Tests	Acceptance criteria	T0*	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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed†	Conforms
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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed†	Conforms
Haemophilus immunogenicity	Not less than 50% of the vaccinated mice are seroconverted. Their titer is not less than 4 times that of the pooled control serum	Conforms	NP	Conforms at 7 months	NP	Conforms	Conforms at 19 months	Conforms	Not Performed†	Conforms
Non-adsorbed PT	For information (µg/mL)§	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Non-adsorbed FHA	For information (µg/mL)§	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Percent adsorption – tetanus toxoid	For information (%)	31	NP	36	NP	30	41	33	34	34
Percent adsorption – diphtheria toxoid	For information (%)	44	NP	42	NP	44	52	46	48	52
Poliomyelitis potency on chicken	Type 1 ≥ 2 Type 2 ≥ 2 Type 3 ≥ 2	3.51 4.05 3.77	NP NP NP	3.32 3.35 3.28	NP NP NP	2.68 2.54 3.14	3.35 3.14 3.25	3.28 3.25 3.39	2.98 2.83 3.17	2.96 2.54 3.48

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
D-antigen content	Type 1: 20 – 43 DU/dose	27.6	NP	27.5	NP	28.0	26.9	27.5	28.7	26.3
	Type 2: 5 – 9 DU/dose	6.0	NP	6.0	NP	5.5	5.8	5.6	5.7	5.9
	Type 3: 17 – 36 DU/dose	22.6	NP	23.4	NP	22.5	24.2	24.2	22.5	22.6
Percent adsorption – hepatitis B (ELISA)	For information (%)	81	59	55	67	41	35	55	44	47
Hepatitis B in-vitro relative potency (IVRP)	For information (relative potency)	1.07	1.38	1.14	1.33	0.93	1.16	1.61	1.05	1.01
Hepatitis B immunogenicity	Upper confidence limit (P = 0.95) of the estimated relative potency is not less than 1.0	0.71	NP	NP	NP	1.16	NP	1.63	NP	0.81
Lower limit		0.37	NP	NP	NP	0.68	NP	0.93	NP	0.45
Upper limit		1.38	NP	NP	NP	2.24	NP	3.30	NP	1.39
Bacterial and fungal sterility test	No microbial growth	Conforms	NP	NP	NP	NP	NP	NP	NP	Conforms
Pyrogen test	Conforms to Ph. Eur. criterion	0.35 (0.20 - 0.10 - 0.05)	NP	NP	NP	NP	NP	NP	NP	0.13 (0.00 - 0.08 - 0.05)

* All the results are release results of the Final Bulk Product excepted for the following tests: appearance, extractable volume, D-antigen content, bacterial and fungal sterility test and pyrogen test. For these tests, the results are obtained from the T0 of the Filled Product.

† Not Performed due to industrial constraints

‡ Not Planned as per protocol

§ Expected value: ≤ 2.5 µg/mL

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Table 5: Stability Study Results for Marcy l'Etoile Filled Product Batch S4106 at +5°C ± 3°C

Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Appearence	Whitish and cloudy suspension	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
pH measurement	6.5 – 8.0	7.03	7.24	7.24	7.23	7.26	7.41	7.13	7.20	7.20
Free formaldehyde content	≤ 30 µg/mL	Not Performed†	Not Performed†	10.41	10.32	10.76	10.74	10.38	11.08	12.02
Extractable volume	At least the nominal volume	Conforms	NP‡	NP	NP	NP	NP	NP	NP	Conforms
Osmolality measurement	250 - 450 mosmol/kg	Not Performed†	Not Performed†	331	333	334	332	327	336	335
Non-adsorbed PRP	≥ 16 µg/mL	19.6	21.2	22.2	22.6	24.4 at 13 months	24.5 at 19 months	23.4	25.8	25.5
Depolymerized PRP	For information (%)	7.7	16.6 at 4 months	18.6 at 7 months	21.4	28.9 at 15 months	30 at 19 months	38.4 at 25 months	38.9	42.5
Diphtheria potency : **Activity** **Lower limit** **Upper limit**	Activity ≥ 30 IU/mL Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 20 IU/mL	 77 47 138	 NP NP NP	 79 50 147 at 7 months	 NP NP NP	 84 57 120	 73 49 119 at 13 months	 79 55 125	 52 36 75	 48 29 80
Tetanus potency : **Activity** **Lower limit** **Upper limit**	Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 40 IU/mL	 516 294 796	 NP NP NP	 880 564 1238 at 7 months	 NP NP NP	 883 621 1463	 939 729 1239	 558 411 782	 Not Performed† Not Performed† Not Performed†	 1130 807 1518

