


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° S4313 (clinical batch)

152/180

**CONCENTRATED TETANUS PROTEIN**

TESTS	SPECIFICATIONS
<b>TETANUS PROTEIN</b>	
PROTEIN NITROGEN CONTENT (PN)	For calculation
TOTAL NITROGEN CONTENT (TN)	For calculation
PN/TN RATIO	≥ 0.8
OD280/OD260 RATIO	≥ 1.3
FLOCCULATING TITRE	For calculation
ANTIGENIC PURITY	> 1500 Lf/mg of protein nitrogen
MOLECULAR SIZE DISTRIBUTION	≥ 50 % of monomers
BACTERIAL AND FUNGAL STERILITY	No microbial growth
<b>CONCENTRATED TETANUS PROTEIN</b>	
PROTEIN NITROGEN CONTENT	For calculation
OD280/OD260 RATIO	≥ 1.3
PHOSPHORUS CONTENT	< 1.5 µg/mg of protein
RESIDUAL FORMALDEHYDE CONTENT	< 10 µg/mg of protein
FLOCCULATING TITRE	For calculation
ANTIGENIC PURITY	> 1500 Lf/mg of protein nitrogen
MOLECULAR SIZE DISTRIBUTION	≥ 50 % of monomers
BACTERIAL AND FUNGAL STERILITY	No microbial growth
SPECIFIC TOXICITY	Conforms
IRREVERSIBILITY OF TETANUS TOXOID	Conforms
PYROGENS	Conforms

  
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 hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus  
 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 153/180  
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**CONCENTRATED TETANUS PROTEIN**  
 lot number : **FA302562**

Date of manufacture : 27.03.2008  
 Storage temperature : + 5 °C ± 3°C  
 Expiry date : 27 MARCH 2009  
 Volume : 4.143 liters

**TETANUS PROTEIN CONTROLS :**

**Protein nitrogen content (PN)**

Method : Kjeldahl after trichloroacetic acid precipitation  
 Date : 26.04.07  
 Result : 0.112 mg/ml

**Total nitrogen content (TN)**

Method : Kjeldahl  
 Date : 26.04.07  
 Result : 0.127 mg/ml

**PN/TN ratio : 0.88 - Conforms**



**OD280/OD260 ratio : 1.83 - Conforms**

**Flocculating titre**

Method : Flocculation determined from in-house reference  
 Date : 07.05.07  
 Result : 270 Lf/ml

**Antigenic purity**

Result : 2411 Lf/mg of protein nitrogen - Conforms

  
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**Molecular size distribution**

Method : size exclusion Chromatography  
 Date : 22.05.07  
 Result : 69.50 % of monomers – **Conforms**

**Bacterial and fungal sterility**

Method	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	:	30-35° C	20-25° C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	26.04.07	
Test off	:	10.05.07	
Result	:	<b>No microbial growth - Conforms</b>	

**CONCENTRATED TETANUS PROTEIN CONTROLS :**

**Protein nitrogen content**

Method : Kjeldahl after trichloroacetic acid precipitation  
 Date : 08.04.08  
 Result : 4.95 mg/ml



**OD280/OD260 ratio : 1.91 - Conforms**

**Phosphorus content**

Method : Chen  
 Date : 09.04.08  
 Result : <0.04 µg/mg of protein - **Conforms**

**Residual formaldehyde content**

Method : Nash  
 Date : 09.04.08  
 Result : 0.70 µg/mg of protein - **Conforms**



  
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 hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus  
 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 155/180**

**Flocculating titre**

Method : Flocculation determined from in-house reference  
 Date : 31.03.08  
 Result : 12000 Lf/ml

**Antigenic purity**

Result : 2424 Lf/mg of protein nitrogen - **Conforms**

**Molecular size distribution**



Method : size exclusion Chromatography  
 Date : 10.04.08  
 Result : 68.00 % of monomers – **Conforms**

