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If Poliomyelitis vaccine is administered to individuals with an immune deficiency or undergoing any type of immunosuppressive therapy the expected immune response can fail to occur.

The potential risk of apnoea and the need for respiratory monitoring for 48 -72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

4.5 Interaction with other medicinal products and other forms of interaction

Poliomyelitis vaccine can be administered simultaneously with other vaccines, if administered on different injection locations.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data on a large number of exposed pregnancies indicate no adverse effects of Poliomyelitis vaccine on pregnancy or on the health of the foetus/new-born child. However Poliomyelitis vaccine should only be used during pregnancy when there is a clear risk of infection.

Breastfeeding
Poliomyelitis vaccine can be used during lactation.

4.7 Effects on ability to drive and use machines

It is not likely that Poliomyelitis vaccine has an effect on driving skills or the capability to operate machines.

4.8 Undesirable effects

Based on Post Marketing information (voluntary reporting) it has been established that the following adverse reactions could occur. The reported adverse reactions following vaccination with Poliomyelitis vaccine mostly occurred within the first three days following vaccination and were temporary of nature.

Neural disorders
Very Seldom (< 1/10.000): (Poly-) Neuropathy

Respiratory, thoracic and mediastinal disorders
Apnoea in very premature infants (≤ 28 weeks of gestation) (see section 4.4).

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General disorders and reactions:
Local reactions
Seldom (>1/10.000, <1/1.000): Swelling, redness and pain on injection site.
Systematic reactions
Seldom (>1/10.000, <1/1.000)): Fever, discomfort.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose

No cases of overdosing have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Viral Vaccines, ATC-code: J07BF03
In animals (monkeys or rats) the administration of the vaccine results in the formation of neutralizing antibodies.
Immunogenicity in humans
Administration of the vaccine in humans results in the formation of antibodies and immunological memory. Administration of a second dose of the vaccine results in a secondary response characterized by a rapid increase of antibody levels that indicates the existence of immunological memory.
In general, the antibody level is indicative for protection. For poliomyelitis a titer (reciprocal dilution in neutralisation assay) of ≥ 8 is protective. A complete vaccination series in general results in protective titers against poliomyelitis type 1, 2 and 3.
The percentage seroprotection in the general Dutch population has been studied s in 1995 – 1996 (Immunity to Poliomyelitis in the Netherlands, Am.J.Epid., 2001:153,3). During the decade prior to this investigation, the vaccination level for the primary immunization of DTP-IPV (3 doses at 3, 4 and 5 months) in the Dutch national immunization program was 97%. The age of the investigated persons was in the range of 1 to 79 year. The level of seroprotection can be dependent of the moment of collecting blood samples after vaccination, which was not as in most clinical studies 1 month after vaccination. The interval of blood sampling after vaccination varied depending on the age of the person. Furthermore it needs to be mentioned that the data is obtained using plain Poliomyelitis vaccine or a combination vaccine with a Poliomyelitis vaccine component. The percentage of seroprotection is measured in this study is shown in the following table.

	percentage seroprotection (%)	95 % confidence interval
Polio type 1	96,6 %	95,9 - 97,2
Polio type 2	93,4 %	92,3 - 94,5
Polio type 3	89,7 %	88,3 -91,0

5.2 Pharmacokinetic properties

Not applicable for vaccines.

5.3 Preclinical safety data

Pre-clinical studies do not show any special risk for humans. These results are obtained of conventional studies in the area of pharmacological safety and toxicology by repeated administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde (12.5 µg) (E240),
2-phenoxyethanol (2.5 mg),
Medium 199 primarily consisting of amino acids, minerals and vitamins,
disodium hydrogenphosphate dehydrate (E339),
sodium chloride,
potassium chloride (E508),
magnesium sulphate (E518),
phenol red,
calcium chloride (E509),
potassium dihydrogenphosphate (E340),
polysorbate 80 (E433),
water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at 2 - 8 °C. Do not freeze.

6.5 Nature and contents of container

The vaccine is filled in:

- ampoules (type 1 hydrolytic glass) containing 0,5 mL vaccine.
- vials (type 1 hydrolytic glass) sealed with a rubber stopper (free of latex) and an aluminium flip-off cap that contain 0.5 mL vaccine (1 dose) or 2.5 mL (5 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No specific requirements.

7 MARKETING AUTHORISATION HOLDER

Bilthoven Biologicals B.V.
Antonie van Leeuwenhoeklaan 13
3721 MA Bilthoven, the Netherlands
Telephone: +31 30 800 4800

8 MARKETING AUTHORISATION NUMBER

Poliomyelitisvaccine, suspension for injection 0.5 mL RVG 17642
Poliomyelitisvaccine multidose, suspension for injection 2.5 mL RVG 114720

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2 December 1993.
Date of latest renewal: August 25th, 1994

10 DATE OF REVISION OF THE TEXT

Latest complete revision: June 2014.