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Histamine-sensitizing activity	≥ 95% survival (%)	98	NP	NP	NP	95	NP	100	NP	100
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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed†	Conforms
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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed†	Conforms
Haemophilus immunogenicity	Not less than 50% of the vaccinated mice are seroconverted. Their titer is not less than 4 times that of the pooled control serum	Conforms	NP	Conforms at 7 months	NP	Conforms	Conforms	Conforms	Not Performed†	Conforms
Non-adsorbed PT	For information (µg/mL)§	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Non-adsorbed FHA	For information (µg/mL)§	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Percent adsorption – tetanus toxoid	For information (%)	24	NP	25	NP	30	40	41	31	37
Percent adsorption – diphtheria toxoid	For information (%)	35	NP	33	NP	31	39	30	38	45

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Poliomyelitis potency on chicken	Type 1 ≥ 2 Type 2 ≥ 2 Type 3 ≥ 2	3.00 3.21 3.01	NP NP NP	2.91 3.39 3.80	NP NP NP	2.65 2.74 2.86	< 2 < 2 < 2 average of retests : 2.97 2.94 3.08	2.79 2.33 2.77	2.69 3.07 2.91	2.31 2.30 2.38
D-antigen content	Type 1: 20 – 43 DU/dose Type 2: 5 – 9 DU/dose Type 3: 17 – 36 DU/dose	28.2 5.5 20.0	NP NP NP	26.4 6.1 22.5	NP NP NP	26.8 5.7 21.7	26.5 5.9 21.7	27.5 6.0 22.1	30.1 6.0 23.8	25.1 5.7 20.1
Percent adsorption – hepatitis B (ELISA)	For information (%)	85	73	72 at 7 months	68	58	56	63	57	60
Hepatitis B in-vitro relative potency (IVRP)	For information (relative potency)	0.87	1.26	1.54 at 7 months	0.78	0.96	0.94	1.05	1.09	1.06
Hepatitis B immunogenicity	Upper confidence limit (P = 0.95) of the estimated relative potency is not less than 1.0	1.09	NP	NP	NP	1.96	NP	1.12	NP	1.36
Lower limit		0.69	NP	NP	NP	1.11	NP	0.61	NP	0.76
Upper limit		1.72	NP	NP	NP	3.76	NP	2.26	NP	2.61
Bacterial and fungal sterility test	No microbial growth	Conforms	NP	NP	NP	NP	NP	NP	NP	Conforms

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Pyrogen test	Conforms to Ph. Eur. criterion	1.10 (0.00 - 1.00 - 0.10)	NP	NP	NP	NP	NP	NP	NP	0.28 (0.09 - 0.20 - 0.00)

* All the results are release results of the Final Bulk Product excepted for the following tests: appearance, extractable volume, D-antigen content, bacterial and fungal sterility test and pyrogen test. For these tests, the results are obtained from the T0 of the Filled Product.

† Not Performed due to industrial constraints

‡ Not Planned as per protocol

§ Expected value: ≤ 2.5 µg/mL

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Table 6: Stability Study Results for Marcy l'Etoile Filled Product Batch S4107 at +5°C ± 3°C

Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Appearence	Whitish and cloudy suspension	Conforms	Conforms	Conforms	Conforms	Whitish and cloudy suspension, presence of 1 white particule in 1 syringe†	Conforms	Conforms	Conforms	Conforms
pH measurement	6.5 – 8.0	7.01	7.27	7.18	7.21	7.14	7.29	7.19	7.22	7.19
Free formaldehyde content	≤ 30 µg/mL	Not Performed‡	Not Performed‡	10.66	11.26	11.00	11.58	11.38	11.60	12.16
Extractable volume	At least the nominal volume	Conforms	NP§	NP	NP	NP	NP	NP	NP	Conforms
Osmolality measurement	250 - 450 mosmol/kg	Not Performed‡	Not Performed‡	333	336	337	336	337	338	334
Non-adsorbed PRP	≥ 16 µg/mL	20.6	22.4	23.1	22.9	25.0	25.1	24.5	25.8	26.2
Depolymerized PRP	For information (%)	8.0	15.6 at 4 months	17.9 at 7 months	20.1	25.9 at 15 months	29.0	38.6	39.7	41.8
Diphtheria potency:	Activity ≥ 30 IU/mL									
Activity	Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 20 IU/mL	53	NP	49	NP	92	49	54	42	45
Lower limit		39	NP	36	NP	55	28	33	27	23
Upper limit		79	NP	67 at 7 months	NP	177 at 13 months	90 at 19 months	88	62	86

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Tetanus potency: **Activity** **Lower limit** **Upper limit**	Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 40 IU/mL	449 312 658	NP NP NP	509 276 806 at 7 months	NP NP NP	422 296 609	1652 1133 2462	1050 707 1713	Not Performed‡ Not Performed‡ Not Performed‡	526 356 814
Histamine-sensitizing activity	≥ 95% survival (%)	100	NP	NP	NP	98	NP	98	NP	100
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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed‡	Conforms
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	Conforms	NP	Conforms	Conforms	Conforms	Not Performed‡	Conforms
Haemophilus immunogenicity	Not less than 50% of the vaccinated mice are seroconverted. Their titer is not less than 4 times that of the pooled control serum	Conforms	NP	Conforms at 7 months	NP	Conforms	Conforms	Conforms	Not Performed‡	Conforms

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Non-adsorbed PT	For information (µg/mL)**	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Non-adsorbed FHA	For information (µg/mL)**	NP	NP	NP	NP	NP	NP	NP	NP	< 2.5
Percent adsorption – tetanus toxoid	For information (%)	25	NP	35	NP	26	37	31	38	41
Percent adsorption – diphtheria toxoid	For information (%)	39	NP	37	NP	41	43	43	43	46
Poliomyelitis potency on chicken	Type 1 ≥ 2 Type 2 ≥ 2 Type 3 ≥ 2	2.84 2.40 2.55	NP NP NP	2.79 2.96 3.77	NP NP NP	2.58 3.05 2.83	< 2 < 2 < 2 average of retests : 3.11 3.09 3.30	2.65 2.56 3.05	3.00 2.77 2.58	2.72 2.27 2.23
D-antigen content	Type 1: 20 – 43 DU/dose Type 2: 5 – 9 DU/dose Type 3: 17 – 36 DU/dose	27.2 6.0 21.7	NP NP NP	25.5 6.1 22.1	NP NP NP	26.3 5.7 20.9	27.5 6.0 21.7	24.8 5.8 23.0	25.7 6.2 21.0	26.3 5.9 22.1
Percent adsorption – hepatitis B (ELISA)	For information (%)	81	57	61	63	49	45	56	44	54
Hepatitis B *in-vitro* relative potency (IVRP)	For information (relative potency)	0.84	1.13	1.39	0.88	1.01	0.91	0.98	1.14	0.94
Hepatitis B immunogenicity	Upper confidence limit (P = 0.95) of the estimated relative potency is not less than 1.0	1.10	NP	NP	NP	1.01	NP	1.30	NP	0.74
Lower limit		0.69	NP	NP	NP	0.53	NP	0.63	NP	0.42
Upper limit		1.73	NP	NP	NP	1.76	NP	3.48	NP	1.27
Bacterial and fungal sterility test	No microbial growth	Conforms	NP	NP	NP	NP	NP	NP	NP	Conforms

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Tests	Acceptance criteria	T0*	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Pyrogen test	Conforms to Ph. Eur. criterion	0.17 (0.16 - 0.02 - 0.00)	NP	NP	NP	NP	NP	NP	NP	0.49 (0.17 - 0.32 - 0.00)

* All the results are release results of the Final Bulk Product excepted for the following tests: appearance, extractable volume, D-antigen content, bacterial and fungal sterility test and pyrogen test. For these tests, the results are obtained from the T0 of the Filled Product.

