

7. ベトナム

1. 審査・承認

1.1 法的根拠

健康省令 (No. 3042/QD-BYT Article 2)

1.2 所轄機関

健康省予防医学部門 (Vietnamese Administration of Preventive Medicine, VAPM)。傘下の国立ワクチンおよび生物製剤管理研究所 (National Institute for Control of Vaccine and Biologicals, NICVB) が2006年にNRAとして承認された。

1.3 承認済み製剤の種類

5社で15種類ほどのワクチンが製造されている。(表1)

2. 審査・承認の相互承認

無し

3. 国家検定

3.1 法的根拠

健康省法令 (MOH No. 3042/QD-BYT Article 2)

3.2 所轄機関 (図1)

国立ワクチンおよび生物製剤管理研究所 (National Institute for Control of Vaccine and Biologicals, NICVB) がEPI等を担当。インフルエンザワクチンは別部門が担当しているという情報もある。

3.3 試験機関の認証規格

NICVBはISO17025の承認規格の申請準備中

3.4 検定(文書審査)

SLP審査(書式は標準規格に従う)

3.5 検定(試験)

試験項目は表2を参照

3.6 検定の頻度

新規製剤は全ロット。年間のトレ解析結果に従い、品質の均一性が低い製剤にはすべ

でのロットについて行う。

3.7 検定品の種類と数

表3参照

3.8 検定品の抜き取り、提出方法

製造所からの検定品抜き取り、輸入製剤の抜き取り、市場からの抜き取りに手順とシステムがある。国立EPI (NEPI)からの抜き取り、および査察時の抜き取りについても同様である

3.9 検定事務処理時間

3.10 検定の相互承認

ある。輸入製剤について承認申請が可能

4. GMP査察

4.1 所轄機関

WHOがNICVBの機能強化のためにポリオと麻疹を中心に毎年査察している製造所である Pasteur Instituteに対してもWHOが査察を行っている。

4.2 査察の頻度(定期、不定期と理由)

5. 標準品

国際標準品、国内標準品の準備状況等

6. 感染症情報、副作用情報

6.1 所轄機関

感染症情報は健康省予防医学部門 (Vietnamese Administration of Preventive Medicine, VAPM) 傘下の国立衛生疫学研究所 (National Institute of Hygiene and Epidemiology, NIHE) が担当し副作用情報は VAPMとNICVBが協力して行っている。

6.2 収集・分析方法等

麻疹・ポリオの症例報告はE-repotシステムで各県から中央に報告される。NIHE傘下の National EPIが国内3カ所にAFFIサーベランスシステムの導入を開始している(2006年)。