IMMUNE RESPONSE TO INACTIVATED POLIO VACCINE ADMINISTERED IN A TWO DOSE SCHEDULE

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Introduction

Developments in the technology of inactivated poliovirus vaccine (IPV) production which have made it possible to increase its efficacy (1) have led to the use of a modified vaccine schedule consisting of a primary immunization based on the administration of two successive doses early infancy, followed by a reinforcing dose given 6-12 months later (2,3). On this occasion, it was repeatedly observed that after the second IPV dose, in a high proportion of children an immune response of anamnestic type was present. Further studies have shown that infants whose age ranged between 2-24 months, given one dose of IPV of enhanced potency, responded in a high proportion with production of neutralizing antibody to a second dose of IPV (4-8).

Since in several areas of the world, infants are still vulnerable to paralytic poliomyelitis, mainly because of logistic obstacles to completing the vaccination schedule, and because of immunization failures following the use of oral polio vaccine (OPV), it was considered worthwhile to evaluate the immune response to a simplified IPV schedule by using a potent polio antigen which, administered in early infancy, would sensitize the immune system for an anamnestic response to a second antigenic dose given six months later.

Material and Methods

Two groups of 61 and 68 healthy infants were primed at the age of 2 months with one dose of either 160-32-128 or 80-16-64 D antigen units, corresponding to the three poliovirus types, respectively. Six months later both the groups were boostered with one dose of the standard 40-8-32 D ag units. As a control group, 79 infants were administered two doses of 40-8-32

D ag u at the age of 2 and 3½ months and boostered at 9 months, which is the routine polio immunization schedule in a limited area of Israel.

The vaccine in three different concentrations of D antigen units: 160-32-124, 80-16-64 and 40-8-32 for each of the three polio virus types, respectively was prepared at the Dutch National Institute of Public Health at Bilthoven.

Bloods were collected on the day of the first injection, one month later, at the date of the booster, and one week, one month and one year after it.

Polio neutralizing antibody (NA) were measured by neutralization assay in microtitration plates - microneutralization test. Antibody were considered present when a titer of ≥ 1:4 was found.

As shown in Table 1, a considerable proportion of infants in the study and control groups carried low titers of maternal antibody.

Results

One month after priming, NA were present in a considerably higher percent of infants given 160-32-124 and 80-16-64 D ag.u. vaccine, respectively, than in the control group immunized with the standard 40-8-32 D ag.u. vaccine (see Fig. 1). In contrast, geometric mean (GM) values were uniformly low in the three groups.

At the date of the second vaccine dose administration, the percentage distribution of NA ≥ 1:4 and the GM values in children primed with one dose of 160-32-124 and 80-16-64 D ag.u. were clearly lower that at the date of start of immunization.

One month after second dose of vaccine, an very high antibody response, in parallel with considerable GM values, was observed in the three groups.

A dose effect (highest values in the control group, lowest values in the study group given 80-16-64 D ag.u. vaccine) was noted, particularly in response to type 1 and type 2, and less for type 3.

Follow-up to one year after the second dose of vaccine revealed practically no change in the percent distribution of NA ≥ 1:4. Simultaneously, there was a considerable drop in GM levels, particularly for types 1 and 3, in the study group, as compared with a more attenuated decline observed in the control group. Nevertheless, GM levels of protective value against the three types of polio virus were found.

The booster response to the administration of an antigen of lower potency was demonstrable, as seen in Figure 2, by the cumulative percent distribution of polio NA antibody to type 1: one week after the reinforcing dose, the considerable proportion of high titers of NA antibody observed was very similar to the percent distribution of antibody observed one month after the booster dose.

A similar pattern was observed for NA to type 3 poliovirus, as shown in Figure 3, which indicated the occurrence of an intense and rapid antibody response of anamnestic type.

Comment

The very high proportion of babies in the study group with NA ≥ 1:4 one month after the first vaccine dose administration, in spite of the high percentage of infants covered by maternal antibody at the date of priming, demonstrates again that a primary immune effect can be accomplished when immunization is started at the age of 2 months.

The evident decrease in the percentage distribution of polio NA to the three poliovirus types six months after priming, observed elsewhere also (2,3) supports the probability of absence of exposure of the study group to natural infection up to the date of booster.

After the second dose of antigen, high titers of NA antibody to the three types of poliovirus were present in 100% of immunized babies, as reported in several previous trials with IPV of enhanced potency (3-8) administered in a two dose schedule or following the second dose if more than two IPV doses were used. In most of these studies, in which the standard 40-8-32 D ag.u. vaccine was mostly used for both priming and booster, the age at first vaccine administration as well as the interval until the booster date varied considerably, as shown in Table 2.

