

Tabla a): Resultados de estabilidad para los lotes de la suspensión celular almacenada a  $-70 \pm 10^{\circ}\text{C}$  y purificada a escala de laboratorio

Tipo de VPH	Prueba	Criterios de aceptación	Punto en el tiempo (meses)				
			0	12	24	36	48
Tipo 6 (lote 2084752)	Productividad de HS	Valor inicial $\pm 1,2\text{g/Kg}$	3,8 g/Kg	3,3 g/Kg	4,0 g/Kg	3,6 g/Kg	4,2 g/Kg
	Porcentaje de pureza	$\geq$ (valor inicial menos 20%)	66%	73%	73%	78%	80%
	Porcentaje de monómero intacto	$\geq$ (valor inicial menos 20%)	61%	68%	68%	71%	73%
Tipo 11 (lote 2081129)	Productividad de HS	Valor inicial $\pm 1,2\text{g/Kg}$	2,7 g/Kg	NR	NR	NR	2,8 g/Kg
	Porcentaje de pureza	$\geq$ (valor inicial menos 20%)	84%	NR	NR	NR	78%
	Porcentaje de monómero intacto	$\geq$ (valor inicial menos 20%)	60%	NR	NR	NR	72%
Tipo 16 (lote 2083531)	Productividad de HS	Valor inicial $\pm 1,2\text{g/Kg}$	3,0 g/Kg	2,6 g/Kg	3,5 g/Kg	2,9 g/Kg	3,3 g/Kg
	Porcentaje de pureza	$\geq$ (valor inicial menos 20%)	73%	83%	80%	74%	78%
	Porcentaje de monómero intacto	$\geq$ (valor inicial menos 20%)	65%	76%	71%	66%	70%
Tipo 18 (lote 2078583)	Productividad de HS	Valor inicial $\pm 1,2\text{g/Kg}$	3,7 g/Kg	3,2 g/Kg	3,4 g/Kg	4,8 g/Kg	3,8 g/Kg
	Porcentaje de pureza	$\geq$ (valor inicial menos 20%)	91%	94%	91%	92%	92%
	Porcentaje de monómero intacto	$\geq$ (valor inicial menos 20%)	78%	83%	78%	79%	80%

NR= No requerido por el protocolo

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Tabla b) Estudio de estabilidad del granel monovalente Tipo 6, lote 2085434 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.1	6.2	6.2	6.3
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	391 µg/mL	308 µg/mL	431 µg/mL	321 µg/mL	275 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	92%	89%	90%	89%	88%
Potencia en ratón	N/A	0,2 µg	0,06 µg	0,1 µg	0,08 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

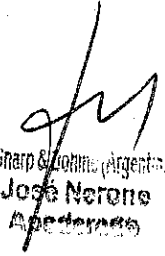
  
 Merck Sharp & Dohme (Argentina) S.A.  
**José Nereis**  
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Tabla c) Estudio de estabilidad del granel monovalente Tipo 6, lote 2087097 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.3	6.3	6.3	6.3
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	305 µg/mL	310 µg/mL	330 µg/mL	270 µg/mL	311 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	96%	94%	93%	91%	91%
Potencia en ratón	N/A	0,1 µg	0,1 µg	0,1 µg	0,1 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

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Tabla d) Estudio de estabilidad del granel monovalente Tipo 6, lote 2092662 (protocolo completo), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)								
		Inicial	3	6	9	12	18	24	36	48
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.4	6.2	6.2	6.2	6.2	6.2	6.2	6.1	6.1
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	316 µg/mL	433 µg/mL	353 µg/mL	368 µg/mL	313 µg/mL	363 µg/mL	324 µg/mL	335 µg/mL	335 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	94%	95%	93%	93%	93%	92%	93%	91%	90%
Potencia en ratón	N/A	0,06 µg	NR	NR	NR	0,08 µg	NR	0,22 µg	0,10 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

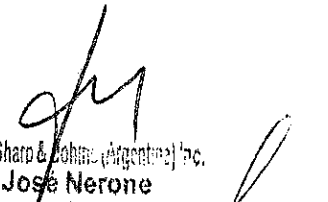
  
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 MERCK SHARP & DOHME ARG. INC.  
 Farm. Sebastián Darío Goldoni  
 DIRECTOR TÉCNICO  
 MATRICULA NACIONAL 12458