図 1. ベトナム国立ワクチンおよび生物製剤管理研究所の組織

Organization of the NICVB

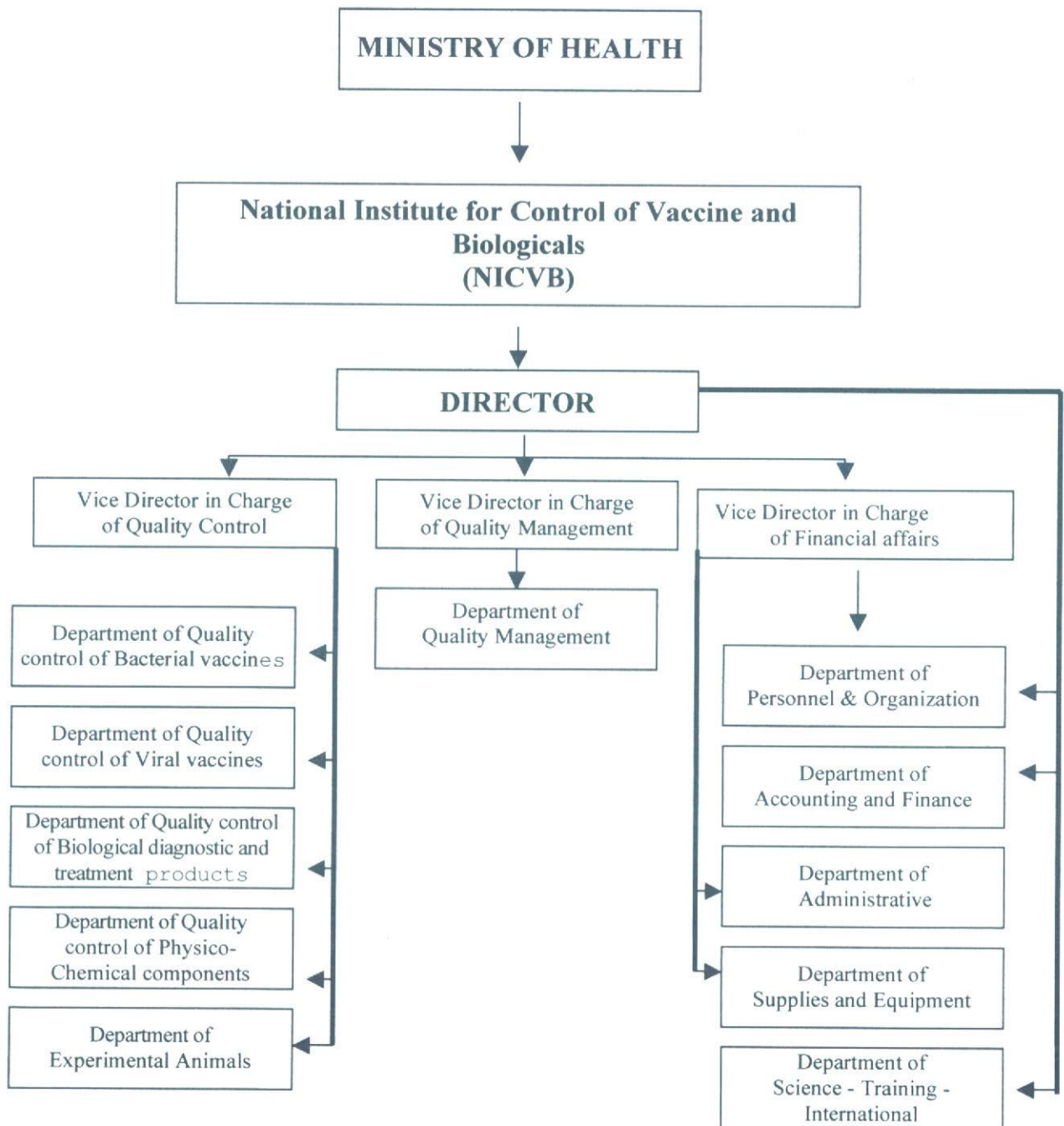


表1. ベトナムで製造承認されているワクチン

Manufacturer	Location	Major products
POLYVAC	Hanoi	Measles vaccine, OPV, IPV (It is still in clinical trial period)
VABIOTECH	Hanoi	Hepatitis A, Hepatitis B, Japanese Encephalitis, Cholerae vaccines
IVAC	Nha Trang	DTwP, BCG, TT, SAT, SAR, SAV, SAD, Biolac
IVAC	Da Lat	<i>Typhoid Vi</i> , Biosubtyl
Pasteur Institute	Ho Chi Minh City	BCG, Verorab (only filling)
BioFarmCo N° 2	Nha Trang	Anti teta II, Biolac

表2. ベトナム検定試験項目（日本との比較）

Comparison of Control Tests for EPI Vaccines between Japan and Vietnam

1. DTaP Vaccine in Japan

Test	Test on final product
Test for pH	△
Test for aluminum content	△
Test for thimerosal content	△
Test for formaldehyde content	△ ▲
Sterility test	△
Test for freedom from abnormal toxicity	△ ▲
Bacterial endotoxin test	△ ▲
Test for mouse body weight-decreasing toxicity	△ ▲
Test for mouse leukocytosis-promoting toxicity	△ ▲
Test for mouse histamine-sensitizing toxicity	△ ▲
Test for detoxification of diphtheria toxin	△ ▲
Test for detoxification of tetanus toxin	△ ▲
Potency test	△ ▲
Identity test	△

▲ : Testing at the NIID

△ : Testing at manufacturer

DTaP Vaccine in Vietnam (imported vaccine)

Test	Test on final product
Test for pH	△ ▲
Test for aluminum content	△ ▲
Test for thimerosal content	△ ▲
Test for formaldehyde content	△ ▲
Sterility test	△ ▲
Test for freedom from abnormal toxicity	△ ▲
Bacterial endotoxin test	△
Test for mouse body weight-decreasing toxicity	△ ▲
Test for mouse leukocytosis-promoting toxicity	△
Test for mouse histamine-sensitizing toxicity	△
Test for detoxification of diphtheria toxin	△ ▲
Test for detoxification of tetanus toxin	△ ▲
Potency test (for D, T and aP/ELISA testing)	△ ▲
Identity test	△ ▲