In the present trial, antigens of higher than usual potency were used for priming with the purpose of stimulating the immune system with an amount of antigen adequate to induce an immunizing effect, as it is agreed that the immunological memory and the degree of humoral antibody response to a booster are determined, among others, by the antigenic content of the vaccine employed (9,10) in the primary immunization. There is a dose response relationship between the quantity of antigen used in the primary stimulation and the level of both primary and secondary antibody response (10). A single dose of IPV with a sufficiently high quantity of antigen was capable of uniformly sensitizing the immune system to respond adequately and consequently the 40-8-32 D ag.u. IPV concentration in the booster dose was enough to induce an immune response in 100% of the infants. On the other hand, by comparing the percentage distribution of NA and the GM values after priming with 160-32-128 and 80-16-64 D ag.u. vaccine, it was evident that over the critical range of 80-16-64 D ag.u. concentration, there is a linear

relationship between the antibody response and the quantity of antigen administered, as stated elsewhere (10). In this respect, one should mention that a 40-8-32 D ag.u. concentration in a two dose schedule proved to be effective in producing a satisfactory antibody response (5,8).

Similarity of humoral antibody levels at one month and one week after booster indicates the presence of immunological memory, revealed by the rapid and high level of antibody response of anamnestic type.

Since larger doses of antigen induce a degree of immunological memory equivalent to that following a homotypic infection, the high content of the three polio antigen types in the vaccine used for priming is also supposed to produce a solid immunological memory to each of the three homotypic infections (11). As the degree of immunological memory varies with the size of the first dose of IPV (10,12), it appears that the use in this study of polio antigens of enhanced potency would contribute to a persistent immunological memory and ensure a durable immunity.

It could be questioned as to whether presence of protective values of polio NA in all the children in the study group one year after booster constitutes definite proof of a persistent immunological memory. On the other hand, the field monitoring of routine IPV programs has indicated long term persistence of seroimmunity (13) and recent personal observations show that following immunization in infancy with a 40-8-32 D ag.u. vaccine in two basic doses and a booster, a protective level of NA antibody was maintained in all children up to 7 years after completion of immunization.

As protection against paralytic disease is associated with presence of either type specific serum antibody or type specific immunological memory, which once induced is irreversible (12), the anamnestic response following the second dose of vaccine observed in this study may be an indicator of

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what would occur after a challenge with natural infection (11). It is very probable that on exposure to infection later in life the immunological memory would recall sufficiently quickly in a case where the humoral antibody level has declined below the protective level.

The results of this study indicate that a two dose immunization schedule based on priming with a potent antigen at 2 months of life followed by a booster six months later is a simple and advantageous formula: it is protective after the first dose administered early in life, before effective immunity can be induced by immunization regimens with oral polio vaccine requiring repeated doses of antigen; it requires a lowest number of immunizing doses; it allows the association of polio antigen with other inactivated vaccines. Furthermore, with a 100% effectivity in terms of induced immunological memory produced after the first dose of vaccine, the program could be especially useful in endemic areas.

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INACTIVATED POLIO VACCINE STUDY DESIGN
ISRAEL 1985-1986

Group	Number of children	Antigenic content* of vaccine at date of immunization		
		2 mo.	3½ mo.	9 mo.
Study				
A	61	160-32-128	—	40-8-32
B	68	80-16-64	—	40-8-32
Control	79	40-8-32	40-8-32	40-8-32

* D antigen units for types 1, 2 and 3 respectively

Table 1

POLIO IMMUNE STATUS OF INFANTS AT THE DATE OF FIRST IPV ADMINISTRATION*

Group	Percent of infants with antibody** to type			Geometric mean titer		
	1	2	3	1	2	3
Study						
A	71.4	85.7	38.1	4.3	13.2	4.7
B	86.6	87.1	60.0	7.3	10.1	4.4
Control	66.7	80.0	50.0	3.9	10.1	1.9