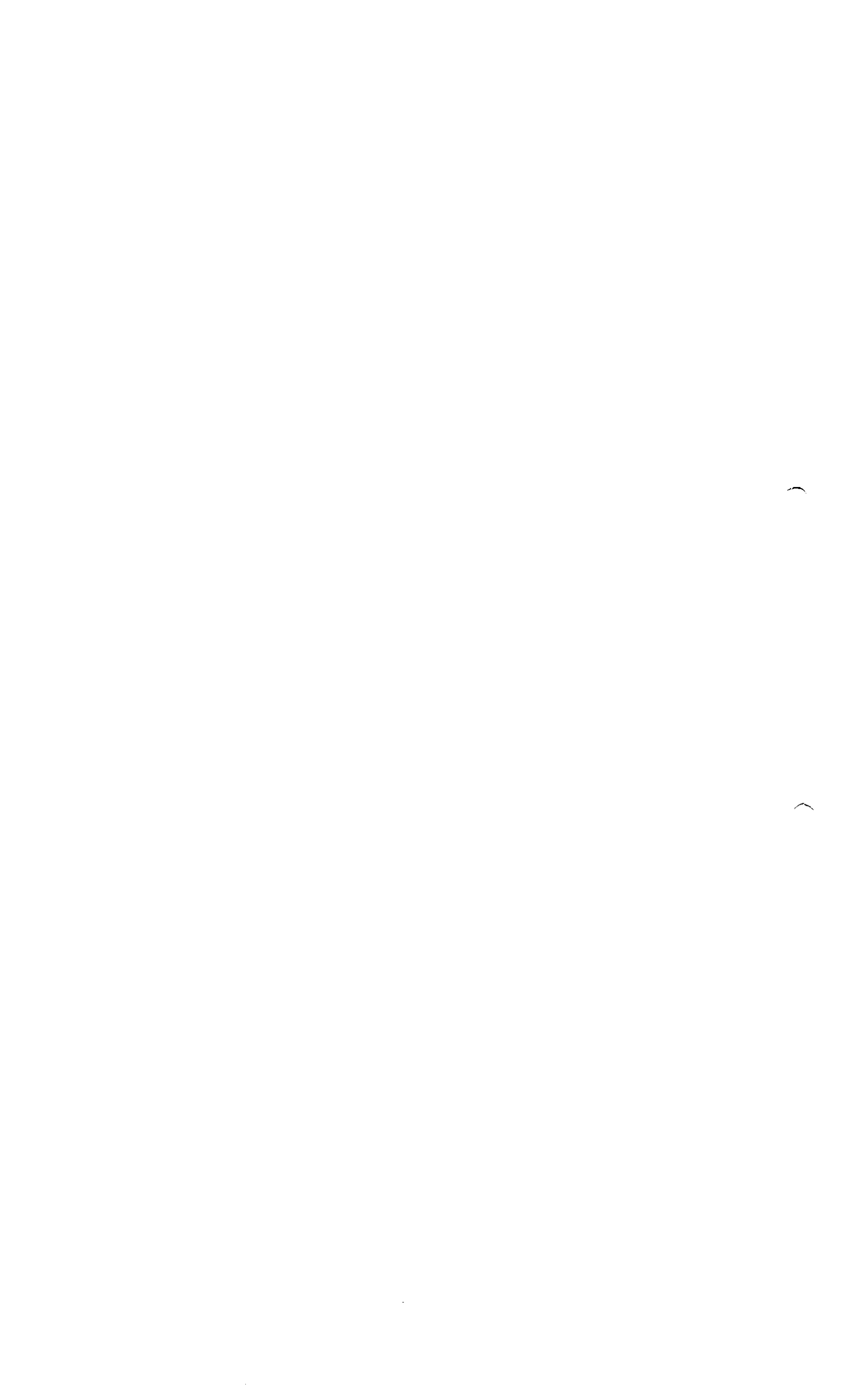
**Bacterial and fungal sterility**

Method	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	:	30-35° C	20-25° C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	31.03.08	
Test off	:	14.04.08	
Result	:	<b>No microbial growth - Conforms</b>	

**Specific toxicity test**

Animals : Guinea-pigs  
 Number of animals : 5  
 Lf of toxoid injected per animal : 2000  
 Route : Subcutaneous  
 Test on : 03.04.08  
 Test off : 24.04.08  
 Result : **Conforms**



  
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**Irreversibility of tetanus toxoid**

Method : WHO method Technical report N° 800  
and 814  
Concentration of the toxoid solution : 15 Lf/ml 15 Lf/ml  
Incubation period  
Temperatures : 5°C ± 3°C 37°C ± 1°C  
Test on : 31.03.08  
Test off : 12.05.08

*Test in animals*

Number of guinea pigs injected : 5 5  
Route : Subcutaneous  
Volume injected : 5 ml 5 ml  
Date of inoculation : 12.05.08  
Date of end of observation : 02.06.08  
Result : Conforms

**Pyrogens**

Method : by intravenous injection of 2 µg/ml/kg of the  
rabbit body weight  
Date : 02.05.08  
Number of rabbits : 3

Weight of each rabbit (kg)	Initial temperature in °C (A)	Intravenous dose (ml)	Maximum temperature in °C (B)	Response (B) - (A)
2.6	38.89	2.60	38.92	0.03
2.4	39.04	2.40	39.05	0.01
2.8	38.84	2.80	39.00	0.17

The sum of the 3 individual maximum temperature rises : 0.21 °C  
Result : Conforms

