to-lot release testing for MAXgene, Transporter 5 and PEI MAX, our PEI-based transfection reagents can support academics and biopharmaceutical companies from the initial small-scale process development phase to large-scale clinical virus manufacturing.

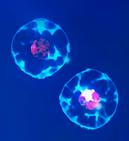


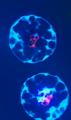
\*Expression of mAb B72-3, 8 days post-transfection using Gibco\* Freestyle F17 cell culture media . For more information, see the following publication: Delafosse, L., Xu, P. & Durocher, Y. Comparative study of polyethylenimines for transient gene expression in mammalian HEK293 and CHO cells. Journal of Biotechnology 227;103–111 (2016). doi:10.1016/j.jbiotec.2016.04.028

MAXgene®, PEI MAX®, & Transporter 5® are registered trademarks of Polysciences. Vi-CELL® is a registered trademark of Beckman Coulter. Gibco® is a registered trademark of Thermo-Fisher Scientific.













### U.S. CORPORATE HEADQUARTERS

### Polysciences

400 Valley Rd. Warrington, PA 18976 1(800) 523-2575 / (215) 343-6484 1(800)343-3291 fax info@polysciences.com

### GLOBAL SALES OFFICES

Europe
Polysciences Europe GmbH
info@polysciences.de

**Asia Polysciences Asia-Pacific, Inc.**info@polysciences.tw

India
Ott Scientific India Pvt. Ltd.
info@ottscientific.in

Brazil
Ott Scientific Brasil
info@ottscientific.com.br