Tabla e) Estudio de estabilidad del granel monovalente Tipo 11, lote 2085860 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.2	6.2	6.3	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	286 µg/mL	365 µg/mL	387 µg/mL	393 µg/mL	289 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	97%	96%	95%	95%	95%
Potencia en ratón	N/A	0,03 µg	0,03 µg	0,06 µg	0,05 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

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Tabla f) Estudio de estabilidad del granel monovalente Tipo 11, lote 2087095 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.2	6.1	6.3	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	323 µg/mL	491 µg/mL	406 µg/mL	419 µg/mL	308 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	96%	93%	94%	92%	90%
Potencia en ratón	N/A	0,03 µg	0,06 µg	0,05 µg	0,04 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

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Tabla g) Estudio de estabilidad del granel monovalente Tipo 11, lote 2092663 (protocolo completo), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)									
		Inicial	3	6	9	12	18	24	36	48	
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	389 µg/mL	357 µg/mL	359 µg/mL	365 µg/mL	415 µg/mL	323 µg/mL	338 µg/mL	362 µg/mL	369 µg/mL	
Porcentaje de monómero intacto	≥ 80% del resultado inicial	95%	95%	95%	96%	95%	93%	94%	92%	91%	
Potencia en ratón	N/A	0,03 µg	NR	NR	NR	0,06 µg	NR	0,04 µg	0,13 µg	NR	

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

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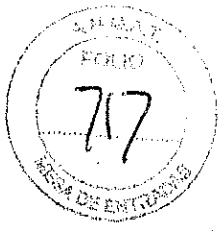


Tabla h) Estudio de estabilidad del granel monovalente Tipo 16, lote 2085432 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.3	6.3	6.3	6.3
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	411 µg/mL	364 µg/mL	347 µg/mL	350 µg/mL	324 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	93%	92%	92%	91%	92%
Potencia en ratón	N/A	0,02 µg	0,03 µg	0,02 µg	0,01 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

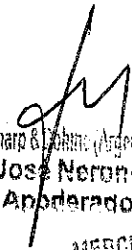
  
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Tabla i) Estudio de estabilidad del granel monovalente Tipo 16, lote 2086710 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.3	6.2	6.3	6.3	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	412 µg/mL	265 µg/mL	426 µg/mL	385 µg/mL	427 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	94%	92%	91%	92%	91%
Potencia en ratón	N/A	0,02 µg	0,03 µg	0,02 µg	0,02 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

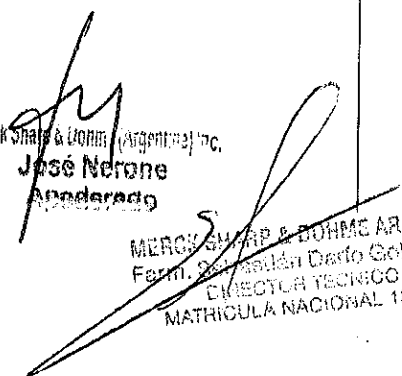
  
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Tabla j) Estudio de estabilidad del granel monovalente Tipo 16, lote 2092059 (protocolo completo), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)										
		Inicial	3	6	9	12	18	24	36	48		
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.3	6.2	6.2	6.2	6.2	6.1	6.1	6.1	6.2	6.2	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	386 µg/mL	329 µg/mL	356 µg/mL	342 µg/mL	325 µg/mL	324 µg/mL	322 µg/mL	331 µg/mL	335 µg/mL		
Porcentaje de monómero intacto	≥ 80% del resultado inicial	93%	95%	94%	92%	93%	91%	93%	93%	91%		
Potencia en ratón	N/A	0,02 µg	NR	NR	NR	0,02 µg	NR	0,02 µg	0,02 µg	0,02 µg	NR	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

Merck Sharp & Dohme (Argentina) Inc.

