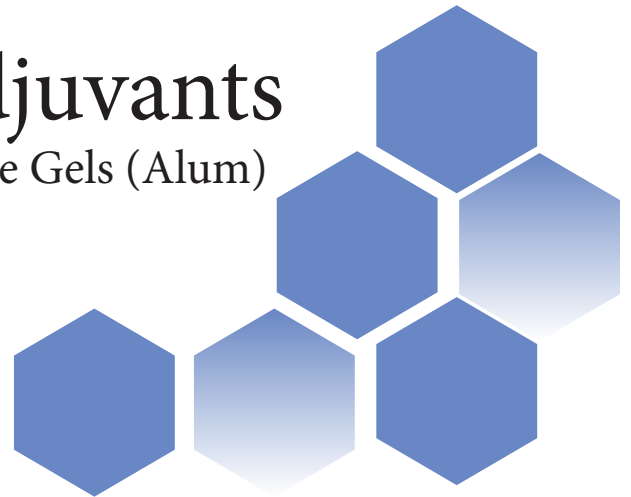




Vaccine Adjuvants

Aluminum Hydroxide Gels (Alum)



Vaccine Adjuvants

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.

What is VAC?

Aluminum hydroxide gel VAC grades for adsorption (Pseudo-Boehmite form) are used as an adjuvant in human and animal vaccines. It is used to bind negatively charged antigens.

Functionality

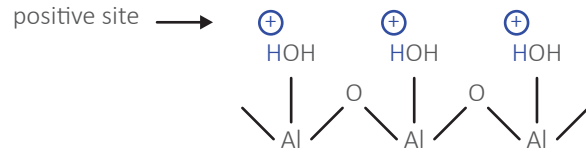
Its functionality is to adsorb a large range of proteins and inactivated viruses. At pH of preparation of vaccines around 5-7, Pseudo-Boehmite gels have the property to:

- + 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

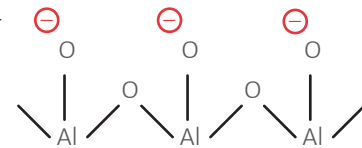
CUSTOMIZATION

SPI Pharma offers the ability to customize our VAC grades to optimize the performance with your antigen or match your current adjuvant.

Adsorbent properties are related to surface area and surface groups, the hydroxyl groups can accept a proton:



donate a proton:
negative site →



Aluminium Hydroxide Adjuvants surface charge is pH dependant.

Figure 1. Schematic of the structure of the gel. When the surface of the aluminum oxyhydroxide is positive, it attracts negatively charged antigens. Adsorption capacity is determined by surface area and surface charge from the hydroxyl groups.

Aluminium Hydroxide gels used as Vaccine Adjuvants:

- + They are called Aluminium Hydroxide but they are not chemically $Al(OH)_3$
- + They are poorly crystalline Boehmite (Pseudo-Boehmite): $AlO(OH), nH_2O$: Aluminium oxyhydroxide
- + Composed of fibrous primary particles of a few nanometers, Pseudo-Boehmite has adsorption properties and a large surface area (around 500 m²/g)

Adjuvants surface charge

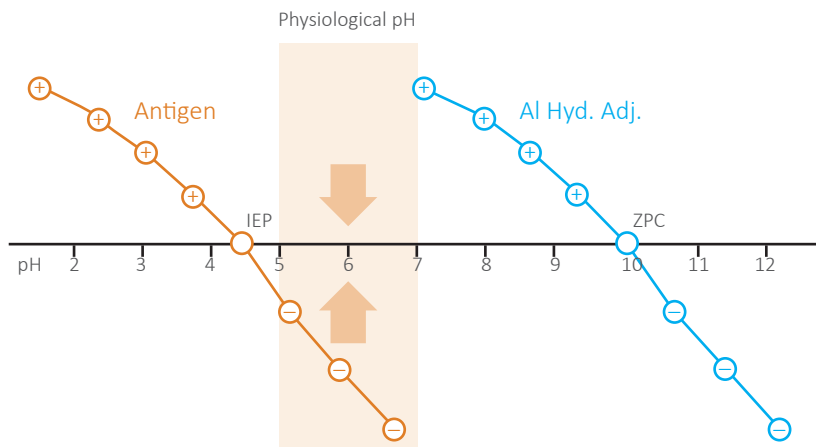


Figure 2. At physiological pH around 5.0 – 7.0, Pseudo-Boehmite gels have the property to adsorb negatively charged antigens. Zero point charge (ZPC) is around pH 10.2.

EXAMPLE APPLICATIONS

Veterinary applications for vaccines for livestock and companion animals (production from inactivated virus)

