SARTORIUS

Product Datasheet

in vivo-jetPEI®

The Gold Standard for In Vivo Delivery of DNA, siRNA, miRNA, shRNA, and Other Oligonucleotides

Product Information

in vivo-jetPEI® is a ready-to-use cationic polymer reagent. It has been specifically developed for the transfection of nucleic acids (DNA, siRNA, miRNA, shRNA, and other oligonucleotides) via any route of administration in any animal model.

With over 650 peer-reviewed publications, in vivo-jetPEI® is well-established in the field of in vivo delivery for functional studies, cancer and gene therapy development, or vaccination. In addition, in vivo-jetPEI® has the advantage of being available in different quality grades (research grade and GMP grade) enabling a seamless transition from the laboratory to the clinic.

Features and Benefits

- **Time-Saving:** Ready-to-use reagent requiring no equipment or formulation expertise
- **GMP Grade:** Manufactured in accordance with US and EU Guidelines
- **Successful:** Widely used excipient from research to clinical trials
- **Proven:** Well-documented technology with over 650 peer-reviewed publications

Introduction

Relevant Applications

- RNA | DNA vaccination
- Gene therapy
- RNA | DNA therapeutics
- Genome editing
- Oncology treatment
- Pulmonary diseases
- Protein replacement therapy
- In vivo proof-of-concept studies
- Academic research

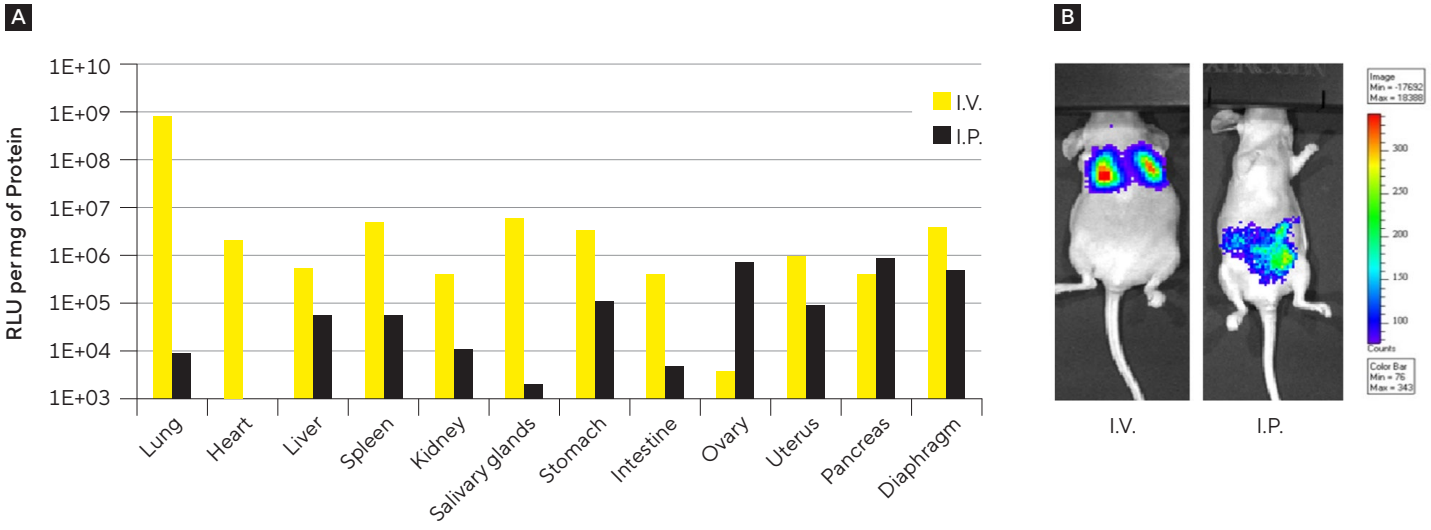
Relevant Process Steps

- Drug product formulation
- Delivery | transfection

Performance

Versatile
in vivo-jetPEI® is effective for the delivery of nucleic acids (DNA, siRNA, miRNA, shRNA, other oligonucleotides) in any animal model (mouse, rat, rabbit, llama, monkey, etc.) and can be used to target a wide range of organs by systemic and local administration. The route of injection largely determines which organs are targeted, allowing scientists to modulate biodistribution according to their needs and objectives (Figure 1). When delivering pDNA, cell-specific promoters can also be combined with a local injection route to restrict expression to a specific organ | tissue.

Figure 1: *in vivo-jetPEI® Leads to Efficient Gene Expression in Different Organs Depending on the Administration Route*