▲ : Testing at the NICVB

△ : Testing at manufacturer

2. Measles Vaccine in Japan

Test	Processing Stage			
	Virus suspension	Bulk materials	Final bulk	Final product
Staining test		△ ▲	△	
Sterility test	△	△ ▲	△	△
Mycoplasma test	△			
Mycobacterial sterility test	△			
Test for freedom from abnormal toxicity			△	
Test for freedom from extraneous viruses				
1. Tests in animals				
-Inoculation of adult mice		△ ▲		
-Inoculation of suckling mice		△ ▲		
-Intracerebral inoculation of guinea pig		△ ▲		
2. Tests in cell cultures				
-Inoculation of human tissue culture cells	△	△ ▲		
-Inoculation of primary tissue cultures of embryonic chick cells	△	△ ▲		
-Inoculation of primary renal tissue culture of chick cells	△	△ ▲		
3. Inoculation of embryonated chicken eggs		△ ▲		
Identification test		△ ▲		
Test for confirmation of attenuation of virus		△ ▲		
Test for virus content		△ ▲		
Test for moisture content				△ ▲
Potency test				△ ▲

▲: Testing at the NIID

△: Testing at manufacturer

3. Measles Vaccine in Vietnam

Test	Processing Stage			
	Virus suspension	Bulk materials	Final bulk	Final product
Staining test		△	△	
Sterility test	△	△	△	△ ▲
Mycoplasma test	△		△	
Mycobacterial sterility test	△		△	
Test for freedom from abnormal toxicity			△	△ ▲
Test for freedom from extraneous viruses				
3. Tests in animals				
-Inoculation of adult mice		△		
-Inoculation of suckling mice		△		
-Intracerebral inoculation of guinea pig		△		
4. Tests in cell cultures				
-Inoculation of human tissue culture cells	△	△		
-Inoculation of primary tissue cultures of embryonic chick cells	△	△		
-Inoculation of primary renal tissue culture of chick cells	△	△		
3. Inoculation of embryonated chicken eggs		△		
Identification test		△		
Test for confirmation of attenuation of virus		△		
Test for virus content		△		
Test for moisture content				△
Potency test				△ ▲

▲ : Testing at the NICVB

△ : Testing at manufacturer

4. BCG Vaccine in Japan

Test	Processing Stage	
	Final bulk	Final product
Staining test	△	△
Sterility test	△	△
Test for freedom from virulent mycobacteria	△ ▲	
Test for moisture content		△ ▲
Test for pH		△
Test for total bacterial content		△ ▲
Potency test (Viability test)		△ ▲
Identity test		△

▲: Testing at the NIID

△: Testing at manufacturer

BCG Vaccine in Vietnam

Test	Processing Stage	
	Final bulk	Final product
Identity (Staining test, colonies forming on Lowenstein Jensen media)	△	△ ▲
Sterility test	△	△ ▲
Test for freedom from virulent mycobacteria	△	▲ (±)
Test for moisture content		△ ▲
Test for pH		△
Test for total bacterial content	△	△ ▲
Test for dispersion		△ ▲
Potency test (Viability test and heat Stability test)	△	△ ▲
Visual test		△ ▲
Abnormal toxicity test		△ ▲
Skin test		△ ▲ (±)

▲: Testing at the NICVB

△: Testing at manufacturer

5. Live Oral Poliomyelitis Vaccine in Japan (OPV)

Test	Processing stage			
	Monovalent bulk suspension before filtration	Monovalent bulk suspension after filtration	Final bulk	Final product
Test in <i>Cercopithecus</i> monkey kidney-cell cultures	△* ▲*			
Test in rabbit kidney cell cultures	△* ▲*			
Test in human cell cultures	△* ▲*			
Sterility test	△	△	△	△
Mycoplasma test	△			
Mycobacterial sterility test	△			
Tests for freedom from extraneous viruses				
-Test in adult mice	△ ▲			
-Test in suckling mice	△ ▲			
-Intracerebral test in guinea pigs	△ ▲			
-Intraperitoneal test in guinea pigs	△ ▲			
-Test in rabbits	△ ▲			
Test for identification of type of virus		△ ▲		
Test for virus content		△ ▲		△ ▲
Test for rct/40 marker		△ ▲		
Test for d-marker		△ ▲		
Neurovirulence test		△ ▲		
Test for thermal stability				△
Confirmation of the labelling				△

▲: Testing at the NIID

△: Testing at manufacturer

△* ▲*: Applied to single harvested viruses

Live Oral Poliomyelitis Vaccine in Vietnam (OPV)