José Nerone

Aprobado

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Tabla k) Estudio de estabilidad del granel monovalente Tipo 18, lote 2085433 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.1	6.1	6.2	6.3
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	305 µg/mL	218 µg/mL	220 µg/mL	257 µg/mL	245 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	86%	83%	83%	84%	83%
Potencia en ratón	N/A	0,2 µg	0,2 µg	0,02 µg	Inválido	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

Merck Sharp & Dohme (Argentina) S.A.  
José Noroña  
Acreditado

*[Handwritten signature]*

MERCK SHARP & DOHME ARG. INC  
Fern. Saiz - aka Darío Goldentur  
DIRECTOR TÉCNICO  
MATRICULA NACIONAL 15433



Tabla I) Estudio de estabilidad del granel monovalente Tipo 18, lote 2085437 (protocolo abreviado), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)				
		Inicial	12	24	36	42
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.2	6.2	6.2	6.2
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	283 µg/mL	225 µg/mL	233 µg/mL	226 µg/mL	241 µg/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	87%	87%	86%	86%	83%
Potencia en ratón	N/A	0,1 µg	0,09 µg	0,07 µg	0,60 µg	NR

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización

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 Apoderado

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Tabla m) Estudio de estabilidad del granel monovalente Tipo 18, lote 2093109 (protocolo completo), almacenado a 2-8°C

Método	Especificación	Puntos en el tiempo (meses)									
		Inicial	3	6	9	12	18	24	36	48	
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio
pH	5.7-6.7	6.2	6.2	6.2	6.1	6.2	6.2	6.1	6.3	6.2	6.1
Absorción completa	≥ 90%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%
IVRP	≥ 50% del resultado inicial	386 µg/mL	317 µg/mL	313 µg/mL	345 µg/mL	336 µg/mL	308 µg/mL	284 µg/mL	278 µg/mL	319 µg/mL	
Porcentaje de monómero intacto	≥ 80% del resultado inicial	86%	87%	87%	87%	88%	86%	86%	86%	82%	
Potencia en ratón	N/A	0,07 µg	NR	NR	NR	0,2 µg	NR	0,27 µg	0,08 µg	NR	

NR: No requerido por el protocolo; N/A: No aplica. La potencia ratón se realiza para caracterización


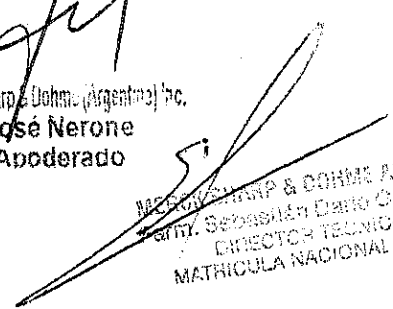
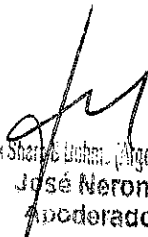
  
 Merck Sharp & Dohme (Argentina) Inc.  
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Tabla n) Estudio de estabilidad del granel monovalente Tipo 6, lote 2099996, almacenado a 23-27°C

Método	Especificación	Puntos en el tiempo (meses)			
		Inicial	3	6	12
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	NR
pH	5.7-6.7	6.4	6.4	6.4	NR
Absorción completa	≥ 90%	99%	99%	99%	NR
IVRP	N/A	305 unidades/mL	280 unidades/mL	368 unidades/mL	310 unidades/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	MT	91%	87%	NR

NR= No requerido por el protocolo; MT = punto perdido

  
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Apoderado

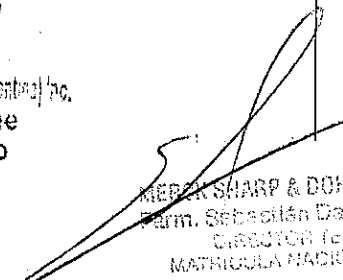
  
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Farm. Sebastián Darío Goldentul  
CRACITOR TÉCNICO  
MATRICULA NACIONAL 18428







Tabla p) Estudio de estabilidad del granel monovalente Tipo 16, lote 2097784, almacenado a 23-27°C

Método	Especificación	Puntos en el tiempo (meses)			
		Inicial	3	6	12
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	NR
pH	5.7-6.7	6.4	6.3	6.3	NR
Absorción completa	≥ 90%	99%	99%	99%	NR
IVRP	N/A	369 unidades/mL	345 unidades/mL	391 unidades/mL	324 unidades/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	92%	90%	90%	NR

