

Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Pertussis immunogenicity anti-FHA	Anti-Filamentous Hemagglutinin (FHA) antibody titer obtained for the vaccine is not significantly ( $P = 0.95$ ) less than that of the reference vaccine	Conforms	NP	NP	Conforms	NP	Conforms	/4\$	On-going	On-going	On-going
Pertussis immunogenicity anti-PT	Anti-Pertussis Toxoid (PTxd) and antibody titer obtained for the vaccine is not significantly ( $P = 0.95$ ) less than that of the reference vaccine	Conforms	NP	NP	Conforms	NP	Conforms	Conforms\$	On-going	On-going	On-going
Haemophilus immunogenicity	For information**	Conforms	NP	NP	Conforms	NP	Conforms	Conforms	On-going	On-going	On-going
Non-adsorbed PT	For information ( $\mu\text{g/mL}$ )††	< 2.5	NP	NP	< 2.5	NP	< 2.5	NP	On-going	NP	On-going
Non-adsorbed FHA	For information ( $\mu\text{g/mL}$ )††	< 2.5	NP	NP	< 2.5	NP	< 2.5	NP	On-going	NP	On-going
Percent adsorption -- tetanus toxoid	For information (%)	27	NP	37	43	NP	43	36	On-going	On-going	On-going
Percent adsorption -- diphtheria toxoid	For information (%)	55	NP	57	77	NP	60	59	On-going	On-going	On-going
Rat immunogenicity assay for IPV	For information (relative potency)										
Type 1		0.5	NP	NP	NP	NP	1.2	NP	On-going	NP	On-going
Type 2		0.5	NP	NP	NP	NP	1.2	NP	On-going	NP	On-going
Type 3		1.6	NP	NP	NP	NP	1.2	NP	On-going	NP	On-going
Be-antigen content	Type 1: 20 - 43 DU/dose Type 2: 5 - 9 DU/dose Type 3: 17 - 36 DU/dose	26.6	NP	25.6	26.4	NP	25.5	26.9	On-going	On-going	On-going
		6.7	NP	6.9	6.8	NP	6.5	6.7	On-going	On-going	On-going
		26.4	NP	25.0	25.5	NP	26.2	26.8	On-going	On-going	On-going

ROXANA MONTEMILONE  
DIRECTORA TECNICA  
SANOFI PASTEUR S.A.

CHRISTIAN DOMINGUEZ  
APODERADO  
SANOFI PASTEUR S.A.