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**HAEMOPHILUS type b POLYSACCHARIDE**

TESTS	SPECIFICATIONS
PHOSPHORUS CONTENT	7.5 – 9.4 %
RIBOSE CONTENT	≥ 35 %
PROTEIN CONTENT	≤ 1.0 %
NUCLEIC ACID CONTENT	≤ 1.0 %
BACTERIAL ENDOTOXINS	< 25 IU/μg of polysaccharide
MOLECULAR SIZE : polysaccharide eluted before K <sub>d</sub> 0.30	> 50 %
HAEMOPHILUS B IDENTIFICATION	Positive
PYROGENS	Conforms


  
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)**
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HAEMOPHILUS type b POLYSACCHARIDE

lot number : FA292031

Date of manufacture : 29.11.07  
 Storage temperature : ≤ - 35°C  
 Expiry date : 29 NOVEMBER 2010  
 Quantity : 56.830 g

**CONTROLS :**

**Phosphorus content**

Method : Chen  
 Date : 07.01.08  
 Result : 8.13 % - Conforms

**Ribose content**



Method : Mejbaum  
 Date : 27.12.07  
 Result : 43.0 % - Conforms

**Protein content**

Method : Lowry  
 Date : 04.01.08  
 Result : <0.11 % - Conforms

**Nucleic acid content**

Method : Absorbance at 260 nm  
 Date : 28.12.07  
 Result : 0.14 % - Conforms



  
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 159/180  
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**Bacterial endotoxins**

Method : LAL  
 Date : 03.12.07  
 Result : 0.81 IU/µg – Conforms

**Molecular size**

Method : size exclusion Chromatography  
 Date : 11.12.07  
 Result : 72.2 % - Conforms

**Haemophilus identification**


Method : Double diffusion in gel  
 Date : 12.12.07  
 Result : Positive - Conforms


**Pyrogens**

Method : by intravenous injection 1 µg/ml/kg of the  
 rabbit body weight  
 Date : 07.12.07  
 Number of rabbits : 3

Weight of each rabbit (kg)	Initial temperature in °C (A)	Intravenous dose (ml)	Maximum temperature in °C (B)	Response (B) - (A)
2.8	39.12	2.80	39.29	0.18
2.7	38.81	2.70	39.07	0.26
2.3	38.97	2.30	38.90	0.00

The sum of the 3 individual maximum temperature rises : 0.44 °C  
 Result : Conforms

  
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**HAEMOPHILUS AH POLYSACCHARIDE DERIVATIVE**

TESTS	SPECIFICATIONS
RESIDUAL CYANIDES CONTENT	≤ 5 µg/ml
POLYSACCHARIDE CONTENT (PHOSPHORUS CONTENT)	For calculation
PERCENTAGE OF POLYSACCHARIDE LINKED ADH	1.8 - 2.9 %
FREE ADH/TOTAL ADH RATIO	≤ 0.1
MOLECULAR SIZE : - Polysaccharide eluted before K <sub>d</sub> 0.20 - K <sub>d</sub> of polysaccharide	≤ 15 % 0.40 - 0.60
HAEMOPHILUS IDENTIFICATION	Positive

  
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 hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus  
 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 161/180  
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**HAEMOPHILUS AH**  
**POLYSACCHARIDE DERIVATIVE**  
  
 lot number : FA318451

Date of manufacture : 28.07.08  
 Storage temperature : ≤ -35°C  
 Expiry date : 28 JULY 2010  
 Volume : 2.299 liters

**CONTROLS :**

**Residual cyanides content**

Method : Gas Chromatography, cyanide or cyanate ions are transformed  
 into cyanogen chloride by chlorination  
 Date : 07.08.08  
 Result : <0.004 µg/ml – Conforms



**Polysaccharide content**

Method : Calculated from the theoretical phosphorus  
 content of PRP  
 Date : 28.08.08  
 Result : 10.8 mg/ml

**Percentage of polysaccharide linked ADH (Adipic DiHydrazide acid)**

Method : Colorimetry  
 Date : 11.09.08  
 Result : 2.58 % - Conforms

**Free ADH/total ADH ratio : 0.022 - Conforms**

  
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**Molecular size**

Method : size exclusion Chromatography  
Date : 08.09.08  
Result : - Percentage of polysaccharide eluted before  $K_d$  0.20 : 1.94 % - Conforms  
-  $K_d$  of polysaccharide : 0.51 - Conforms

**Haemophilus identification**

Method : Double diffusion in gel  
Date : 30.07.08  
Result : Positive - Conforms