Test	Processing stage			
	Monovalent bulk suspension before filtration	Monovalent bulk suspension after filtration	Final bulk	Final product
Test in <i>Cercopithecus</i> monkey kidney-cell cultures	△*			
Test in rabbit kidney cell cultures	△*			
Test in human cell cultures	△*			
Sterility test	△	△	△	△ ▲
Mycoplasma test	△			
Mycobacterial sterility test	△			△ ▲
Tests for freedom from extraneous viruses				
-Test in adult mice	△			
-Test in suckling mice	△			
-Intracerebral test in guinea pigs	△			
-Intraperitoneal test in guinea pigs	△			
-Test in rabbits	△			
Test for identification of type of virus		△		
Test for virus content (potency test)		△		△ ▲
Test for freedom from abnormal toxicity			△	△ ▲

▲: Testing at the NICVB

△: Testing at manufacturer

Other National Immunization Program Vaccines in Vietnam

5. Hepatitis B Vaccine in Japan (Recombinante)

	Processing Stage		
	Bulk materials	Final bulk	Final product
Sterility test	△		△
HbsAg polypeptide test	△		
Tests for purity of HbsAg suspension	△		
Test for pH			△
Test for aluminum content			△
Test for thimerosal content			△
Test for protein content			△
Test for freedom from abnormal toxicity			△ ▲
Potency test			△ ▲

▲: Testing at the NIID

△: Testing at manufacturer

Hepatitis B Vaccine in Vietnam (Recombinante)

	Processing Stage		
	Bulk materials	Final bulk	Final product
Potency test		△	△ ▲
Sterility test	△	△	△ ▲
Test for freedom from abnormal toxicity		△	△ ▲
Pyrogen test			△ ▲
Chemical tests (pH, protein, formaldehyde, thimerosal, Aluminum contents)			△ ▲
Identity			△

▲: Testing at the NICVB

△: Testing at manufacturer

Hepatitis B Vaccine in Vietnam (Plasma)

	Processing Stage		
	Bulk materials	Final bulk	Final product
Potency test		△	△ ▲
Sterility test	△	△	△ ▲
Test for freedom from abnormal toxicity		△	△ ▲
Pyrogen test			△ ▲
Chemical tests (pH, protein, formaldehyde, thimerosal, Aluminum contents)	△ (total protein)		△ ▲
Identity	△		

▲: Testing at the NICVB

△: Testing at manufacturer

7. Japanese encephalitis Vaccine in Japan

Test	Processing Stage			
	Virus suspension	Bulk materials	Final bulk	Final product
Sterility test	△	△		△
Staining test		△		
Inactivation test		△		△ ▲
Test for pH				△
Test for protein content				△ ▲
Test for thimerosal content				△
Test for formaldehyde content				△ ▲
Test for freedom from abnormal toxicity				△ ▲
Potency test				△ ▲

▲: Testing at the NIID

△: Testing at manufacturer

Japanese encephalitis Vaccine in Vietnam

Test	Processing Stage			
	Virus suspension (After filtration)	Bulk materials	Final bulk	Final product
Potency test				△ ▲
Sterility test	△	△	△	△ ▲
Test for freedom from abnormal toxicity				△ ▲
Specific toxicity test				△ ▲
Pyrogen test				△ ▲
Chemical tests (pH, protein, formaldehyde, thimerosal contents)				△ ▲

▲: Testing at the NICVB

△: Testing at manufacturer

8. Vi typhoid Vaccine in Japan (Not available)

Test	Processing Stage	
	Final bulk	Final product
Identity		
Sterility test		
Test for O-acetyl content		
Potency test (Vi polysaccharide content)		
Visual test		
Abnormal toxicity test		
Test for phenol content		
Pyrogen test		
Test for pH		

▲: Testing at the NIID

△: Testing at manufacturer

Vi typhoid Vaccine in Vietnam

Test	Processing Stage	
	Final bulk	Final product
Identity	△	△ ▲
Sterility test	△	△ ▲
Test for O-acetyl content	△	△ ▲ (±)
Potency test (Vi polysaccharide content)	△	△ ▲
Visual test		△ ▲
Abnormal toxicity test		△ ▲
Test for phenol content	△	
Pyrogen test		△ ▲
Test for pH		△

▲: Testing at the NICVB

△: Testing at manufacturer

表3. ベトナムの検定品目とロット数

(Name of products and number of lots tested in 2005)