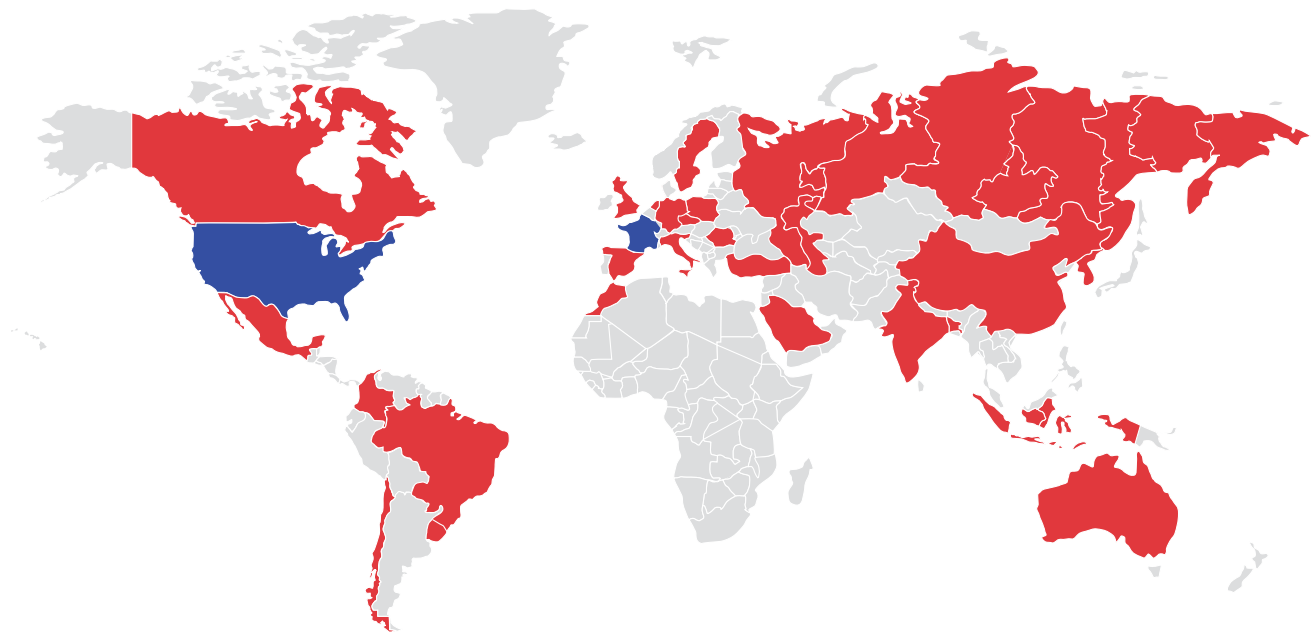
- + Highly contagious diseases:
Foot and Mouth Disease, Classical Swine Fever, Aujeszky's Disease (Pseudorabies), Infectious Bovine Rhinotracheitis (IBR), Avian influenza
- + Swine, Poultry diseases
- + Multiple species diseases:
Anthrax, Bluetongue, Brucellosis (Brucella abortus), Leptospirosis, Paratuberculosis, Q fever, Rabies, Rinderpest, West Nile fever

SPI'S ADVANTAGES

SPI has two facilities for the production of its VAC products, one in France and the other in US. This allows us to ensure security of supply. Both sites produce under cGMP conditions and are regularly audited by ANSM (French Health Agency), FDA and many customers.

Locations where VAC has been sold

- Manufacturing & Sales
- Sales



Vaccine Adjuvants

DESCRIPTION					
White pumpable suspension, used as a vaccine support.					
Retest Date: 3 years from the date of manufacture					
Storage: Protect from excessive temperature and from freezing in its original package. *: around					
Characteristics	Grades	Ph. Eur. Specification	VAC 15	VAC 20	VAC 30
Assay Al ₂ O ₃ % Aluminum stated on the label		90 - 110% Aluminum stated on the label	1.4 – 1.6%	1.9 – 2.1%	2.9 – 3.1%
Corresponding to Al(OH) ₃ %			2.14 – 2.45%	2.91 – 3.21%	4.44 – 4.74%
Corresponding to Al %			0.74 – 0.85%	1.00 – 1.11%	1.54 – 1.64%
Protein Binding Capacity, For Info Only			2 mg BSA/mg Al ₂ O ₃ *		
Adsorption Power (Ph. Eur. Test)		Conforms No detectable BSA in solution	Conforms No detectable BSA in solution	Conforms No detectable BSA in solution	Conforms No detectable BSA in solution
Point of Zero Charge, For Info Only			10.2	10.2	10.2
Sedimentation (Ph. Eur. Test) @ 5mg Al/mL		NMT 5 mL	NMT 5 mL	NMT 5 mL	NMT 5 mL
Viscosity, For Info Only			NMT 500 cps (Brookfield V3/30)	NMT 1000 cps (Brookfield V3/30)	NMT 1500 cps (Brookfield V3/30)
Nitrate (NO ₃) (Ph. Eur. Test)		NMT 100 ppm	NMT 100 ppm	NMT 100 ppm	NMT 100 ppm
Ammonium (NH ₄) (Ph. Eur. Test)		NMT 50 ppm	NMT 50 ppm	NMT 50 ppm	NMT 50 ppm
Sulfate (Total SO ₄) (Ph. Eur. Test)		NMT 0.5%	NMT 0.5%	NMT 0.5%	NMT 0.5%
Chloride (Cl) (Ph. Eur. Test)		NMT 0.33%	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	NMT 20 ppm
Arsenic (As) (Ph. Eur. Test)		NMT 1 ppm	NMT 1 ppm	NMT 1 ppm	NMT 1 ppm
Iron (Fe) (Ph. Eur. Test)		NMT 15 ppm	NMT 15 ppm	NMT 15 ppm	NMT 15 ppm
pH (Ph. Eur. Test)		5.5 – 8.5	5.5 – 8.5	5.5 – 8.5	5.5 – 8.5
Endotoxins (Ph. Eur. Test)		LT 5 IU	LT 5 IU	LT 5 IU	LT 5 IU
Standard Packaging			50kg plastic drum	25kg Jerrycan	50kg plastic drum
Sterilization			All products can be sterilized.		

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