* Age of 2 months

** Neutralizing antibody ≥ 1.4

Figure 1

Percentage Distribution of Polio Neutralizing Ant
in Three Immunization Sch

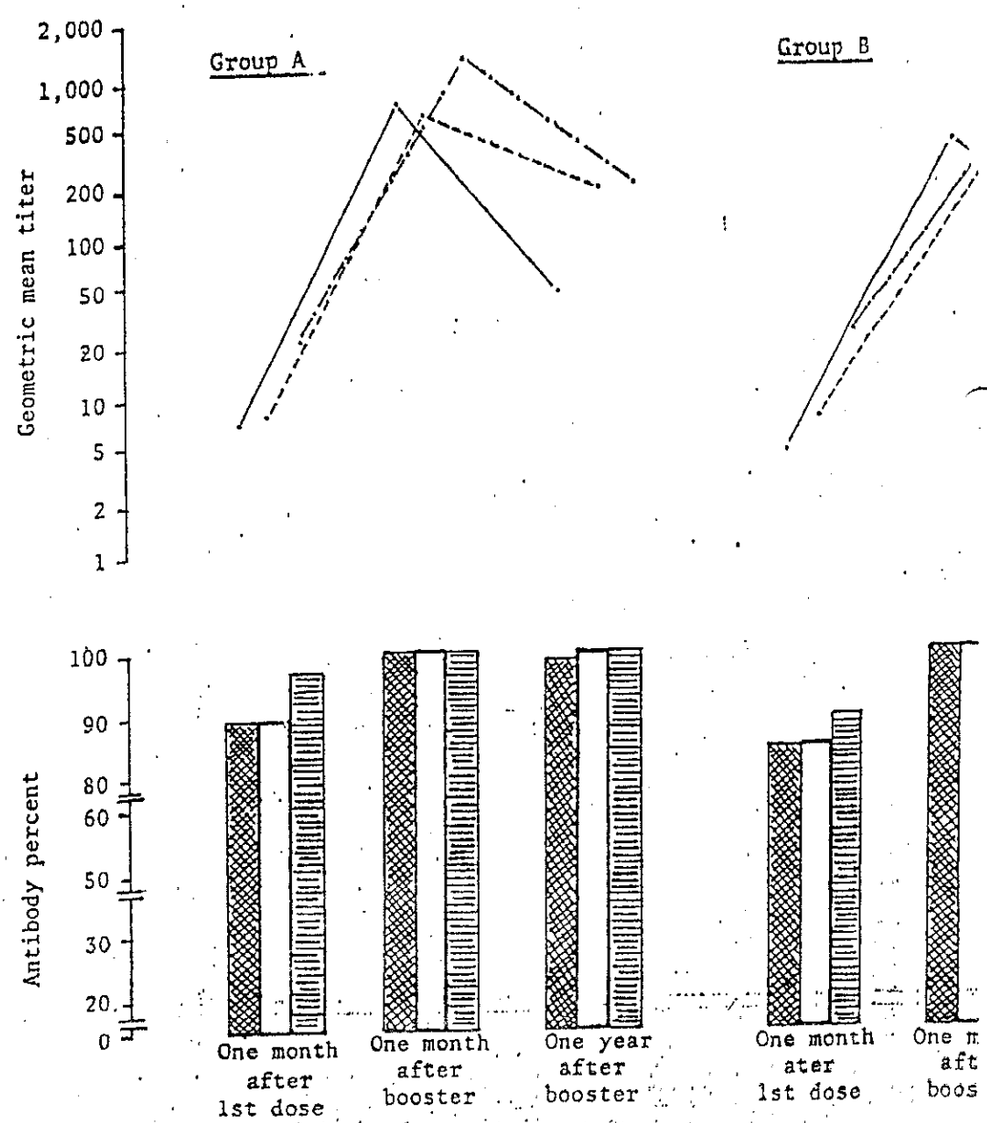


Figure 1

lio Neutralizing Antibody (≥ 1:4) and Geometric Mean Titer
ree Immunization Schedules with I.P.V.