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**HAEMOPHILUS POLYSACCHARIDE CONJUGATE (CONCENTRATED BULK)**

TESTS	SPECIFICATIONS
PH	6.5 - 7.5
PHOSPHORUS CONTENT	No specification
POLYSACCHARIDE CONTENT	No specification
SUCROSE CONTENT	No specification
PROTEIN/POLYSACCHARIDE RATIO (after dialysis)	1.8 - 3.0
RESIDUAL EDAC CONTENT	< 10 µmol/l
RESIDUAL PHENOL CONTENT	< 1 µg/ml
FREE POLYSACCHARIDE CONTENT	< 20 %
MOLECULAR SIZE : Percentage of polysaccharide eluted before $K_d$ 0.20	≥ 60 %
FREE TETANUS PROTEIN CONTENT	< 1 %
BACTERIAL AND FUNGAL STERILITY	No microbial growth


  
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 164/180  
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**HAEMOPHILUS POLYSACCHARIDE  
 CONJUGATE (CONCENTRATED BULK)**  
 lot number : FA328213

Date of manufacture : 23.10.08  
 Storage temperature : ≤ -35°C  
 Expiry date : 23 OCTOBER 2011  
 Volume : 30.798 liters

**CONTROLS :**

**pH**

Method : Glass electrode  
 Date : 06.11.08  
 Result : 7.09 - Conforms

**Phosphorus content**

Method : Chen  
 Date : 03.11.08  
 Result : 17.4 µg/ml

**Polysaccharide content**

Method : Calculated from the theoretical phosphorus  
 content of PRP  
 Date : 04.11.08  
 Result : 207.14 µg/ml

