

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

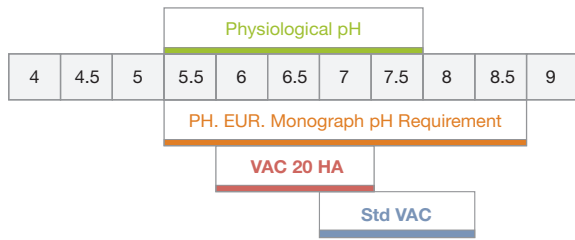


Figure 1. VAC 20 HA stays within range of physiological pH

Adsorption Capacity

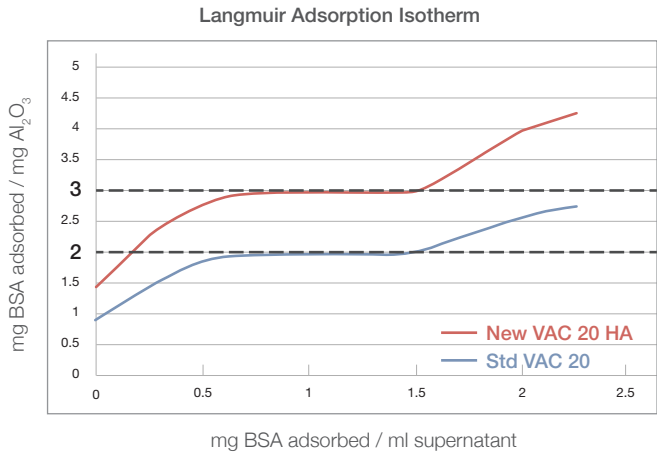
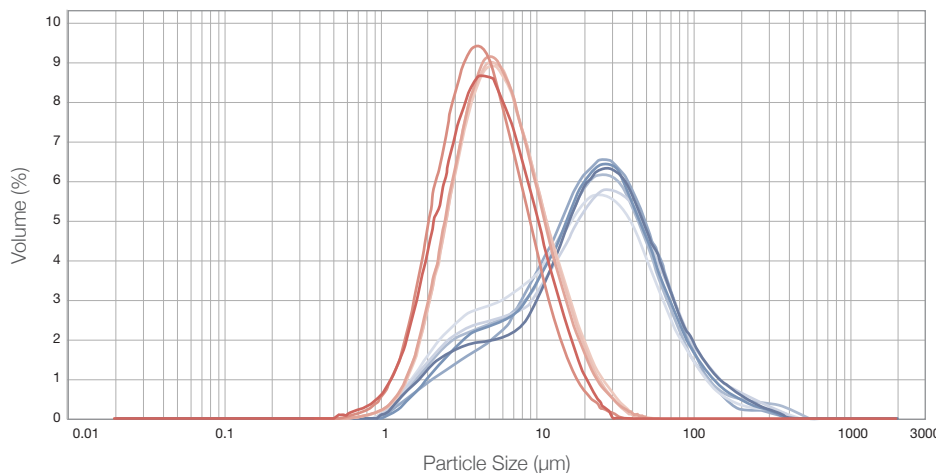


Figure 2. VAC 20 HA has 50% more Adsorption Capacity than the Standard VAC 20 grade

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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