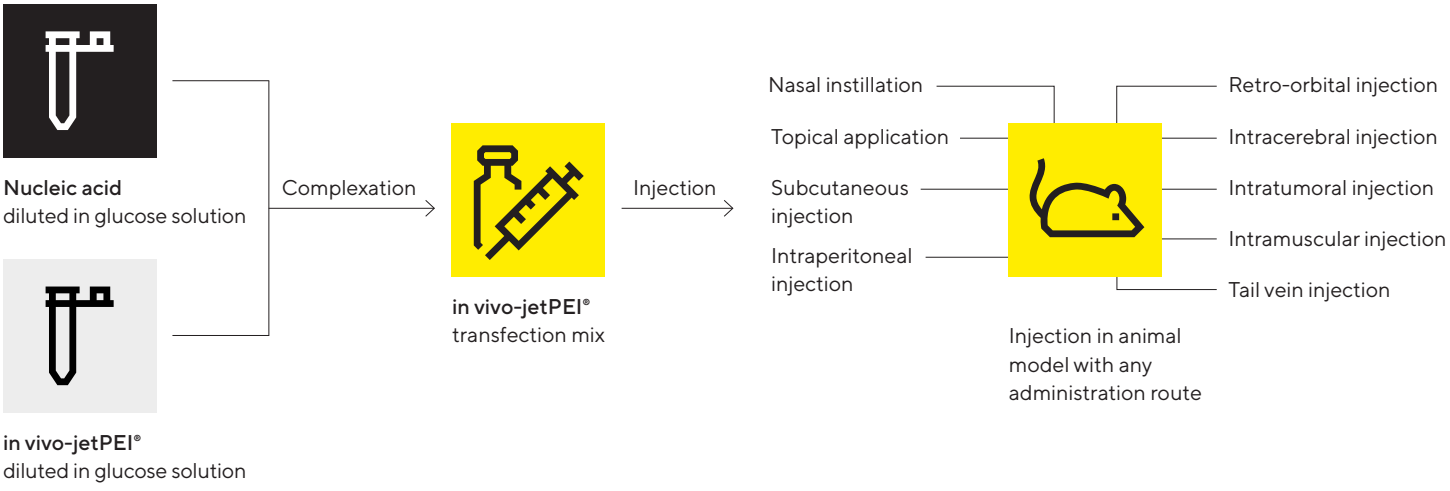


Note. Complexes were formed using 40 or 100 µg of Luciferase-expressing plasmid and in vivo-jetPEI® at an N | P ratio of 8, in 200 or 500 µL of 5% glucose and injected either through the retro-orbital sinus (IV) or intraperitoneally (IP), respectively. Different organs were extracted 24 hours after injection, and (A) luciferase expression was measured or (B) live imaging was performed using the IVIS system (Perkin Elmer).

Time-Saving

in vivo-jetPEI® is a ready-to-use reagent with a straightforward protocol, saving time and cost on formulation. The nucleic acid and in vivo-jetPEI® complexes are prepared in just two steps and are ready to be injected into the animal model within 15 minutes (Figure 2).

Figure 2: *Two-Step Protocol for In Vivo Delivery of in vivo-jetPEI®*



Note. This protocol is suitable for direct injection of nucleic acid | in vivo-jetPEI® complexes through any local or systemic administration route.

Seamless Transition From Fundamental Research to Human Clinical Trials

In addition to being used for in vivo functional and proof-of-concept studies, in vivo-jetPEI® has been chosen as a delivery vehicle for several drug development programs thanks to its reliability, safety, and efficacy. Several preclinical studies and human clinical trials are currently underway for cancer therapy, vaccination, and immunization using the GMP-compliant grade of in vivo-jetPEI® (Table 1).

Table 1: *Overview of in vivo-jetPEI® Transfection Reagent Offering for Non-Viral In Vivo Delivery*

Characteristics	in vivo-jetPEI®	in vivo-jetPEI® GMP
	Fundamental In Vivo Research and Proof-of-Concept Studies	Clinical Trials and Commercialization
Product pack size	0.1 mL | 0.5 mL | bulk quantities	10 g
Quality controls (QC)	Standard QCs	Validated QCs according to US and | or European Pharmacopeia assessing identity, potency, purity, and safety
Quality and regulatory documents	▪ Certificate of analysis (CoA) ▪ Material safety data sheet (MSDS)	▪ CoA ▪ Certificate of Compliance (CoC) ▪ MSDS ▪ Chemistry, manufacturing, and controls (CMC) documentation ▪ Drug master file (DMF) submitted to the FDA ▪ Quality agreement
Manufacturing environment	According to ISO 9001 2015	According to GMP guidelines

Note. in vivo-jetPEI® is suitable for applications from fundamental research to proof-of-concept and preclinical studies. A GMP-compliant grade is also available to meet the quality and regulatory requirements of human clinical trials.

Technical Specifications

Attribute	in vivo-jetPEI® 0.1 mL	in vivo-jetPEI® 0.5 mL	in vivo-jetPEI® GMP Powder 10 g
Quality grade	Research-grade	Research-grade	GMP-grade
Type	Ready-to-use cationic polymer solution	Ready-to-use cationic polymer solution	Bulk powder
Volume	0.1 mL	0.5 mL	10 g powder
Container	Polypropylene vial	Polypropylene vial	Borosilicate glass bottle
Storage	–20 °C ± 5	–20 °C ± 5	–20 °C ± 5
Expiry date	Indicated in the CoA and on the product	Indicated in the CoA and on the product	Indicated in the Certificate of Analysis
Provided with	10% glucose solution (10 mL bottle)	10% glucose solution (2 x 10 mL bottle)	—
Number of injections	Sufficient for 15 to 20 IV injections in mice	Sufficient for 78 to 104 IV injections in mice	—

Ordering Information

Item	Description	Package | Volume | Quantity | Size	Order Number
in vivo-jetPEI® 0.1 mL	One 0.1 mL vial of in vivo-jetPEI® reagent supplied with one 10 mL bottle of 10% glucose solution	0.1 mL vial (+ 10 mL 10% glucose solution)	101000040
in vivo-jetPEI® 0.5 mL	One 0.5 mL vial of in vivo-jetPEI® reagent supplied with 2 × 10 mL bottle of 10% glucose solution	0.5 mL vial (+ 2 × 10 mL 10% glucose solution)	101000030
in vivo-jetPEI® GMP powder 10 g	10 g of bulk powder of in vivo-jetPEI® GMP supplied in a borosilicate glass bottle	10 g bulk powder in a borosilicate glass bottle	102000003

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