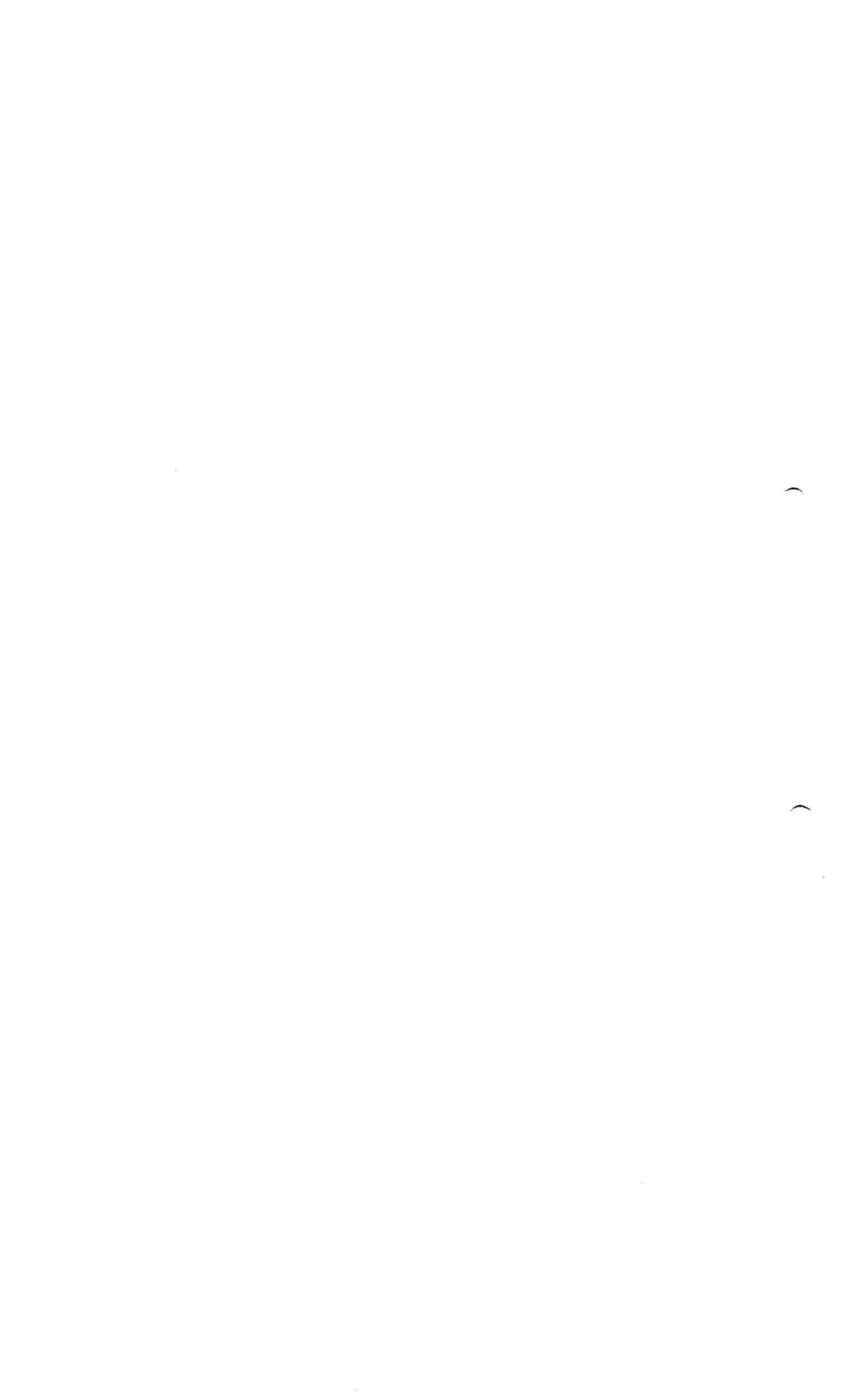
**Sucrose content**

Method : quantitative analysis of glucose before and after enzymatic  
 hydrolysis  
 Date : 05.11.08  
 Result : 86.31 g/l

**Protein/Polysaccharide ratio** : 2.2 - Conforms  
352\_CC5\_SPL\_AE.dot /19.09.11

  
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**Residual EDAC content (Ethyl-DimethylAminopropyl-Carbodiimide)**

Method : Wilcheck  
Date : 07.11.08  
Result : <10.0 µmol/l - Conforms

**Residual phenol content**

Method : Colorimetry  
Date : 05.11.08  
Result : <1.0 µg/ml - Conforms

**Free Polysaccharide content**

Method : High Performance Anion Exchange  
Chromatography with Pulsed Amperometric  
Detection method (HPAEC-PAD)  
Date : 17.11.08  
Result : <4.2 % - Conforms

**Molecular size**

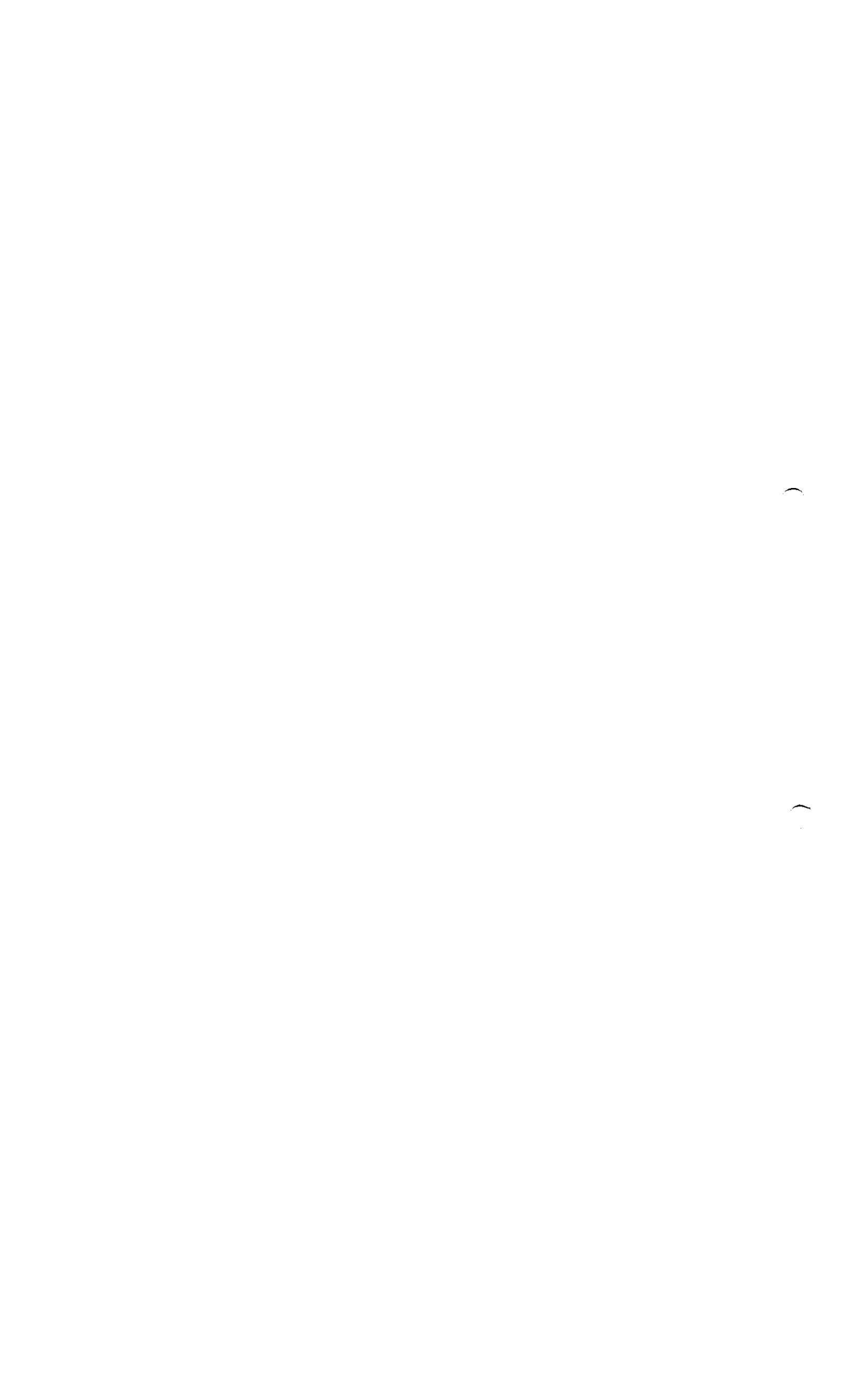
Method : size exclusion chromatography  
Date : 03.12.08  
Result : 76.5 % - Conforms