† Particle composition : zinc phosphate (40 µm)/silicea (20 µm)/tungsten (10 µm)

‡ Not Performed due to industrial constraints

§ Not Planned as per protocol

** Expected value: ≤ 2.5 µg/mL

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1.3 Study 3: Marcy l'Etoile Filled Product – Optimized Formulation – Stability Data on Long-Term Storage Conditions at +5°C ± 3°C

18 months stability data with the optimized formulation on 3 batches of MLE FP are presented in Table 7 to Table 9.

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Table 7: Stability Study Results for Marcy l'Etoile Filled Product Batch FDNC0491 at +5°C ± 3°C

Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Appearence	Whitish and cloudy suspension	Conforms	NP†	Conforms	Conforms	Conforms	Conforms	Conforms	On-going	On-going	On-going
pH measurement	6.5 – 7.5	7.27	NP	7.30	7.32	7.33	7.35	7.35	On-going	On-going	On-going
Free formaldehyde content	≤ 30 µg/mL	3.23	NP	NP	NP	NP	0.39	NP	On-going	NP	On-going
Extractable volume	At least the nominal volume	Conforms	NP	NP	NP	NP	NP	NP	NP	NP	On-going
Aluminium content	0.40 – 0.80 mg/dose	0.61	NP	NP	NP	NP	NP	NP	NP	NP	On-going
Osmolality measurement	300 - 400 mosmol/kg	338	NP	NP	NP	NP	NP	NP	NP	NP	On-going
Non-adsorbed PRP	≥ 16 µg/mL	25.4	21.8	26.5	23.9	23.3	23.0	23.9	On-going	On-going	On-going
Depolymerized PRP	For information (%)	17.9	19.7	21.2	24.2	30.4	30.9	35.6	On-going	On-going	On-going
Diphtheria potency :	Activity ≥ 30 IU/mL										
Activity	Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 20 IU/mL	42	NP	NP	61	NP	64	61	On-going	On-going	On-going
Lower limit		34	NP	NP	43	NP	46	49	On-going	On-going	On-going
Upper limit		52	NP	NP	91 at 7.5 months	NP	97	78	On-going	On-going	On-going
Tetanus potency :	Lower confidence limit ($P = 0.95$) of the estimated potency ≥ 40 IU/mL										
Activity		556	NP	NP	763	NP	647	421	On-going	On-going	On-going
Lower limit		280	NP	NP	464	NP	467	300	On-going	On-going	On-going
Upper limit		853	NP	NP	1091	NP	1026	605 at 20.5 months	On-going	On-going	On-going

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Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Histamine-sensitizing activity	≥ 95% survival (%)	100	NP	NP	NP	NP	100	NP	On-going	NP	On-going
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	In-progress‡	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	In-progress‡	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 (µg/mL)**	< 2.5	NP	NP	< 2.5 at 9 months	NP	< 2.5	NP	On-going	NP	On-going
Non-adsorbed FHA	For information (µg/mL)**	< 2.5	NP	NP	< 2.5 at 8 months	NP	< 2.5	NP	On-going	NP	On-going
Percent adsorption – tetanus toxoid	For information (%)	31	NP	34	37	NP	51	41	On-going	On-going	On-going
Percent adsorption – diphtheria toxoid	For information (%)	53	NP	59	62	NP	63	65	On-going	On-going	On-going
Rat immunogenicity assay for IPV	For information (relative potency)										
Type 1		0.7	NP	NP	NP	NP	0.8	NP	On-going	NP	On-going
Type 2		0.6	NP	NP	NP	NP	1.0	NP	On-going	NP	On-going
Type 3		1.9	NP	NP	NP	NP	0.8	NP	On-going	NP	On-going

Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
D-antigen content	Type 1: 20 – 43 DU/dose	Not Performed††	NP	27.9	26.5	NP	26.9	27.3	On-going	On-going	On-going
	Type 2: 5 – 9 DU/dose		NP	6.4	6.2	NP	6.8	6.7	On-going	On-going	On-going
	Type 3: 17 – 36 DU/dose		NP	25.8	23.5	NP	23.6	25.3	On-going	On-going	On-going
Non adsorbed D Antigen Content	For information										
Type 1		26.9	NP	28.4	27.1	NP	27.1	27.4	On-going	On-going	On-going
Type 2		5.5	NP	5.9	5.2	NP	5.2	5.2	On-going	On-going	On-going
Type 3		26.3	NP	25.9	24.1	NP	23.8	24.4	On-going	On-going	On-going
Percent adsorption – hepatitis B (ELISA)	For information (%)	89	84	87	88	88	85	86	On-going	On-going	On-going
Hepatitis B *in-vitro* relative potency (IVRP)	For information (relative potency)	1.43	NP	1.32	1.33	1.39	1.43	1.33	On-going	On-going	On-going
Hepatitis B Immunogenicity	Upper confidence limit (P = 0.95) of the estimated relative potency is not less than 1.0	1.21	NP	NP	2.11	NP	1.76	1.66	On-going	On-going	On-going
Lower limit		0.628	NP	NP	1.108	NP	0.887	1.038	On-going	On-going	On-going
Upper limit		2.561	NP	NP	4.354	NP	4.393	2.854	On-going	On-going	On-going
Bacterial and fungal sterility test	No microbial growth	Conforms	NP	NP	NP	NP	NP	NP	NP	NP	On-going
Pyrogen test	Conforms to Ph.. Eur. criterion	0.05 (0.00 - 0.00 - 0.05)	NP	NP	NP	NP	NP	NP	NP	NP	On-going
Specific toxicity for diphtheria and tetanus components	There must be no toxic reactions or deaths. All animals must maintain a healthy appearance during the period of observation and weigh no less at the end of the test than at the time of injection	Conforms	NP	NP	NP	NP	NP	NP	NP	NP	On-going

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Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Integrity test	The CCIT‡‡ is acceptable if no presence of dye is detected in the contents of any of the tested syringes	Conforms	NP	NP	NP	NP	Conforms	NP	On-going	NP	On-going

* All the results are obtained from the T0 of the Filled Product excepted for the following tests: free formaldehyde content, osmolality measurement, diphtheria and tetanus potency, histamine-sensitizing activity, pertussis immunogenicity anti-FHA and anti-PT, haemophilus immunogenicity, non-adsorbed PT and FHA, rat immunogenicity assay for IPV, non-adsorbed D-antigen content, hepatitis B immunogenicity and specific toxicity for diphtheria and tetanus components. For these tests, the results are release results of the Final Bulk Product.

† Not Planned as per protocol

‡ The reference vaccine for pertussis immunogenicity test was changed at T18 months. The qualification of this reference standard was performed by a statistical comparison to the previous one

§ Expected results: Not less than 50% of the vaccinated mice are seroconverted. Their titer is not less than 4 times that of the pooled control serum

** Expected value: ≤ 2.5 µg/mL

†† Not Performed due to industrial constraints

‡‡ CCIT: Container Closure Integrity Test

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Tests	Acceptance criteria	T0*	1 month	3 months	6 months	9 months	12 months	18 months	24 months	30 months	36 months
Integrity test	The CCIT‡‡ is acceptable if no presence of dye is detected in the contents of any of the tested syringes	Conforms	NP	NP	NP	NP	Conforms	NP	On-going	NP	On-going

* **All the** results are obtained from the T0 of the Filled Product excepted for the following tests: free formaldehyde content, osmolality measurement, diphtheria and tetanus potency, histamine-sensitizing activity, pertussis immunogenicity anti-FHA and anti-PT, haemophilus immunogenicity, non-adsorbed PT and FHA, rat immunogenicity assay for IPV, non-adsorbed D-antigen content, hepatitis B immunogenicity and specific toxicity for diphtheria and tetanus components. For these tests, the results are release results of the Final Bulk Product.

† **Not** Planned as per protocol

‡ **The** reference vaccine for pertussis immunogenicity test was changed at T18 months. The qualification of this reference standard was performed by a statistical comparison to the previous one

§ **Expected** results: Not less than 50% of the vaccinated mice are seroconverted. Their titer is not less than 4 times that of the pooled control serum

** Expected value: ≤ 2.5 µg/mL

†† **Not** Performed due to industrial constraints

‡‡ **CCIT**: Container Closure Integrity Test