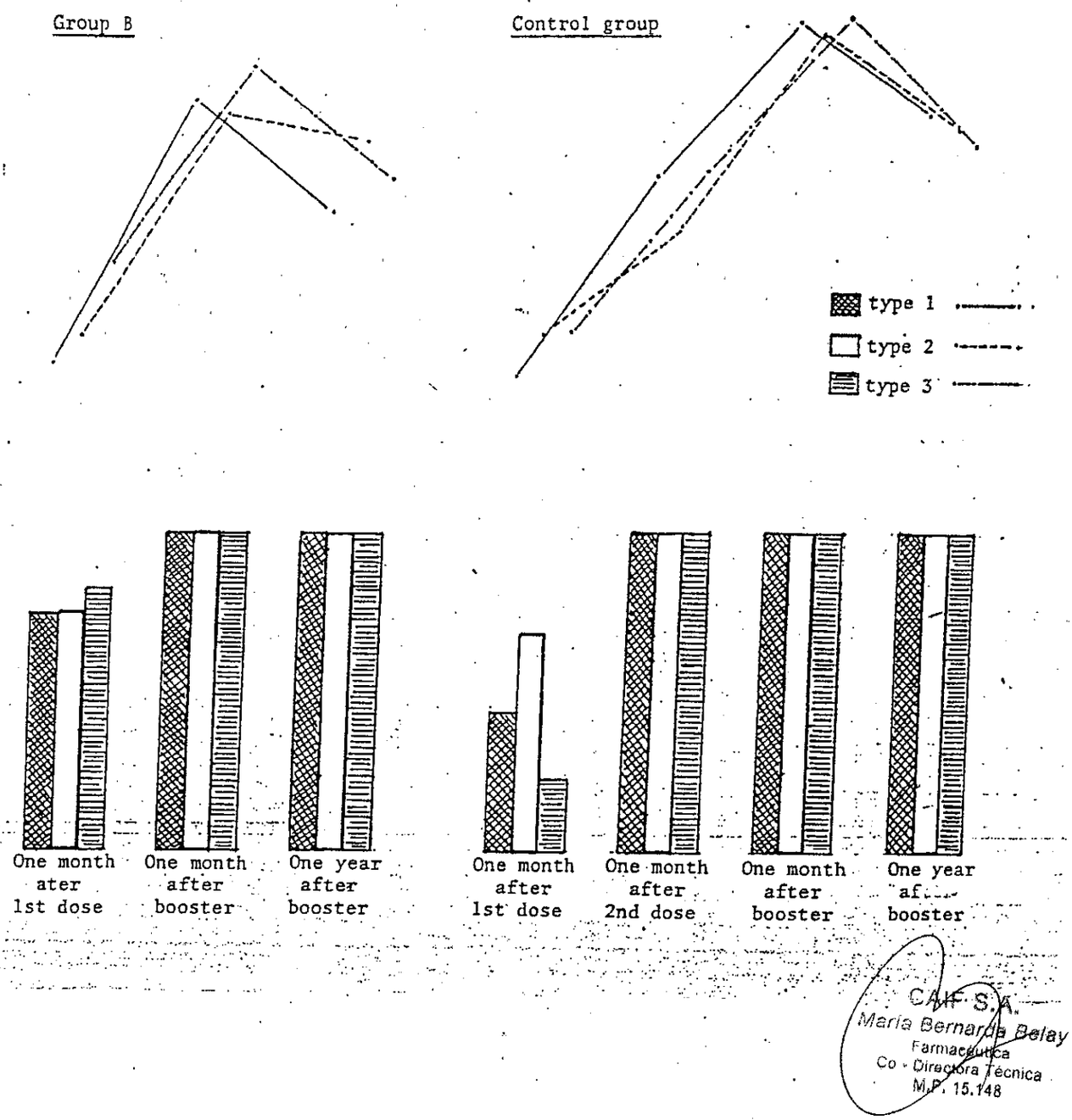
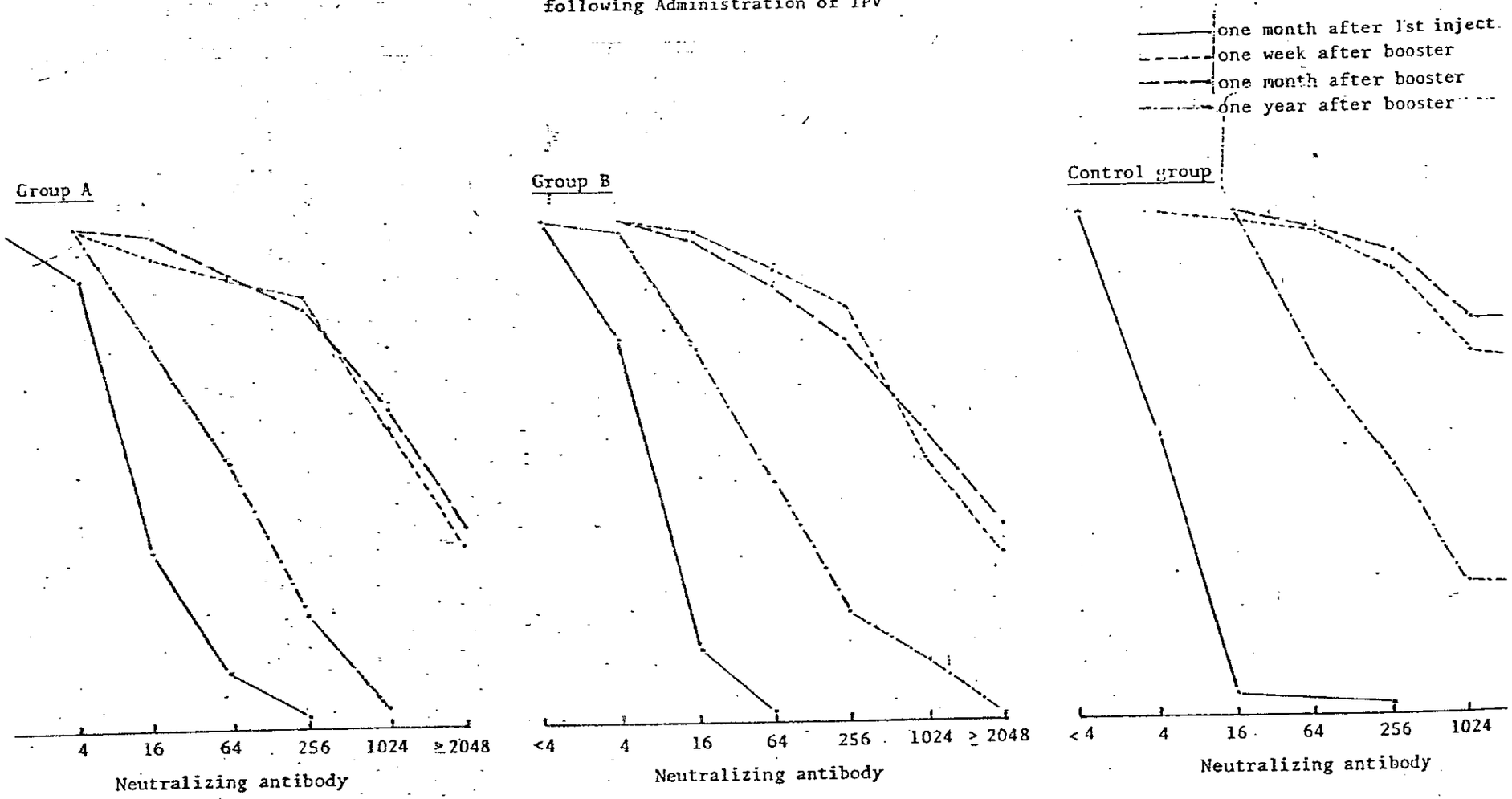