No	Name of products	Quantity of lots tested in 2005
1.	DTwP (From IVAC Nha Trang)	20 lots
2.	TT vaccine	23 lots
3.	Oral Cholerae vaccine	10 lots
4.	Vi polisaccharide typhoid vaccine	03 lots
5.	Pseudomonas vaccine	03 lots
6.	BCG vaccine	68 lots
7.	Hepatitis A vaccine	02 lots
8.	Hepatitis B plasma vaccine	3 lots
9.	Hepatitis B recombinant vaccine	02 lots
10.	J.E vaccine	11 lots
11.	Rabies vaccine	23 lots
12.	OPV vaccine	12 lots
13.	Anti Diphtheria serum (SAD)	02 lots
14.	Anti tetanus serum (SAT)	11 lots
15.	Anti Rabies serum (SAR)	01 lot
16.	Anti Venomous serum (SAV)	03 lots
17.	Superferon	3 lots
18.	Tuberculin	4 lots
19.		
20.	HIV diagnostic kit: - HIV 1/2 Whole Blood rapid test (from: Phamatech, USA) - HIV 1/2 EIA (from: Phamatech, USA) - HIV 1/2 Q Spot (from: Phamatech, USA) - HIV 1/2 test (Guangzhou, China) - HIV ASE 1+2 (Genaral Buiological, Taiwan) - Architech HIV Ag/Ab Combo (Abbot, USA) - HIV 1/2 rapid 3.0-CT1 (Vabiotech No.1, Vietnam)	03 lots 03 lots 03 lots 3 lots 3 lots 3 lots 3 lots
21.	- Architech anti HBs (Abbot, USA) - Anti HBs rapid Device-CT1 (Vabiotech No.1, Vietnam) - Anti HBsAg rapid Device-CT1 (Vabiotech No.1, Vietnam)-	3 lots 3 lots 3 lots
22.	HBsAg diagnostic kit - HBsAg EIA (Phamatech, USA) - HBsAg one step (Phamatech, USA) - Architech HBsAg (Abbot, USA) - Quick stick HBsAg Phamatech, USA)	3 lots 3 lots 3 lots 3 lots
23.	HCV diagnostic kit: - HCV card test (Amvibiotech, USA) - HCV One step (Phamatech, USA) - HCV EIA (Phamatech, USA)	3 lots 3 lots 3 lots
24.	LH Urine Strip(Wondfo Biotech,	3 lots
25.	Bioferon 3 MIU-Biosidus	3 lots
26.	Hemax- Biosidus USA	3 lots
27.	Tetraxim	3 lots

28.	Tetrac-Hib	3 lots
29.	Tetanus antitoxin (Hunggary, India)	6 lots
30.	Pneumo 23 (Sanofi Pasteur)	3 lots
31.	Rotarix (GSK)	3 lots
32.	HepavacGen (Green Cross)	3 lots
33.	Avaxim(Sanofi Pasteur)	3 lots
34.	Varivax	3 lots
35.	Quimi HiB (Berna Biotech)	3 lots
36.	Priorix (GSK)	3 lots
37.	Varicella (Green-Cross)	3 lots
38.	Agripal (Chiron)	3 lots
39.	Bioline Rotavirus (Standard Diagnostic)	3 lots
40.	Bioline Chlamydia (Standard Diagnostic)	3 lots
41.	Bioline H. pylory (Standard Diagnostic)	3 lots
42.	SD rapid TB test (Standard Diagnostic)	3 lots
43.	Malaria antigen – gamma USA	3 lots
44.	SP nanbase (Genaral Boiological)	3 lots
45.	SD Bioline Chlamydia (Standard Diagnostic)	3 lots
46.	SD Bioline Syphilis 3.0 (Standard Diagnostic)	3 lots
47.	Chlamidia (Amvi Biotech USA)	3 lots
48.	Dengue fiver rapid test (AmviBiotech, USA)	3 lots
49.	Chlamidia for female (Nugen Biotech)	3 lots
50.	Anphafetoprotein (AFP)/Nugen Biotech	3 lots
51.	AFP card test (Amvibiotech)	3 lots
52.	Carcinoembryonic (Nugen Biotech)	3 lots
53.	Tooponin I test (Nugen Biotech)	3 lots
54.	Tuberculosis test (Nugen Biotech)	3 lots
55.	Myoglobin test (Nugen Biotech)	3 lots
56.	Vibilac II (Biopharco Comp. No2)	3 lots
57.	LH ovulation (AmviBiotect, USA)	3 lots
58.	PSA (AmviBiotect USA)	3 lots
59.	Toponin I (AmviBiotect USA)	3 lots
60.	Malaria (AmviBiotect USA)	3 lots
61.	CEA (AmviBiotect USA)	3 lots
62.	RPR reagent (Phamatech)	3 lots
63.	Malaria PF, PV rapid test	3 lots
64.	Test kit for diagnostic of Meninginitis /antiserum (IVAC Dalat)	3 lots

