



Product Quality and Disposition Department

Diphtheria, tetanus, pertussis (acellular, component),
 hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus
 influenzae type b conjugate vaccine (adsorbed) lot n° S4312 (clinical batch) 2/229

**SUMMARY PROTOCOL FOR DIPHTHERIA, TETANUS, PERTUSSIS (ACELLULAR, COMPONENT),
 HEPATITIS B (RDNA), POLIOMYELITIS (INACTIVATED) AND HAEMOPHILUS INFLUENZAE TYPE
 B CONJUGATE VACCINE (ADSORBED)**

Name and address of manufacturer	Sanofi Pasteur S.A. 2 avenue Pont Pasteur 69007 Lyon
Sites of production	Sanofi Pasteur S.A. 1541, avenue Marcel Merieux 69280 Marcy l'Etoile Parc Industriel d'Incarville 27101 Val de Reuil Cedex
Clinical batch submitted according to the procedure number (Article 58)	: EMEA/H/W/002495
Lot number	: S4312
Date of manufacture of final lot	: 08.02.2010
Final bulk	: FDV01398
Volume of final bulk	: 242.1 Liters
Nature of final product	: suspension for injection
Type of container	: white glass (type I) vial
Number of doses per container	: 1 per vial
Number of containers	: 20 318
Target group	: immunizing agent
Volume of single dose	: 0.5 ml
Release date	: 22.07.2010
Starting of validity period	: 09.11.2009
Expiry date	: October 2012
Storage temperature	: + 5 °C ± 3°C


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Composition of single human dose * :

Purified diphtheria toxoid	: 30 Lf (≥ 20 IU [†])
Purified tetanus toxoid	: 10 Lf (≥ 40 IU [†])
<i>Bordetella pertussis</i> antigens	
Adsorbed purified pertussis toxoid	: 25 µg
Adsorbed purified filamentous haemagglutinin	: 25 µg
Inactivated poliomyelitis virus (produced on Vero cells)	
Type 1 (Mahoney)	: 40 DU §
Type 2 (MEF-1)	: 8 DU §
Type 3 (Saukett)	: 32 DU §
Hepatitis B surface antigen **	: 10 µg
Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate)	: 12 µg
Conjugated to Tetanus protein (PRP-T)	: 18-30 µg
Aluminium hydroxide, hydrated, for adsorption	: 0.6 mg Al ³⁺
Buffer solution :	
Disodium hydrogen phosphate	: 1.528 mg
Potassium dihydrogen phosphate	: 1.552 mg
Essential amino acids ††	: 1.115 mg
Trometamol	: 0.1515 mg
Saccharose	: 10.625 mg
Water for injections	: up to 0.5 ml



* NaOH, acetic acid, or HCl can be used for pH adjustment. these components are only present in trace amount.

† As lower confidence limit (p = 0.95)

§ Or equivalent antigenic quantity determined by suitable immunochemical method

** Produced in yeast *Hansenula polymorpha* cells by recombinant DNA technology

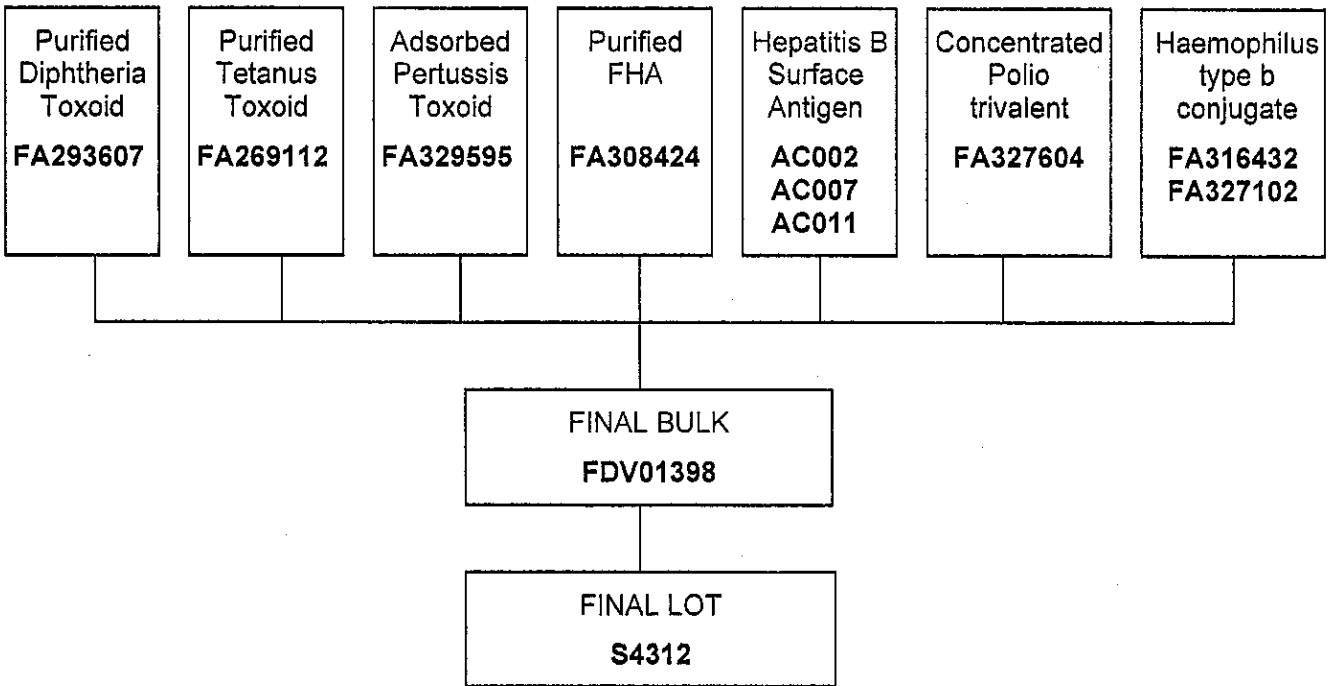
†† Essentials amino acids including L-phenylalanine




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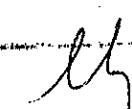
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PRODUCTION FLOW SHEET




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PART 1
ACTIVE INGREDIENTS

- A - PURIFIED DIPHTHERIA TOXOID**
- B - PURIFIED TETANUS TOXOID**
- C - 2 COMPONENT ACELLULAR PERTUSSIS**
- D - HEPATITIS B**
- E - INACTIVATED POLIOMYELITIS TRIVALENT**
- F - HAEMOPHILUS type b CONJUGATE**



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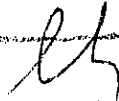
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- A - PURIFIED DIPHTHERIA TOXOID

	
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