NR= No requerido por el protocolo; MT = punto perdido

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Tabla q) Estudio de estabilidad del granel monovalente Tipo 18, lote 2102337, almacenado a 23-27°C

Método	Especificación	Puntos en el tiempo (meses)			
		Inicial	3	6	12
Apariencia física	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	Líquido blanco turbio	NR
pH	5.7-6.7	6.2	6.2	6.1	NR
Absorción completa	≥ 90%	99%	99%	99%	NR
IVRP	N/A	385 unidades/mL	318 unidades/mL	294 unidades/mL	335 unidades/mL
Porcentaje de monómero intacto	≥ 80% del resultado inicial	MT	85%	81%	NR


NR= No requerido por el protocolo; MT = punto perdido

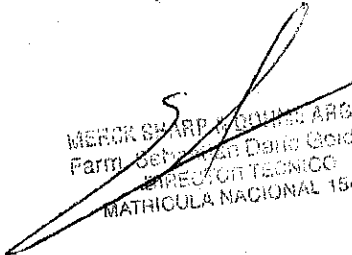
Merck Sharp & Dohme (Argentina) S.A.  
 José Nerone  
 Apoderado

MERCK SHARP & DOHME ARG. INC.  
 Farm. S.A. Dr. Greg. Cordantu  
 DIRECTOR TÉCNICO  
 MATRICULA NACIONAL 15438



# Listado de SOPs

  
Merck Sharp & Dohme (Argentina) Inc.  
José Nerone  
Apoderado

  
MERCK SHARP & DOHME ARG. INC  
FARM. GERMANYAN Daniel Gordano  
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WP-5705	WP 14-Oct-2011 135-103 SOP/CJA Control and Tracking System Within Barrier Operations	06-mar-13
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WP-348	WP 25-MAR-2013 22-QUA-406X West Point MMD GMP Documentation Practices	25-mar-13
WP-4845	WP 05-May-2012 135-208 Accountability for Physical Discard of Filled Material	12-mar-13
WP-2820	WP 27-Aug-2013 22-BAR-115X Handling Procedures and Review of Batch Records	27-ago-13
WP-4924	WP 30-Nov-2012 24-BAR-342 Creating Syringe Developmental Set for EISAI Automated Inspection Machines	19-mar-13
WP-4983	WP 22-Oct-2011 135-348 SFL Syringe ID Application Machine Setup and Operation	19-mar-13
WP-4986	WP 07-Jun-2013 24-BAR-344 SFL EISAI Inspection Machine Set Up	07-jun-13
WP-4987	WP 16-Jan-2014 24-BAR-345 SFL EISAI Inspection Machine Operation	16-ene-14
WP-5076	WP 02-Mar-2011 174-252X Operation of the Automatic Stretch Wrapping System	19-mar-13
WP-5244	WP 20-Dec-2012 24-BAR-357 SFL Export Processing	19-mar-13
WP-5430	WP 16-Dec-2013 27-PAC-218X Packaging Time Out of Refrigeration (TOR) Limits and Management	16-dic-13
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WP-5586	WP 10 SEP 2013 24-BAR-359 SFL Offline Inspection and Labeling	10-sep-13
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WP-5664	WP 31-Oct-2012 24-BAR-234 Re-Inspection Qualification and Techniques for Barrier Operations	19-mar-13
WP-5709	WP 20 SEP 2013 24-BAR-121X Glass Breakage Monitoring Logbooks	20-sep-13
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WP-5760	WP 10-Jan-2014 24-LYO-233X Glass Breakage Management	10-ene-14
WP-5788	WP 14-Aug-2011 135-240X Cold Vault CV-134 Oxyten (O2) Sensor	19-mar-13
WP-5956	WP 26-Jul-2011 135-241X Barrier Operations Transferring of Items into Grade C Controlled Job Aids	19-mar-13
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WP-6204	WP 27-May-2011 135-604A D135 Daily Housekeeping and Disinfection Log Sheets	19-mar-13
WP-6205	WP 27-May-2011 135-604B D135 Weekly Disinfection Log Sheets	19-mar-13
WP-6206	WP 27-May-2011 135-604C D135 Environmental Response Level and Monthly Decontamination and Cleaning	19-mar-13