Figure 2

Cumulative Percentage Distribution of Type 1 Polio Neutralizing Antibody following Administration of IPV



COMPAÑÍA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

Buenos Aires, Agosto de 2014

INAME

PRODUCTOS BIOLOGICOS

S / D

Ref: Expte: 1-47-006823-13-1

Producto: VAXIPOLIO,
Suspension Inyectable

De nuestra mayor consideración:

Por medio de la presente, *Compañía Argentina de Investigaciones Farmacéuticas S.A.* se dirige a Uds. a los efectos de informar la composicion cuali-cuantitativa del Producto Vaxipolio, suspension inyectable:

Cada dosis de 0,5ml de vacuna antipoliomielítica (VPI) contiene:

Virus inactivado de la poliomielitis tipo 1(Mahoney)* 40 U.D.

Virus inactivado de poliomielitis tipo 2(MEF_1)* 8 U.D.

Virus inactivado de poliomielitis tipo 3(Saukett)* 32 U.D.

U.D: Unidades de Antigeno D

* Cultivado en celulas Vero

CAIF S.A.
Dra. Verónica Grimoldi
Directora Técnica y Apoderada
M.N. 13.075

CAIF

COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

Excipientes:

Formaldehido 12.5 mcg

2-fenoxietanol 2.5 mg

Medio 199 0.1 ml

Solución diluyente * + Buffer 0.08 ml

Agua para inyectable csp 0.5 ml

*Solución diluyente: fosfato de sodio, cloruro de sodio, cloruro de potasio, sulfato de magnesio, rojo fenólico y cloruro de calcio.

Sin otro particular saludamos atte.

CAIF S.A.
Dra. Verónica Grinoldi
Directora Técnica y Apoderada
M.N. 13.075

COORDINACION DE EVALUACION DE MEDICAMENTOS

LABORATORIO:	CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.
PRODUCTO:	VAXIPOLIO
FECHA:	01/07/2013

JEFE DE COORDINACION DE EVALUACION DE MEDICAMENTOS

Este Departamento sugiere dar curso a la presente solicitud por responder el producto cuya inscripcion al R.E.M. se solicita, a la definición de especialidad medicinal estabelecida en el artículo 1.o del Decreto 150/92.

COORDINACION DE EVALUACION DE MEDICAMENTOS

Buenos Aires, 1 de Julio de 2013
Expediente N.o 1-0047-0000-006823-13-1

INFORME DE MICROBIOLOGIA

4 de Abril de 2014

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

	Acepta	Objeta
Producto Terminado:		
Concentración: SUSPENSION INYECTABLE	X	
Fórmula por unidad de forma farmacéutica o porcentual:	X	
Metodos de Control:		
Técnicas de muestreo:	X	
Control Higiénico: No corresponde su evaluación		
Control de Esterilidad:	X	
Valoración, Límites de aceptabilidad:	X	
Identificación y pureza de Principios Activos:	X	
Métodos de Elaboración:		
Productos Biológicos:	X	
Estabilidad del Producto Terminado:		
Número de Lotes Estudiados: SUSPENSION INYECTABLE	X	
Métodos de Valoración Específicos:	X	
Medicamentos de Preparación extemporánea: No corresponde su evaluación		
Condiciones a la que fue sometido el producto:	X	
Productos de degradación y Límites de detección:	X	
Frecuencia de Valoración:	X	

Condiciones de Almacenamiento:

Período de vida útil (en meses):
24

Conservar:
desde: 2
hasta: 8

4/4/2014

Es copia impresa del original del Sist. de expedientes por imágenes

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

	Acepta	Objeta
Antecedentes Bibliográficos: SUSPENSION INYECTABLE	X	
Estudios Farmacodinámicos:	X	
Estudios Toxicológicos agudos:	X	

Estudios Toxicologicos Prolongados:

Toxicidad subaguda:	X	
Toxicidad cronica:	X	
Teratogenesis Embriotoxicidad:	X	
Estudios de Fecundidad y capa reproductiva:	X	

Toxicidad Especial:

Mutagenesis:	X	
Carcinogenesis:	X	

Origen del Producto:

Origen del Producto:	X	
Inocuidad:	X	
Estudios Farmacodinámicos:	X	

Fojas: 6 Origen: 3

Informacion Complementaria:

Estudios de Irritación Local: SUSPENSION INYECTABLE	X	
Estudios de sensibilización:	X	
Otros Estudios Programados:	X	
Toxicidad de Excipientes:	X	

Composiciones Aceptadas:

19/05/2014

la copia fiel

VIRUS DE POLIO INACTIVADO TIPO 1 40,0000 UNIDADES D
VIRUS DE POLIO INACTIVADO TIPO 2 8,0000 UNIDADES D
VIRUS DE POLIO INACTIVADO TIPO 3 32,0000 UNIDADES D
Excipientes:
2-FENOXIETANOL 2,5000 MG
FORMALDEHIDO 12,5000 MCG
MEDIO 199 0,1000 ML
SOLUCION DILUYENTE + BUFFER 0,0400 ML

