

Vaccine Adjuvants

Your solution for therapeutic vaccines



Montanide™ ISA 51 VG
Montanide™ ISA 720 VG

Nota

The analytical specifications warranted are only those mentioned on the certificate of analysis supplied with each delivery of the product.

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Subsidiary of the AIR LIQUIDE Group



MONTANIDE™ ISA are ready-to-use adjuvants which allow the manufacture of water in oil emulsions with an easy process. They can be based on mineral oil or non mineral oil. Seppic has launched this range of vaccine adjuvants since 1992 with a high safety profile suitable for human injection. It is today widely used in clinical trials all over the world in therapeutic vaccines mainly against cancer but also HIV, malaria or autoimmune diseases.

Product's characteristics

Montanide ISA 51 VG is based on Mineral oil and is mainly used in cancer vaccine application.
 Montanide ISA 720 VG is based on non mineral oil and is mainly used in infectious disease vaccine application.

Current status

Today Montanide ISA 51VG and Montanide ISA 720 VG have been used in more than 150 clinical trials from phase I to phase III. Montanide ISA 51 VG is approved in a commercial vaccine against lung cancer.

Seppic has filed drug master files (CTD module 3) for both grades and can provide complete information under confidential agreement as listed in table 1

From pre-clinical to vaccine commercialization, Seppic brings you full support to make your vaccine development a success. Exemple: Validation and qualification of the emulsion, process optimization, regulatory assistance, adapted batch size and packaging...

	MONTANIDE™ ISA 51 VG Sterile grade	MONTANIDE™ ISA 720 VG Sterile grade
PRODUCTION	GMP Aseptic filing	GMP Aseptic filing
PACKAGING	3 ml vials	3 ml vials
DMF	US, Canada, European CTD Japan	US, European CTD
ICH STABILITY	3 years	2 years
INVESTIGATOR BROCHURE	Available	Available
TOXICITY DATA	Acute toxicity, Mutagenicity (AMES), Micronucleus, Repeated toxicity	Acute toxicity, Mutagenicity (AMES), Micronucleus, Repeated toxicity

Table1: Product's Information

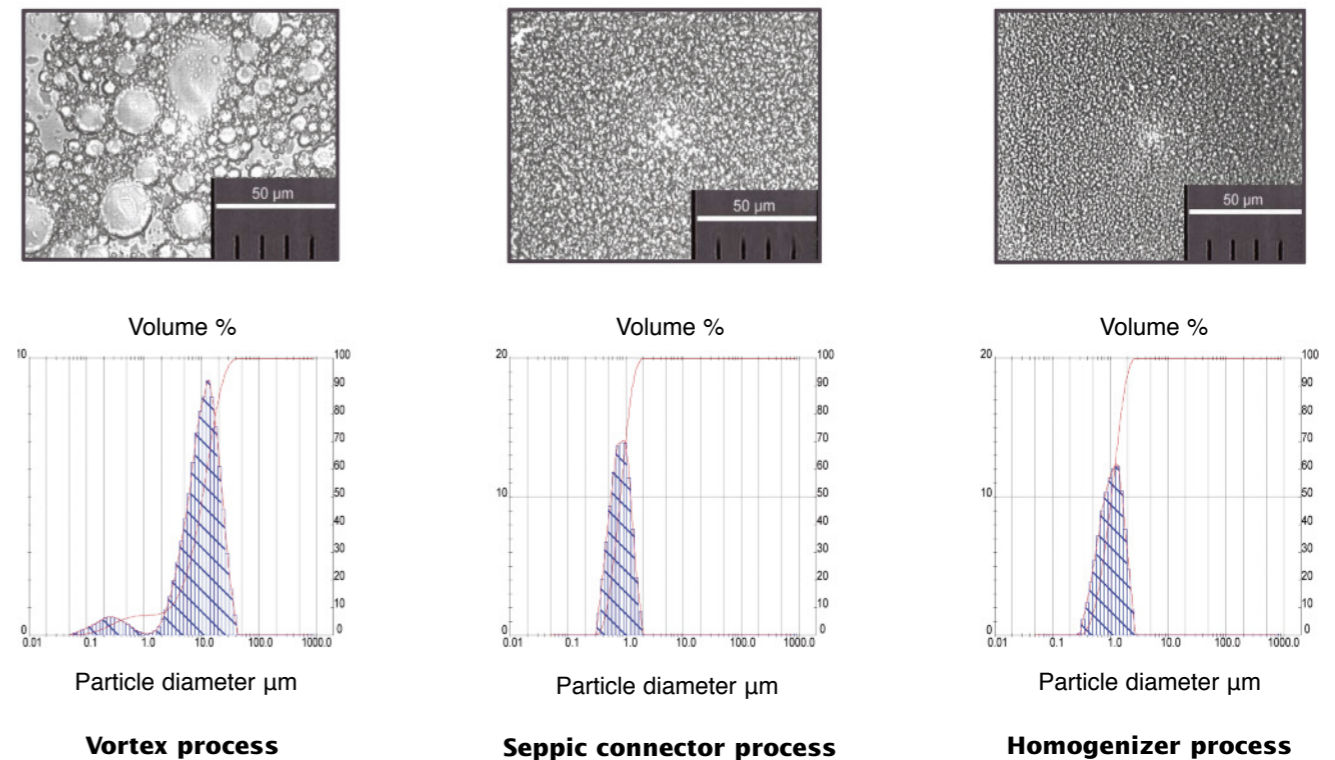
Delivering a healthier future



Process

Seppic has developed an easy process using a small connector between 2 syringes to manufacture small volume of emulsion, ready to inject. This process is ideal for clinical trials as it allows the manufacture of a stable emulsion with a reproducible and repeatable quality (data available on request). The quality of the emulsion with Seppic process is equivalent to the quality obtained with an homogenizer (Reference for Seppic). See in the figure 1 the difference between 3 different processes.

Figure 1



Production

Seppic ensures a complete GMP process for the manufacture of its adjuvants, from raw materials to QA batch release. Montanide adjuvants are manufactured under aseptic conditions in a pharmaceutical facility.