8. タイ

1. 審査・承認

1.1 法的根拠

医薬品法(The Drug Act of B.E. 2510、1967)、Drug Act of B.E. 2546、2003)

1.2 所轄機関

タイ食品医薬品庁 (Food and Drug Administration Thailand, ThaiFDA)。バンコック地域では医薬品管理部門 (Drug Control Division)。その他の地域では地方事務所 (Provincial Public Health Offices) が担当。医科学部生物製剤部門 (Department of Medical Sciences. Biological Products Division、NCL)、

1.3 承認済み製剤の種類

ワクチンと抗血清 (表1) を参照

血液製剤 (表2) を参照

2. 審査・承認の相互承認

無し

3. 国家検定

3.1 法的根拠

医薬品法(The Drug Act of B.E. 2510、1967)、Drug Act of B.E. 2546、2003)

3.2 所轄機関 (図1)

タイ FDA の医科学部生物製剤部門 (Department of Medical Sciences. Biological Products)

3.3 試験機関の認証規格

ISO17025 相当の国際的認証を受けている

3.4 検定 (文書審査)

SLP審査 (書式は標準規格に従う)

3.5 検定 (試験)

表3を参照

3.6 検定の頻度

全ロット。

3.7 検定品の種類と数

ワクチンと抗血清 (表4) を参照

血液製剤 (表5) を参照

3.8 検定品の抜き取り、提出方法

地方の GMP 査察官による

3.9 検定事務処理時間

試験: 平均で 60 日

書類審査: 10 日程度

3.10 検定の相互承認

無し

4. GMP査察

4.1 所轄機関

医科学部生物製剤部門 (Department of Medical Sciences. Biological Products Division、NCL)、

4.2 査察の頻度

定期査察: 少なくとも3年に1度

不定期査察: 必要に応じて (設備の変更、製造工程の重要な変更、GMP遵守が疑わしい時など)

5. 標準品

所轄機関は医科学部生物製剤部門

国際標準品に対応した力価試験用標準沈降破傷風トキシノイドを製造している。国内製造所が製造し、毒素攻撃法 (マウス法) で標準化した。標準化 (評価) に2機関が参加した。現在新ロットを作製中である

6. 感染症情報、副作用情報

6.1 所轄機関

感染症情報はタイCDC

市販後調査は健康省医科学部 (Medical Sciences Department, Ministry of Public Health) が担当。市販後の製品の品質と安全性のモニタリングを行っている

6.2 収集・分析方法

調査中

表 1. 承認済みワクチン

Vaccines (anti-sera)		local	imported
1	Influenza HA Vaccine		○
2	Japanese Encephalitis Vaccine	○	
3	Freeze-dried Japanese Encephalitis Vaccine		○
4	Adsorbed Diphtheria-purified Pertussis-tetanus Combined Vaccine	○	
5	Adsorbed Diphtheria Tetanus Combined Toxoid	○	
6	Adsorbed Diphtheria Toxoid for Adult Use	○	
7	Adsorbed Teatanus Toxoid	○	
8	Recombinant Adsorbed Hepatitis B Vaccine (Prepared from Yeast)		○
9	Adsorbed Hepatitis B Vaccine (Prepared from huGK-14 Cells)		○
10	Freeze-dried Inactivated Tissue Culture Hepatitis A Vaccine		○
11	Freeze-dried Inactivated Tissue Culture Rabies Vaccine	○	○
12	Pneumococcal Vaccine Polyvalent		○
13	Cholera Vaccine		○
14	Weil's Disease and Akiyami Combined Vaccine		○
15	Live Oral Poliomyelitis Vaccine		○
16	Freeze-dried Live Attenuated Measles,Mumps, Rubella, Combined Vaccin	○	○
17	Freeze-dried Live Attenuated Measles Vaccine	○	○
18	Freeze-dried Live Attenuated Rubella Vaccine		
19	Freeze-dried Live Attenuated Mumps Vaccine		
20	Freeze-dried Live Attenuated VaricellaVaccine		○
21	Freeze-dried BCG Vaccine (for Percutaneous Use)	○	
22	Freeze-dried BCG for Intravesical Use (Connaught Strain)		○
23	Freeze-dried BCG for Intravesical Use (Japanese Strain)		○
24	Yellow Fever Vaccine		
25	Freeze-dried Smallpox Vaccine Prepared in Cell Culture		
30	Varicella Antigen		
34	Freeze-dried Gas Gangrene Antitoxin, Equine		
35	Freeze-dried Diphtheria Antitoxin, Equine		○
36	Freeze-dried Mamushi Antivenom, Equine		
37	Freeze-dried Habu Antivenom, Equine		
38	Freeze-dried Botulism Antitoxin, Equine		○
39	Purified Tuberculin		○
	TOTAL		