Composiciones Objetadas:

Genéricos (Objetados):
SUSPENSION INYECTABLE

Excipientes (Objetados):

Envases Aceptados:
FRASCO AMPOLLA DE VIDRIO INCOLORO TIPO I CON TAPON DE GOMA BROMOBUTILO Y PRECINTO DE AL

Envases Objetados:

19/05/2014

INFORME DE PRODUCTOS BIOLOGICOS

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

	Acepta	Objeta
Producto Terminado:		
Concentración:	X	
Formnula por unidad de forma farmceutica o porcentual:	X	
Metodos de Control:		
Técnicas de muestreo:	X	
Productos:	X	
Valoración, Límites de aceptabilidad:	X	
Identificación y pureza de Principios Activos:	X	
Inocuidad:		
Piretógenos:	X	
Estabilidad del Producto Terminado:		
Numero de Lotes Estudiados:	X	
Méodos de Valoración Específicos:	X	
Descripción del Envase Definitivo:		
Medicamentos de Preparación:	X	
Condiciones a la que fue sometido el producto:	X	
Productos de degradación y Límittes de deteccción:	X	
Frecuencia de Valoración:	X	
Condiciones de Almacenamiento:		
Período de vida útil:		

INFORME DE QUIMICA

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

Metodos de Control:

	Acepta	Objeta
Técnicas de muestreo:	X	
Valoración, Límites de aceptabilidad:	X	
Identificación y pureza de Principios Activos:	X	

Estabilidad del Producto Terminado:

Numero de Lotes Estudiados:

VIRUS DE POLIO INACTIVADO TIPO 3 32,00000 UNIDADES D Genérico	X
VIRUS DE POLIO INACTIVADO TIPO 2 8,00000 UNIDADES D Genérico	
VIRUS DE POLIO INACTIVADO TIPO 1 40,00000 UNIDADES D Genérico	
2-FENOXIETANOL 25,00000 MG Excipiente	
FORMALDEHIDO 125,00000 MCG Excipiente	
MEDIO 199 1,00000 ML Excipiente	
SOLUCION DILUYENTE + BUFFER 4,00000 ML Excipiente	
Métodos de Valoración Específicos:	X
Medicamentos de Preparación extemporanea:	X
Condiciones a las que fue sometido el producto:	X
Productos de degradación y Límites de detección:	X
Frecuencia de Valoración:	X

Período de vida útil (en meses):

Condiciones de Almacenamiento

Período de vida util del reconstituído

Conservar:

desde (grados):

hasta (grados): 2

8

Composiciones Aceptadas:

VIRUS DE POLIO INACTIVADO TIPO 1 40,00000 UNIDADES D
VIRUS DE POLIO INACTIVADO TIPO 2 8,00000 UNIDADES D
VIRUS DE POLIO INACTIVADO TIPO 3 32,00000 UNIDADES D
2-FENOXIETANOL 25,00000 MG
FORMALDEHIDO 125,00000 MCG
MEDIO 199 1,00000 ML
SOLUCION DILUYENTE + BUFFER 4,00000 ML

Composiciones Objetadas:

Sergio Hugo Sisto

27/05/2014

Firma y Sello

INFORME DE INSPECTORIA

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

Acepta Objeta

Lugares de Elaboración:

Establecimientos Propios:

Aptitud para el Control de Calidad:
No corresponde evaluar dicho ítem

Aptitud para Elaboración:
No corresponde evaluar dicho ítem

Establecimientos Contratados:

Aptitud para Control de Calidad:
No corresponde evaluar dicho ítem

Aptitud para elaboración:
No corresponde evaluar dicho ítem

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Firma y Sello

DEPARTAMENTO DE INSPECTORIA

Buenos Aires, 23 de Mayo de 2014

INAME - DEPARTAMENTO DE GALENICA

1488

EXPEDIENTE : 1-0047-0000-006823-13-1

LABORATORIO: CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES FARMACEUTICAS S.A.

PRODUCTO: VAXIPOLIO

FORMA FARMACÉUTICA: SUSPENSION INYECTABLE

	Acepta	Objeta
Equivalencia Farmacéutica:		
No corresponde su evaluación.		
No Corresponde Evaluar Dicho ítem		
Alternativa Farmacéutica:		
No Corresponde Evaluar Dicho ítem		
Metodos de Elaboración:		
Adecuabilidad a la Forma Farmacéutica:	X	
Métodos de Control:		
Controles Farmacotécnicos y de Liberación:	X	
Estabilidad del Producto Terminado		
Controles Farmacotécnicos y de Liberación	X	
Descripción del Envase Definitivo:	X	
Medicamentos de Preparación extemporánea		
No Corresponde Evaluar Dicho ítem		

Envases Aceptados:

FRASCO AMPOLLA DE VIDRIO INCOLORO TIPO I CON TAPON DE GOMA BROMOBUTILO Y PRECINTO DE AL

Envases Objetados:

SUSPENSION INYECTABLE

Buenos Aires, 17 de Junio de 2014

Ministerio de Salud
Secretaría de Politicas Regulaciòn
e Institutos
A.N.M.A.T.