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 Director de Control de Calidad  
 Autorizado~~

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WP-6207	WP 27-May-2011 135-604D D135 Quarterly Housekeeping Log Sheets	19-mar-13
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WP-6222	WP 20-Jun-2013 24-BAR-251 Time Conversion Chart for 12 Hour and 24 Hour Clocks	20-jun-13
WP-6233	WP 06-Sep-2011 174-109X Inspector Qualification For Manual and Semi-Automated Inspection	19-mar-13
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WP-6235	WP 30 JAN 2014 24-INS-111X Techniques for Manual and Semi-Automated Visual Inspection of Sterile In	30-ene-14
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19925	WP 25-Sep-2013 Quadrivalent HPV Syringe Sampling Form 2004985 2002075 2003418 2005476 2006108	25-sep-13
23824	WP 04-Oct-2013 23-BAR-004X Reconciling TOR Tags for Existing Inventory Being Transferred for Final P	03-oct-13
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WP-2753	WP 04 JUL 2013 21-S29-292X Inventory Control: Vial and Stopper Returns via Room 148 Airlock	04-jul-13
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WP-2876	WP 16-Dec-2013 24-BAR-214 Set Up and Operation of Labeler System and Tray Loading of Filled Product	16-dic-13

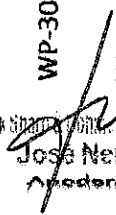
*Merck Sharp & Dohme (MSD) Animal Health*  
 Rosa Noriega  
 Animal Health

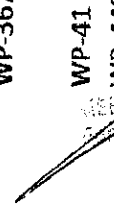
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WP-2898	WP 17-Jan-2013	21-BAR-602 Disposal of Rejected Containers of Product	19-mar-13
WP-2900	WP 18 SEP 2013	24-BAR-280X Responses To Filling Alarms, Unplanned Wetted Path	18-sep-13
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WP-3238	WP 27-May-2011	135-604 Housekeeping Procedures for Production Areas	19-mar-13
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WP-4850	WP 12-Feb-2013 23-BAR-354 SFL Volume of Fill Checks and Stopper Depth Verification	06-mar-13
WP-4847	WP 17-Dec-2011 135-339 SFL Filling Machine Operations Setup	06-mar-13
15887	WP 07-Jun-2013 14-BAR-002X Syringe Filling Line (SFL) Automation Recipe Selection	07-jun-13
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26966	WP 06 Jan 2014 15-QUE-217XF1 Cleaning and Use Log	
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WP-113	WP 16-Dec-2013 07-QUR-105X Batch Record Review and Approval	16-dic-13

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WP-125	WP 15-Nov-2013 06-QUA-341X Management of Site Internal Commitments and Corrective Action/Preventativ	15-nov-13
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 J. O. V. V. V.  
 Algodóndero

MERON S.A. S. DE C.V.  
 Farm. San José de los Rios, S. de C. V.  
 DIRECTOR TECNICO  
 MATRICULA NACIONAL 16438






