

I. GENERAL INFORMATION OF THE CLINICAL TRIAL

Clinical trial title:	

Sponsor:		Company/Institution/Other Executor:		
Clinical phase of		Protocol code		
the study		Test code		
		Clinical (INS)		

II. REPORT IDENTIFICATION

Notification of the	(autogenerated)	Notification of the	(autogenerated)
INS		Sponsor	

2.1. Type of Report of the Pregnant Woman										
First Trimester Second Trim	mester				third trime	ester			Part	
2.2. Type of Newborn Report First Trimester of life of the										
Second trimester of the new	wborn life of	the ne	wborn				First yea	ar of life	1	

III. PREGNANT INFORMATION

3.1 Information about the Pregnant Woman					
Patient Identification Code		Age:			
Sex:		Talla:			
Occupation:					
Education Level:		Weight:			
Continued in Clinical Trial 3.2 Obstetric	•No •Si	Justification:			
History					
3.2.1. Number of previous pregnancie	es and outcome				
· · · · · · · · · · · · · · · · · · ·					
3.2.2. Previous pregnancy complications					
3.2.3. Neonatal/fetal abnormalities previously and type					
3.2.4. History of subfertility					

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	NOTIFICATION OF THE PREGNANT WOMAN AND THE NEWBORN BORN IN CLINICAL TRIALS			Edition No. 01	
3.2.5. Medic	al history o	f the pregnant woman			
3.3 Pregnancy inf	ormation				
3.3.1. Date of last	menstruatior	<u>)</u> period			
3.3.2. Gestational others.		ontacting the principal invention (dd/mm/aaaa)	astigator (specify if it is based of a state	•No •Yes, detail the	
			pregnancy		
3.3.5. Treatment fo	or infertility (s	specify) •No •Yes			
3.3.6. Illnesses du	ring current p	pregnancy and other com	plications		
	ntrol (specify	dates and results of ultra			
3.3.7. Prenatal Co serological test	s, clinical	examination, among	, •		
	ts, clinical	<u>examination, among</u>			

IV. INFORMATION ON THE PRODUCT UNDER INVESTIGATION.

4.1 Description of the Product under investigation						
Name of Lot Numbe	r Dose and Fred	uency and Administra	ation	Duration of therapy	Therapy start date	Date of last feeding
4.2. The cecum opened due to pregnancy						
•No •Yes, Blind opening date:						
4.3. Measurements t	aken with the re	search subject				

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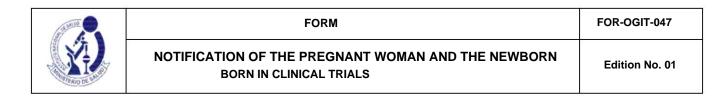
Medication therapy was given		Supportive therapy was given:
No action was taken		
4.4. This item applies IF the research subje	ect is the pregnant woman (*):	
Measurements taken with the What is the t	ype of measurement taken w	ith the product in Investigational Product
	investigation?	
 Suspended •Temporarily suspended 		
	•lt was definitively suspend	ed
•It was not suspended	•Justificación:	
-	 Specify Other Measure(s) 	Taken:

V. Concomitant medication information

List the concomitant medications you were taking at the time of pregnancy diagnosis						
Tradename	Dosage and concentration	Frequency and route	Duration of therapy	Therapy start date	Date of last feeding	Reason for prescription

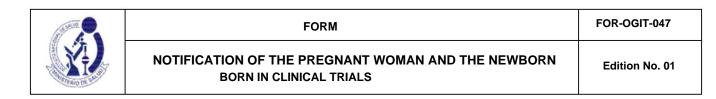
SAW. FETAL INFORMATION IN CASE OF: SPONTANEOUS ABORTION AND DEATH LATE FETAL

Source of information:	Date of receipt of information:	Gestational age of pregnancy term:
Reasons for termination of pregnancy		
Results of physical examinations (gender, external a	bnormalities) and pathologies	
	Neonate sex:	Gestational age •F •M
Birthdate:		of the fetus:
Physical exam:		
Weight:	Head circumference:	Talla:
Clinical examination:		
Laboratory tests (anatomo-pathological):		



VII. Neonate information

Source of information:					
	Date of receipt of				
	information				
Pregnancy outcome (alive at birth, spontaneous abortion, late fetal death, ectopic pregnancy, molar					
pregnancy, etc.)					
Birthdate:	Neonate sex:	Gestational age at			
		birth:			
	•F •M				
Premature: •No •Yes, specify age:					
Neonatal physical examination results in					
Birth weight:	Head circumference:	Talla:			
Malformations/anomalies diagnosed at	birth: •No •Yes				
Conditions at birth (including 1-5 minute	APGAR test, need for resuscitation, intensive care	e admissions)			
Neonatal illness, hospitalization and medications					
Developmental Evaluation (describe the pediatric controls in the reports in section 2.2)					



VIII. Infant information (Applies to reports for the first trimester, second trimester and first year of life)

Source of information:		Date of receipt of information			
Birthdate:	Neonate sex:	Current age:			
	•F •M				
Premature: •No •Yes, specify age:					
Neonatal physical examination results including:					
Weight: Talla:					
Malformations/anomalies diagnosed	• Yes				
Developmental Evaluation (describe pediatric controls according to the reports in section 2.2)					
Infant illness, hospitalizations, medications, breastfeeding					

IX. Research Center Source.

Research Center:			
Principal investigator		Telephone	
(names and surnames)			
Èmail			
Date of notification of the	Dd/mm/aaaa		
surrogate mother			
Legal representative of		Job that	
the sponsor or OIC		performs	
(names and surnames)			
Àddress			
Email		Telephone	
Signature of the legal			
representative of the sponsor /	OIC:		
INS notification date (autogenerated)			