Informe:

VAXIPOLIO (Vacuna antipoliomelitica inactivada (VPI)- suspensión inyectable)

DESCRIPCION:

Es una nueva vacuna antipoliomielítica inactivada, para la prevención de la poliomielitis, enfermedad viral, ocasionada por un enterovirus, que se transmite por vía fecal –oral. El virus es neurotrópico y produce una destrucción de las motoneuronas en el hasta anterior y medula espinal, llevando a parálisis fláccida con distribución espinal o bulbar.
Antes del siglo 19 la enfermedad fue esporádica, durante el siglo 19 y 20 se presento en forma epidémica con el pico de incidencia y prevalencia en la década de 1950. Luego de esto debido a campañas masivas de vacunación promovidas por la Organización Moundial de la Salud la incidencia ha caído drásticamente.
Es una vacuna de administración inyectable formada por virus inactivado de la poliomielitis del tipo 1, 2 y 3.

El virus poliomielítico tipo 1 tiene su origen en el Dr Salk (Cepa Mahoney)
El virus poliomielítico tipo 2 tiene su origen en el Statens Serum Institute en Copenhague (cepa MEF1).
El virus poliomielítico tipo 3 tiene su origen en el Statens Serum Institute en Copenhague (cepa Saukett).

El esquema de primovacunación, consiste en tres dosis de 0, 5 ml administradas con un intervalo mínimo de 4 semanas, los niños deberán ser inmunizados con las tres primeras dosis en los 6 primeros meses de vida (Ej: 2, 4, 6 meses de vida). Luego de completarse el esquema inicial el (3 dosis) el refuerzo puede administrarse a partir del 6to mes de la ultima dosis.
Se sugiere ver prospecto adjunto y ajustar a las recomendaciones oficiales locales.

Es una vacuna de administración subcutánea o intramuscular.

Esudios pre-clinicos: fojas 696 a 705
Estudios Clínicos : **Consta a fojas 1193 a 1235 y a fojas 1388 a 1460**

Riesgos:

Los efectos adversos más frecuentes descriptos en el plan de gestión de riesgo, que surge de la experiencia aportada post- autorización son los siguientes:

Reacciones locales: inflamación, enrojecimiento y dolor en el sitio de inyección
Reacciones sistémicas:

- Neuropatía en menos de 1 caso por cada 10.000 pacientes expuestos
- Sistema respiratorio:apneas en bebes muy prematuros (<_ 28 semanas de gestación)

Situaciones especiales de Reacciones Adversas por vacunas:

- Enfermedad por la vacuna: No hay casos reportados con Vaxipolio de enfermedad por Vacuna.

- Patología desmielinizante: No hay reportados casos de patología desmielinizante del Sistema Nervioso Central asociado a Vaxipolio

Aprobación de Dirección del Iname: 4 de abril de 2014

Proyecto de Rotulo: Consta a foja 671 a 673

Proyecto de Prospecto: **Consta a foja 674 a 692**
Farmacovigilancia: El plan de gestión de riesgos consta a fojas 599 a 606

INAME

Buenos Aires, 21 de Agosto de 2014

DEPARTAMENTO PRODUCTOS BIOLOGICOS
Buenos Aires 09 de abril del 2014

DRA. MARIANA VILLA
Dirección de Evaluación de Medicamentos
A.N.M.A.T.

1502

DIRECCION INAME

Atento a lo solicitado por *CAIF COMPAÑIA ARGENTINA DE INVESTIGACIONES F.* encuadrado en el trámite 1.2. 5 ,en el expediente Nro: 1-0047-0000-006823-13-1 la información y documentación contenida en los ítems reúne los requisitos que contempla la norma legal vigente para la temática de competencia del INAME figurando a continuación los datos identificatorios característicos que convalida este instituto para su transcripción en los proyectos de Disposición Autorizante y de su correspondiente Certificado:

correspondiente Certificado:

Forma Farmacéutica: SUSPENSION INYECTABLE
Composición:
VIRUS DE POLIO INACTIVADO TIPO 1 40,00000 UNIDADES D

VIRUS DE POLIO INACTIVADO TIPO 2 8,00000 UNIDADES D

VIRUS DE POLIO INACTIVADO TIPO 3 32,00000 UNIDADES D

2-FENOXIETANOL 2,50000 MG

FORMALDEHIDO 12,50000 MCG

MEDIO 199 0,10000 ML

SOLUCION DILUYENTE + BUFFER 0,04000 ML

Envase/s:
FRASCO AMPOLLA DE VIDRIO INCOLORO TIPO I CON TAPON DE GOMA BROMOBUTILO Y PRECINTO DE AL

17/07/2014

Farm. Rodolfo H. Mocchetto
Director Nacional
Instituto Nacional de Medicamentos