

Vaccine Adjuvants – VAC 20 HA

What is an adjuvant?

An adjuvant is a substance that enhances and helps the ability of an antigen to stimulate the immune system. An antigen alone does not stimulate a significant response. Less vaccine antigen (inactive bacteria, virus or toxin) is needed when paired with the right adjuvant.

Functionality

Its functionality is to adsorb a large range of proteins and inactivated viruses. At pH of preparation of vaccines around 5-7, Pseudo-Boehmite gels have the property to:

- + Adsorb negatively charged antigens
- + Slow the release of an inactivated virus or bacteria
- + Activate and stimulate the immune response
- + Create a more rapid development of high titered and long-lasting antibody responses after primary immunization

pH

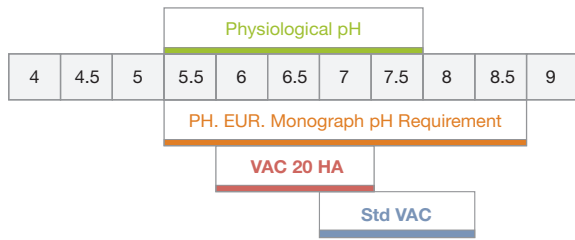


Figure 1. VAC 20 HA stays within range of physiological pH

Adsorption Capacity

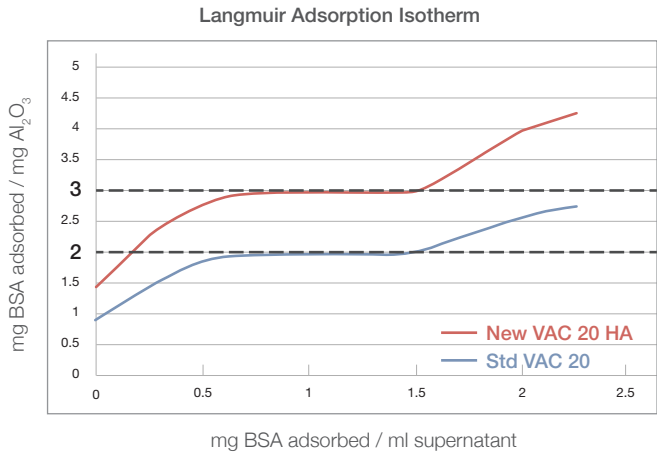
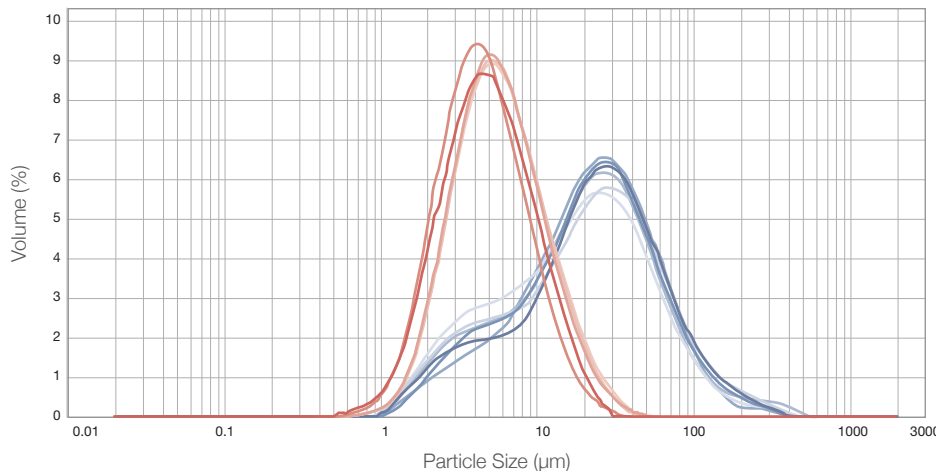


Figure 2. VAC 20 HA has 50% more Adsorption Capacity than the Standard VAC 20 grade

High Adsorption Grade – VAC 20 HA

The vaccine adjuvant manufacturing process used by SPI Pharma has been developed and optimized to include a gel, VAC 20 HA, that offers higher protein adsorption capacity with a finer particle size (PSD with a D50 of around 5 µm) and a narrower pH range (6.0-7.0). These characteristics make VAC 20 HA a high performance adjuvant compared to other regular adjuvants.

Our VAC 20 HA grade has a 2% Assay Al₂O₃%. SPI can customize the assay level with this improved adsorption capacity. This new grade is validated at our facility in France, which is FDA and ANSM approved.



Particle Size Distribution

- New VAC 20 HA
D50%: ~5µm
- Std VAC 20
D50%: ~25µm

Figure 3. VAC 20 HA has a finer particle size that reduces inflammation at the point of injection. The finer PSD means more surface area for more adsorption capacity.

Vaccine Adjuvants – VAC 20 HA

DESCRIPTION

White or almost white, translucent, viscous, colloidal gel. A supernatant may be formed upon standing.

Storage: Protect from excessive temperature and from freezing in its original package.

Retest Date: 3 years from the date of mfg.

| Characteristics | Grades | Ph. Eur. Specification | VAC 20 | VAC 20 HA ^{*: around} |
|--|--------|--|--|--|
| Sterility | | | All products can be sterilized | |
| Identification | | Al Test | Al Test | Al Test |
| Assay Al₂O₃ % | | 90 – 110% Aluminium stated on the label | 1.9 – 2.1 % | 1.9 – 2.1 % |
| Corresponding to Al(OH)₃ % | | | 2.91 – 3.21 | 2.91 – 3.21 |
| Corresponding to Al % | | | 1.00 – 1.11 | 1.00 – 1.11 |
| Protein Binding Capacity, For Info Only | | | 2 mg BSA / mg Al ₂ O ₃ * | 3 mg BSA / mg Al ₂ O ₃ * |
| Adsorption Power (Ph Eur Test) | | Conforms | Conforms No detectable BSA in solution | Conforms No detectable BSA in solution |
| Point of Zero Charge, For Info Only | | | 10.2 | 10.2 |
| Sedimentation (Ph Eur Test) @ 5mg Al/ml | | NMT 5 ml | NMT 5 ml | NMT 5 ml |
| Viscosity, For Info Only | | | NMT 1000 cps (Brookfield V3/30) | 1000 – 2000 cps (Brookfield V3/30) |
| Nitrate (NO₃) (Ph Eur Test) | | NMT 100 ppm | NMT 100 ppm | NMT 100 ppm |
| Ammonium (NH₄) (Ph Eur Test) | | NMT 50 ppm | NMT 50 ppm | NMT 50 ppm |
| Sulphate (Total SO₄) (Ph Eur Test) | | NMT 0.5 % | NMT 0.5 % | NMT 0.5 % |
| Chloride (Cl) (Ph Eur Test) | | NMT 0.33 % | NMT 0.33 % | NMT 0.33 % |
| Heavy Metals (as Pb) (Ph Eur Test) | | NMT 20 ppm | NMT 20 ppm | NMT 20 ppm |
| Arsenic (As) (Ph Eur Test) | | NMT 1 ppm | NMT 1 ppm | NMT 1 ppm |
| Iron (Fe) (Ph Eur Test) | | NMT 15 ppm | NMT 15 ppm | NMT 15 ppm |
| pH (Ph Eur Test) | | 5.5 – 8.5 | 5.5 – 8.5 | 6.0 – 7.0 |
| Endotoxins (Ph Eur Test) | | LT 5 IU | LT 5 IU | LT 5 IU |

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Order No. SPI-VAC-20HA-0100-07201400.
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