

Product Name	SDA 15A	Description:	Oil-in-water adjuvant oil phase, to be self-emulsified by slow fixing with aqueous antigen into final emulsion vaccine with particle size of 110-150 nm
Batch Volume	2000 L	Manufacturing Process:	Weigh from 200L barrel, pump using hydrophobic system to 2000L tank, mix at 80rpm, >2h, hydrophobic filtration into 20L Jerry can, nitrogen overlay
Storage	DO NOT FREEZE	Expiration date:	2 Years

Product Composition	Liters in 2000 L Batch	% in Volume	Vaccine Content (mL)
Polysorbate 80	76	3.8	3.8 μ L
Mineral Oil Drakeol 6VR	1690	84.5	84.5 μ L
L121	133	6.65	6.65 μ L
PLGA poly(lactic-co-glycolic) Acid	101	5.05	5.05 μ L

Test	Specification	Result
Appearance	Free flowing, white colored liquid	Satisfactory
Emulsion Stability	Water soluble post-incubation period	Satisfactory
Droplet Uniformity	Uniform upon microscope exam	Uniform
Conductivity (Resistance)	10-30 ohms	10-30 ohms
Bacteria/Fungi Sterility	No Growth	No Growth
Particle Size	110-150 nm	Meet Specification

Small Scale Preparation of Vaccine

Combination of SDA1010 adjuvant and antigen is a self-emulsifying procedure, and does not require high gear homogenization ! For small scale preparation, only a stirring process of moderate speed of 300-500 rpm for ~30 minutes is needed, ideally at under 30° C, under sterile condition.

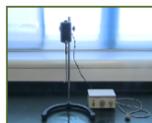
Weigh adjuvant and antigen according to the required ratio



Weigh adjuvant and antigen according to the required ratio
1 Part of adjuvant and 5-9 parts of antigen



Select a stirring equipment with controllable speed



Slowly add adjuvant to stirring antigen (for high adjuvant ratio emulsion, or add antigen to stirring adjuvant ratio (for low adjuvant ratio emulsion). Continue stirring for 10-30 minutes, the combined emulsion is stored at 4° C.



Vaccine Preparation with SDA 15A

To prepare 100 liter of injectable vaccine:
90 liters (or 90 kilograms) of aqueous antigen
Slow speed stir in tank, at temperature of 15-30 °C
10 liters (or 10 kilograms) of SDA 15A
Slowly add to the stirring antigen in tank
Continue low speed stir mix for 20-30 minutes

Large Scale Preparation of Vaccine (100-50,000 kg/L)

Combination of SDA1010 adjuvant and antigen is a self-emulsifying procedure, and does not require high gear homogenization ! High gear reduces stability. For large scale preparation, only a stirring process of moderate speed of 60-160 rpm for ~30 minutes is needed at 20-30° C, under sterile condition, using emulsifying tank well equipped with powered shear force. The speed is critical and depends on the design of stirring tank. Basically the emulsifying material should be seen well mixed as follows:



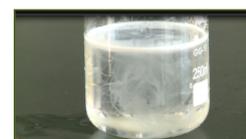
Quick Check of Emulsion Stability

Centrifuge the resulted emulsion at 3000 rpm for 15-30 minutes, there should not be phase separation.



Quick Check of Emulsion Type

Drop emulsion to the surface of water, to observe and confirm the emulsion type is correct, i.e. O/W, W/O/W, W/O, O/P. Immuno-WE, O/W type emulsion slowly diffuses into water, W/O/W diffuses very slow as white strings like cloud. SDA1011 50V, W/O, floats on water surface.



VISCOSITY (mPa.s)	CONDUCTIVITY (mS/cm)	DROPLET SIZE (peak, nm)	STABILITY		
			After storage at 4°C	After storage at 25°C	After storage at 37°C
About 20 at 25°C	10-30 (placebo Media)	110-150	More than 12 months	About 6 month	About 60 days