**Free tetanus protein content**

Method : polyacrylamide gel electrophoresis SDS-PAGE  
Date : 02.12.08  
Result : <1.0% - Conforms

  
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Diphtheria, tetanus, pertussis (acellular, component),  
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch) 166/180  
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**Bacterial and fungal sterility**

Method	:	Membrane filtration	
Media	:	Thioglycollate medium	Soybean Casein Digest medium
Temperatures	:	30-35° C	20-25° C
Volume tested	:	20 ml	
Inoculum per Steritest	:	10 ml	10 ml
Volume of medium per Steritest	:	100 ml	100 ml
Test on	:	27.10.08	
Test off	:	12.11.08	
Result	:	No microbial growth – Conforms	

  
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**PART 2**  
**FINAL BULK PRODUCT**

  
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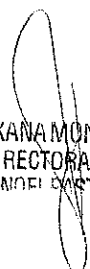
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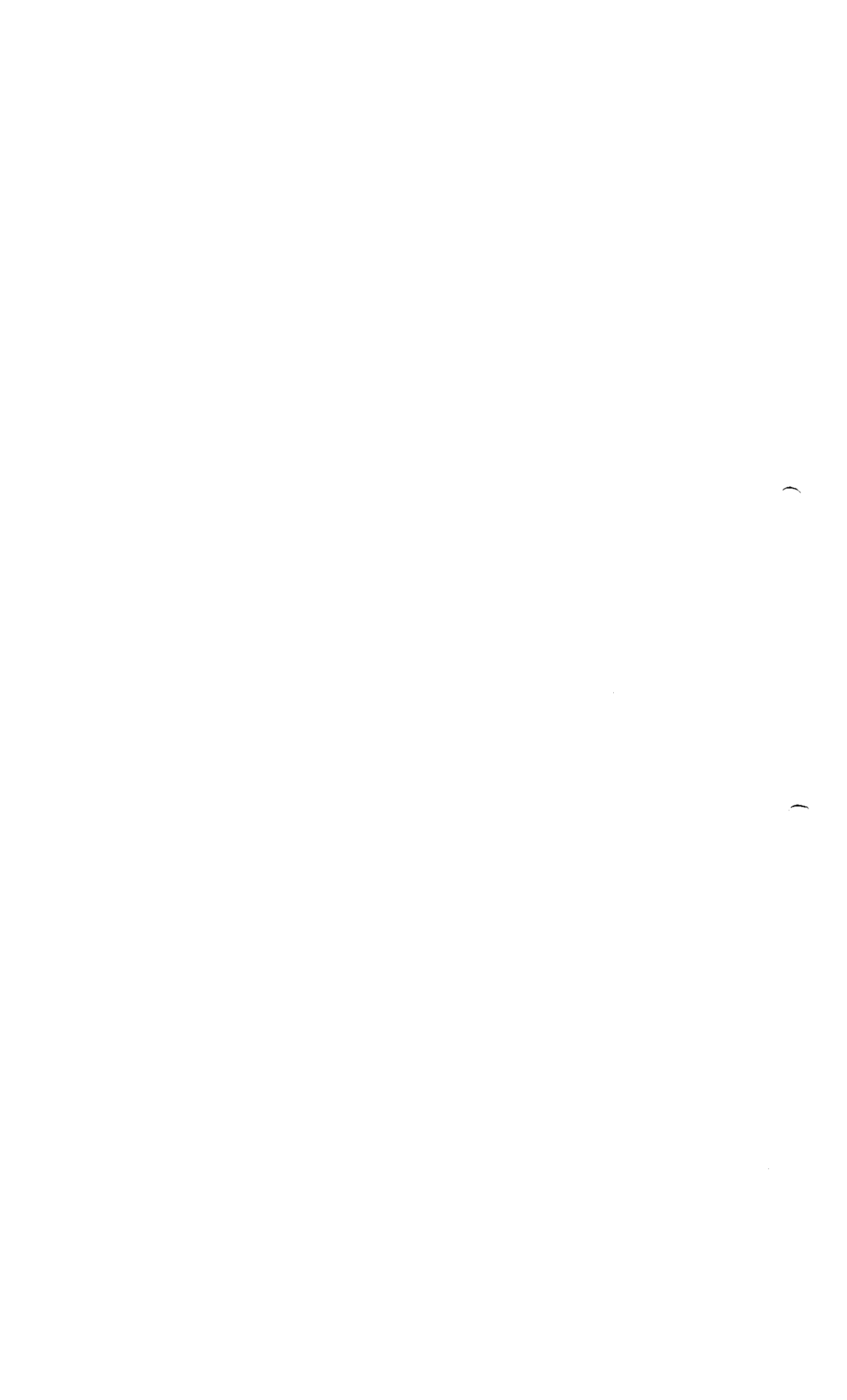
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**FINAL BULK**

