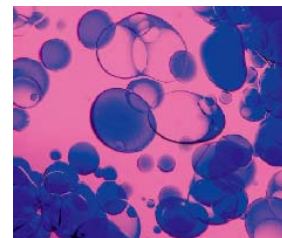




PHA PREMIUM™

GMP Surfactant range



● Future in pharma excipient regulation

● SEPPIC marketing position

● PHA PREMIUM range

● Products already available

Pharma Excipient regulation

Currently, in most of European and North-American countries no regulation exists on how to manufacture excipients for the pharmaceutical industry. In Europe, excipient conditions of use are only defined in regulation relative to the drug products, the directive 2001/83/EC on the Community code relating to medicinal products for human use. This one is itself amended by the directive 2004/27/EC in which **the need for GMP production of some excipients** is emphasized. For the time being, there is no legal basis to inspect excipient manufacturers nor official GMP guidelines.

Different organisms such as the Pharmaceutical Quality Group (PQG), the International Pharmaceutical Excipient Council (IPEC), or the World Health Organisation (WHO) have outlined GMP guidelines specific to starting materials and excipients. These guidelines respect the main steps of the pharmaceutical industry guidelines.

SEPPIC Marketing position

SEPPIC, following an increasing demand from the pharmaceutical industry has developed a new surfactant range that fully complies with **future excipients GMP requirements**. Quality investment is one of our Credo at SEPPIC, especially for products dedicated to the health industry.

PHA PREMIUM range

The **PHA PREMIUM** range will enable **you** to comply with the **future guidelines of excipient GMP** production. This product range is also complying with 2 Pharmacopoeia: USP and Ph.Eur.

PHA PREMIUM range : products already available

The new range; PHA PREMIUM includes -until now- the following surfactants:

Family	Chemical name	SEPPIC GMP grade
GMP Sorbitan Esters	Sorbitan laurate	MONTANE™ 20 PHA PREMIUM
GMP Polysorbates	Polysorbate 20 Polysorbate 80	MONTANOX™ 20 PHA PREMIUM MONTANOX™ 80 PHA PREMIUM

This surfactant range is dedicated to evaluate. To be in line with pharmaceutical industry needs, SEPPIC focus on a quality policy that takes into account future excipient GMP guidelines, thus this range is dedicated to grow according to the global need of the pharmaceutical market.

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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