表 2. 承認済み血液製剤

Blood products		local	imported
1	Whole Human Blood	○	
2	Concentrated Human blood Cells	○	
3	Fresh-frozen Human Plasma	○	
4	Platelet concentrate	○	
5	Human Plasma Protein Fraction	○	○
6	Human Serum Albumin	○	○
7	Freeze-dried Human Fibrinogen		○
8	Freeze-dried Human Concentrated Blood Coagulation Factor VIII		○
9	Recombinant		○
10	Freeze-dried Human Blood Coagulation Factor IX Complex		○
11	Freeze-dried Concentrated Human Blood Coagulation Factor IX		
12	Normal Human Immunoglobulin	○	○
13	Freeze-dried Ion-exchange-resin-treated Normal Human Immunoglobulin		
14	Freeze-dried Sulfonated Normal Human Immunoglobulin		
15	pH 4-treated Normal Human Immunoglobulin		○
16	Freeze-dried pH 4-treated Normal Human Immunoglobulin		
17	Freeze-dried Pepsin-treated Normal Human Immunoglobulin		
18	Polyethylene Glycol-treated Normal Human Immunoglobulin		
19	Freeze-dried Polyethylene Glycol-treated Normal Human Immunoglobulin		
20	Human Anti-HBs Immunoglobulin	○	○
21	Freeze-dried Human Anti-HBs Immunoglobulin		
22	Polyethylene Glycol-treated Human Anti-HBs Immunoglobulin		
23	Human Anti-D(Rho) Immunoglobulin		○
24	Human Ant1-tetanus Immunoglobulin		○
25	Freeze-dried Human Anti-tetanus Immunoglobulin		
26	Polyethylene Glycol-treated Human Anti-tetanus Immunoglobulin		
27	Freeze-dried Human Antithrombin III Concentrate		
28	Freeze-dried Human Activated Protein C Concentrate		
29	Human rabies Immunoglobulin	○	
	TOTAL		

表3 タイ検定試験項目 (Test Items for Lot release)

		Vaccine	blood products
1	Aluminum Content	○	
2	Abnormal Toxicity (General Safety Tests)	○	○
3	Endotoxins Test	○	○
4	Formaldehyde Content	○	
8	Heat Stability	○	
9	Moisture Content	○	○
10	pH	○	○
11	Phenol Content	○	○
12	Protein Content	○	○
13	Protein Nitrogen Content	○	○
14	Pyrogen	○	○
15	Staining Test	○	
16	Thimerosal Content	○	
17	Tetanus Antitoxin Titer Determination	○	○
18	Potency of Human Anti-HBs Immunoglobulin		
19	Potency of Anti-D antibody		
20	Anti-complement Activity		
21	Antibody Assay against Measles Virus		
22	Acetate Membrane Electrophoresis		○
23	Citric Acid Content		
24	Hemoglobin Content		○
25	Freedom from aggregated IgG (IV)		
27	potency test	○	○
28	Identity test	○	○
30	Mouse leukocytosis-promoting toxicity	○	
31	Phosphate content		
32	Neurovirulence test	○	
33	Re-productive capacity		
34	d-marker	○	
35	rct/40 marker		
36	Safety tests for unknown infectious agents		

表4 タイ 検定品目と件数 (ワクチンと抗血清)