TESTS	SPECIFICATIONS
OSMOLALITY	300 - 400 mosmol/kg
FREE FORMALDEHYDE CONTENT	≤30 µg/mL
BACTERIAL AND FUNGAL STERILITY	No microbial growth
HISTAMINE-SENSITIZING ACTIVITY	≥95% survival
NON ADSORBED POLYRIBOSYL RIBITOL PHOSPHATE (PRP)	≥8.0 µg/dose
DEPOLYMERIZED PRP	<20.0%
PERCENT ADSORPTION – DIPHTHERIA TOXOID	≥23% At time of release, this acceptance criterion was not defined
PERCENT ADSORPTION – HEPATITIS B	≥64% At time of release, this acceptance criterion was not defined
DIPHTHERIA POTENCY	Activity ≥30 IU/dose Lower confidence limit (P = 0.95) of the estimated potency ≥ 20 IU/dose
TETANUS POTENCY	Lower confidence limit (P = 0.95) of the estimated potency ≥ 40 IU/dose
IMMUNOGENICITY PERTUSSIS IN MICE	Anti-PT and anti-FHA antibody GMTs for the vaccine are not significantly lower than those of the reference vaccine (analysis of variance) at the level 5%.
D-ANTIGEN CONTENT	TYPE 1 : 20.0 – 43.0 DU/DOSE TYPE 2 : 5.0 – 9.0 DU/DOSE TYPE 3 : 17.0 – 36.0 DU/DOSE
HEPATITIS B IN VITRO RELATIVE POTENCY (IVRP)	≥0.70 At time of release, this acceptance criterion was not defined

  
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 influenzae type b conjugate vaccine (adsorbed) lot n° S4313 (clinical batch)

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**FINAL BULK**  
 Lot number : FDV01416

