

Title (en)  
SINGLE-VIAL FORMULATIONS OF DNA/LIPID COMPLEXES

Title (de)  
EINZELFLÄSCHEHENE FORMULIERUNGEN VON DNA (LIPID-KOMPLEXEN)

Title (fr)  
FORMULATIONS EN AMPOULE UNIDOSE DE COMPLEXES ADN/LIPIDES

Publication  
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Application  
**EP 96911722 A 19960411**

Priority

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Abstract (en)  
[origin: WO9634109A1] The invention relates to single-vial formulations of plasmid DNA/cationic lipid complexes for human clinical use prepared by various different processes, for example, by the process comprising the steps of: (a) autoclave sterilizing a cationic lipid solution at a concentration sufficiently high to substantially prevent lipid degradation during said autoclave sterilization; (b) diluting the sterilized cationic lipid solution of step (a) to a degree sufficient to substantially prevent lipid aggregation during step (d) below; (c) filter sterilizing a plasmid DNA solution; (d) adding the sterilized plasmid DNA solution of step (c) to the diluted sterilized cationic lipid solution of step (b) at an ionic strength that is lower than isotonicity to form DNA/lipid complexes; and (e) adjusting the DNA/lipid complexes of step (d) to near isotonicity.

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IPC 8 full level  
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