Vaccines (anti-sera)		2007	2006
1	Influenza HA Vaccine	19	13
2	Japanese Encephalitis Vaccine	34	59
3	Freeze-dried Japanese Encephalitis Vaccine	3	
4	Adsorbed Diphtheria-purified Pertussis-tetanus Combined Vaccine	26	20
5	Adsorbed Diphtheria Toxoid for Adult Use	9	10
6	Adsorbed Teatanus Toxoid	40	32
7	Tetanus toxoid bulk material for DPT		
8	Recombinant Adsorbed Hepatitis B Vaccine (Prepared from Yeast)	51	67
9	Adsorbed Hepatitis B Vaccine (Prepared from huGK-14 Cells)		
10	Freeze-dried Inactivated Tissue Culture Hepatitis A Vaccine		
11	Freeze-dried Inactivated Tissue Culture Rabies Vaccine		
12	Pneumococcal Vaccine Polyvalent	5	8
13	Cholera Vaccine	1	3
14	Weil's Disease and Akiyami Combined Vaccine		
15	Live Oral Poliomyelitis Vaccine	6	19
16	Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine		
17	Freeze-dried Live Attenuated Measles Vaccine		
18	Freeze-dried Live Attenuated Rubella Vaccine		
19	Freeze-dried Live Attenuated Mumps Vaccine		
20	Freeze-dried Live Attenuated Varicella Vaccine		
21	Freeze-dried BCG Vaccine (for Percutaneous Use)		
22	Freeze-dried BCG for Intravesical Use (Connaught Strain)	2	3
23	Freeze-dried BCG for Intravesical Use (Japanese Strain)	4	19
24	Yellow Fever Vaccine		
25	Freeze-dried Smallpox Vaccine Prepared in Cell Culture		
26	Adsorbed Diphtheria-tetanus Combined Toxoid		
27	Live Attenuated Measles Vaccine (Bulk)		
28	Live Attenuated Rubella Vaccine (Bulk)		
29	Live Attenuated Mumps Vaccine (Bulk)		
30	Varicella Antigen	7	7
31	BCG Vaccine (for Percutaneous Use) (Bulk)		
32	BCG for Intravesical Use (Japanese Strain) (Bulk)		
33	Smallpox Vaccine Prepared in Cell Culture (Bulk)		
34	Freeze-dried Gas Gangrene Antitoxin, Equine		
35	Freeze-dried Diphtheria Antitoxin, Equine		
36	Freeze-dried Mamushi Antivenom, Equine		
37	Freeze-dried Habu Antivenom, Equine		
38	Freeze-dried Botulism Antitoxin, Equine		
39	Purified Tuberculin		
40	Rota vaccine	7	4
41	Hep-A Vaccine	20	4
42	HIB Vaccine	5	5
43	Meningococcal polysaccharide	2	4
44	Typhoid Vi polysaccharide	2	2
45	DTP-HB	4	6
46	DTP-HB-IPV-HIB	9	5
47	DTP-IPV-HIB	12	11
48	DTP-IPV	3	1
49	HepA-HepB	3	2
50	DTP-HIB	1	6
51	IPV vaccine	4	
	TOTAL	279	310

表5 タイ 検定品目と件数(血液製剤と組み替え製剤)

Blood products		2007	2006
1	Albumin	60	55
2	Human rabies immnoglobulin	8	3
3	Anti Hemophillic Factor VIII	21	18
4	Cobra Antivenin	8	3
5	Equine anti Rabies immnoglobulin	23	6
6	Factor IX	2	4
7	Factor XI		1
8	Green Pit Viper Antivenin	9	4
9	Human Hepatitis B immnoglobulin	5	6
10	Human Varicella-Zoster	1	2
11	Immunoglobulin Human	18	19
12	Malayan Pit Viper Antivenin	10	3
13	Rabbit anti-human thymocyte globulin	4	2
14	Russll's Viper Antivenin	2	4
15	Fibrin sealant (Human)	1	
16	Human anti-D Immunoglobulin	1	
17	Human cytomegalo-Immunoglobulin	2	6
18	Polyvalent Human Immnoglobulin	7	8
19	Plasmax (sterile polygeline solution)	3	
20	Solcoseryl	4	8
21	Tetanus Antitoxin	6	14
22	Tetanus Immunoglobulin	6	8
23	Banded Krait Antivenin		1
24	King Cobra antivenin (purified)		2
25	Malayan Krait antivenin (pufified)		3
	TOTAL	201	180

Recombinant Product		2007	2006
1	Basilixmab	2	2
2	Figrastim	11	2
3	Infixmab	2	1
4	Interferin alfa-2b	30	28
5	Interferon beta-1b	2	3
6	Lenograstim	4	3
7	Omalizumab	5	
8	Daclizumab		1
9	Interferin alfa-2a		2
10	rituximab		1
11	Trastuzumab		1
	TOTAL	56	44