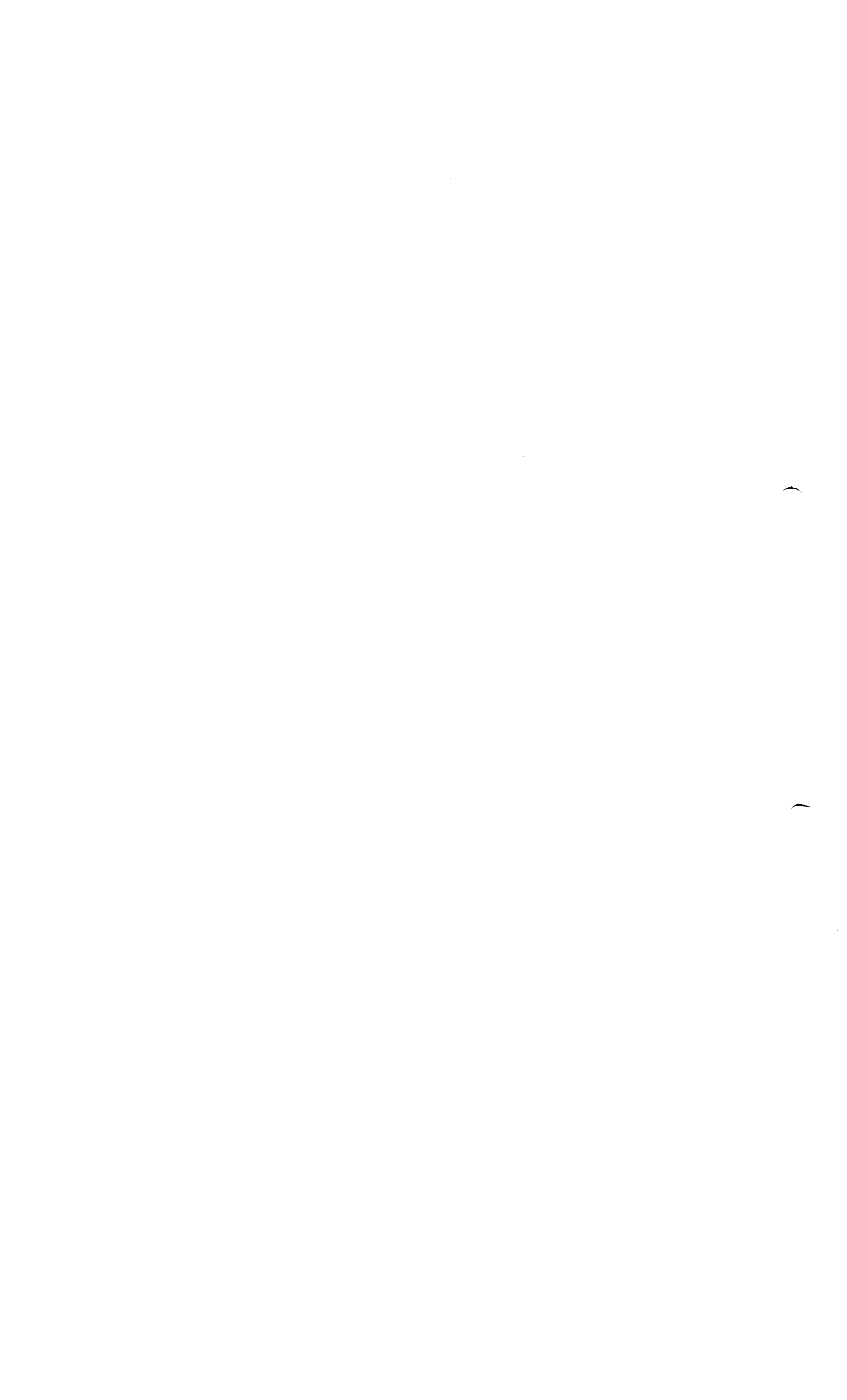
Date of manufacture : 18.11.2009  
 Storage temperature : + 5°C ± 3°C  
 Expiry date : 18 August 2010

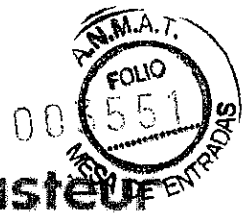
**Composition**

INGREDIENT	Lot number	Volume (ml)
Purified Diphtheria Toxoid	FA293606	2 728
Purified Tetanus Toxoid	FA276217	1 000
Adsorbed Pertussis Toxoid	FA326717	17 944
Adsorbed FHA Pertussis	FA344108	17 620
Concentrated Polio Trivalent (5C)	FA328827	50 020
Hepatitis B Surface Antigene C	AC004	1 712
	AC012	1 656
Haemophilus Polysaccharide Conjugate	FA328213	28 966
Aluminium hydroxide	FA365289	34 323
Buffer solution (Disodium hydrogen phosphate and potassium dihydrogen phosphate)	FA363235	20 002
Essential Amino acids solution	FA367791	25 000
Buffer solution (trometamol and saccharose)	FA363236	6 707
Water for injections	ABS2E321A	42 361
	ABS2E322A	
<b>APPROXIMATE TOTAL VOLUME</b>		<b>240 800</b>

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**CONTROLS :**

**Osmolality**

Method : Measure of the freezing point reduction  
Date : 02.12.2009  
Result : 338 mosmol/kg - **Conforms**

**Free formaldehyde content**

Method : Spectrophotometry / colorimetric assay  
Date : 04.12.2009  
Result : 3.34 µg/ml - **Conforms**

**Bacterial and fungal sterility**

Method	:	Membrane filtration
Media	:	Thioglycollate medium   Soybean Casein Digest medium
Temperatures	:	30-35° C   20-25° C
Volume tested	:	20 ml
Inoculum per Steritest	:	10 ml   10 ml
Volume of medium per Steritest	:	100 ml   100 ml
Test on	:	26.11.2009
Test off	:	10.12.2009
Result	:	No microbial growth – <b>Conforms</b>

**Histamine-sensitizing activity**

**Injection (Day 0)**

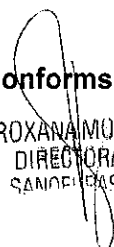
Animals and sex : mice CD1 - Female  
Number of animals : 20  
Route : Intraperitoneal  
Dose tested per mouse : 2 human doses (1ml)  
Date of injection : 23.12.2009


**Histamine challenge (Day 5)**

Challenge dose per mouse : 2 mg histamine base  
Route : Intraperitoneal  
Date of injection : 28.12.2009

**Reading date (Day 6)**

Result : 29.12.2009  
: 100 % of survival – **Conforms**

  
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