WP-5710	WP 10-Dec-2012 24-BAR-365 Barrier Operations Wetted Path Monitoring	19-mar-13
WP-5956	WP 26-Jul-2011 135-241X Barrier Operations Transferring of items into Grade C Controlled Job Aids	19-mar-13
WP-6113	WP 18-Feb-2011 135-122 Vial Filling Line Post Cleaning Guide	19-mar-13
WP-6222	WP 20-Jun-2013 24-BAR-251 Time Conversion Chart for 12 Hour and 24 Hour Clocks	20-jun-13
WP-77	WP 28-NOV-2012 18-BSM-104X West Point Enterprise Asset Management System (EAMS) Asset Records	19-mar-13
WP-97	WP 18 OCT 2013 12-GFM-600X Integrated Pest Control Management (IPM) Program	18-oct-13
WP-113	WP 16-Dec-2013 07-QUR-105X Batch Record Review and Approval	16-dic-13
WP-2773	WP 16-Dec-2011 135-201X Operating Procedures for the Terumo SCD IIB Sterile Tube Welder	04-mar-13
WP-6260	WP 27-Jan-2014 24-BAR-242 Histidine Filtration Set-Up Pre and Post Use Filter Integrity Testing and	27-ene-14
WP-6260	WP 20-Jun-2013 24-BAR-242 Histidine Filtration Set-Up Pre and Post Use Filter Integrity Testing and	20-jun-13
WP-5885	WP 18-Jan-2013 24-V12-380X Vent Filter Label Generation Database - System Use	04-mar-13
WP-5503	WP 13-Jun-2013 05-PLN-217X Management of Hepatitis B and HPV Intermediates	25-jun-13
WP-5189	WP 27 AUG 2013 24-BAR-222X Formulation Area Tubing Transfer Procedure	27-ago-13
WP-4976	WP 24-May-2011 135-210 Setup and Operation of Peristaltic Pump and Sta-Pure Tubing	04-mar-13
WP-4795	WP 29-Aug-2013 15-QUE-204X Process Simulation Requirements For Barrier Operations	29-ago-13
WP-41	WP 22-Apr-2013 24-PLN-400X Storage and Use of Raw Materials, Components, Intermediates, and Product	22-abr-13
WP-3552	WP 28 MAY 2013 24-BTM-231ZX Onsite Shipment of Bulk Biological Product Bottles Sourced From Biotechn	22-may-13
WP-3529	WP 19-JUL-2013 24-S29-318X Sterile Supply Sterility Dating and Sterile Equipment Handling	19-jul-13
WP-2818	WP 17 SEP 2013 22-BAR-114 Batch Report Records Review	17-sep-13
WP-2826	WP 03-Oct-2011 135-269 Formulation Sterile Air System	04-mar-13
WP-2827	WP 04-Feb-2012 135-271 Formulation Docking Station Connections SIP	04-mar-13
WP-2828	WP 21-Mar-2012 135-276X Formulation and Filling Area Maintenance Mode	04-mar-13
WP-2894	WP 19-Apr-2012 135-226 Barrier Operations Portable Glycol Chiller Systems Operation	04-mar-13
WP-2896	WP 31 OCT 2013 24-BAR-264X Filter Designation, Replacement Schedules and Integrity Test Procedures	31-oct-13
WP-2897	WP 01 Aug 2013 24-BAR-268 CIP/SIP of Portable Tanks	01-ago-13
WP-2898	WP 17-Jan-2013 21-BAR-602 Disposal of Rejected Containers of Product	04-mar-13
WP-3040	WP 24-Sep-2013 24-BAR-267 Portable Tank Usage	24-sep-13
WP-3041	WP 01-Aug-2012 135-279 Operation of the CIP Skid	04-mar-13
WP-3145	WP 04-Jul-2013 24-BAR-363X Media Fill and Formulation Area Simulation	01-jul-13

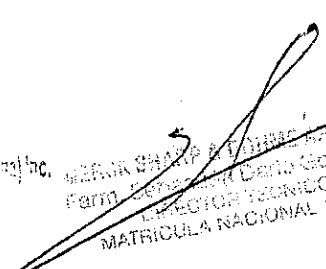
~~Merck Sharp & Dohme Inc.  
Jose Nerone  
Medicamentos~~

~~Merck Sharp & Dohme Inc.  
Farm. S.A.  
MERCOSUR  
MATRICULA NACIONAL 15493~~



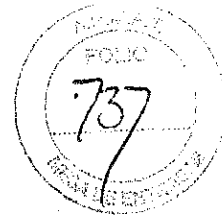
WP-3221	WP 21-May-2013 24-BAR-202X Operating and Maintenance Procedures for the Wave Biotech Sterile Tube	21-may-13
WP-3222	WP 20-Oct-2011 135-207 Operating Procedures for the C-Flex Sealing System	04-mar-13
WP-3228	WP 26-Feb-2013 24-BAR-262 Scale Weight Checks	04-mar-13
WP-3231	WP 19-APR-2013 24-BAR-272 Final Formulated Bulk Sampling Procedures	19-abr-13
WP-3232	WP 01 DEC 2013 23-BAR-284X CIP/SIP Abort Alarm Tracking and Troubleshooting for Formulation	01-dic-13
WP-3233	WP 18-May-2011 135-291 Liquid Collection and Drain (LCD) Panel Operation	04-mar-13
WP-325	WP 16-Dec-2013 24-BSV-245X Single Use Vent Filters - Integrity Testing Life Cycle	16-dic-13
WP-235	WP 06-Jan-2014 15-QUE-217X Cleaning, Disinfection and Decontamination of Classified Areas	06-ene-14
26366	WP 06 Jan 2014 15-QUE-217XF1 Cleaning and Use Log	
WP-7131	WP 25-Oct-2011 135-320X D135 Disinfectant and Cleaning Agent Expiry Dating Job Aid	07-mar-13
WP-6416	WP 09-Apr-2011 135-287 Changeover Procedure for Barrier Operations Manual Re-Inspection Room	08-may-13
WP-5956	WP 26-Jul-2011 135-241X Barrier Operations Transferring of Items into Grade C Controlled Job Aids	07-mar-13
WP-7190	WP 30 SEP 2013 24-CRO-400X Spill Clean Up and Spill Response Procedures	30-sep-13
WP-343	WP 06 Jan 2014 24-QUE-293X Transfer of Items into Classified Processing Areas	06-ene-14
WP-2930	WP 16-Jan-2014 15-QUE-221X Response to Environmental Excursions	16-ene-14
WP-2913	WP 14-Aug-2011 135-603 Approved Lubrication and Cleaner / Polishing Agents	07-mar-13
WP-2829	WP 27-Aug-2013 22-BAR-302X Equipment Cleaning, Use and Maintenance Logbooks	27-ago-13
WP-5538	WP 14-Mar-2012 135-211X, CLEANING AND MOVEMENT OF MATERIALS FROM NON-CLASSIFIED	07-mar-13

  
 Werck Sherwin & Uhlmann (Argentina) Inc.  
 José Nerone  
 Apoderado

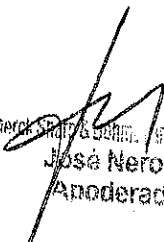
  
 GERARDO BRAGA VILLAR, INC  
 Farm. S. de S. Darío Gordano  
 DIRECTOR TECNICO  
 MATRICULA NACIONAL 15436

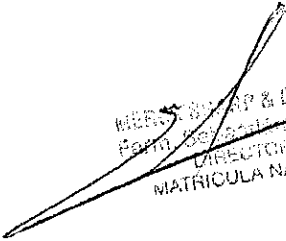






# Ensayos realizados sobre el envase primario

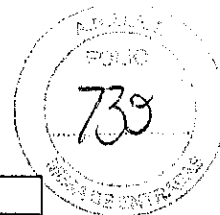
  
Merck Sharp & Dohme Argentina, Inc.  
José Nerone  
Aptoderado

  
MERCK SHARP & DOHME ARG. INC.  
Buenos Aires, Buenos Aires, Argentina  
DIRECTOR TÉCNICO  
MATRICULA NACIONAL 15436









	una suspensión estándar II	
Penetrabilidad	La fuerza necesaria para la perforación, determinada con una precisión de $\pm 0.25N$ no es mayor que 10N para cada cierre.	Cumple
Substancias reducibles (EP)	La diferencia entre los volúmenes de la titulación de la muestra y el blanco no es mayor de 3.0ml	Cumple
Residuo por evaporación (EP)	El peso de los residuos es menor que 2.0mg	1.2 mg
Sulfuros volátiles(EP)	Cualquier mancha negra en el filtro de papel de la muestra no es más intensa que la del Estándar.	Cumple
Identidad – Peso específico	1.33 g/cm <sup>3</sup> +/- 0.04	1.34
Identidad – Cenizas	46.6 +/- 2.0 %	45.7%
Identidad – revestimiento lubricante IR-ATR	El espectro de la muestra exhibe máximo a la misma longitud de onda que la muestra original tratada de la misma forma.	Cumple
Test autosellante	Ninguno de los viales contiene trazas de solución coloreada.	Cumple

Jose Nerone  
Aprobado

SEBASTIÁN GARCÍA GONZÁLEZ  
DIRECTOR TÉCNICO  
MATRICULA NACIONAL 15428

