

Panreac

PANREAC QUIMICA SA

Handwritten signature/initials

ALLGATO 3

RICEVUTO 17 GIU. 2002

TO WHOM IT MAY CONCERN

Date: 10/06/02

Your Ref.

Our Ref.:

JF/LS

Re.: STEROGLOSS ITALY

Equipments	PRO- ATTICO
28 GIU. 2002	
N. 8174	di prot.

Señores,

Por este escrito certificamos que en relación EMEA CPMP/BWP/1230/98-rev-1 (Revisión de Setiembre de 2000): Notas-guía sobre minimización del riesgo de transmisión de agentes portadores de encefalopatías espongiiformes animales transmisibles vía productos medicinales, confirmamos que nuestra Lactosa 1-hidrato PRS-CODEX, código 141375, procede de leche de animales sanos, recogida en las mismas condiciones que la leche destinada al consumo humano.

PANREAC QUIMICA, S.A.  
 Director Aseguramiento Calidad

R. Casassas

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**C.A. BOTTI ROSSI**  
~~C.A. SIGRA FRANCESCA~~

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ANALYSIS CERTIFICATE

CODE: 141375  
PRODUCT: Lactose 1-hydrate (RFE, USP-NF, BP, Ph. Eur.)  
PRS-CODEX  
BATCH: 14205617 0

DATE: 12/03/2003

SPECIFICATIONS	GUARANTEE VALUE	ACTUAL VALUE
Identity according to Pharmacopoeias	p/t.	p/t.
Specific rotation $[\alpha]^{20}_D \text{ c=10}$ (in H <sub>2</sub> O) calc. a.a.s.	+54.4 to +55.9°	+55.38°
<b>MAXIMUM LIMIT OF IMPURITIES</b>		
Appearance of solution	p/t.	p/t.
Insoluble matter in H <sub>2</sub> O	p/t.	p/t.
Loss on drying at 60°C	0.5 %	0.16 %
Residue on ignition (as SO <sub>2</sub> )	0.1 %	<0.1 %
ABS at $\lambda 400$ nm sol. 10% in H <sub>2</sub> O	0.04	<0.04
ABS of $\lambda 270$ to 300 nm sol. 1% in H <sub>2</sub> O	0.07	<0.07
ABS of $\lambda 210$ to 220 nm sol. 1% in H <sub>2</sub> O	0.25	<0.25
Acidity or alkalinity	p/t.	p/t.
Chloride (Cl)	0.01 %	<0.01 %
Sulphate (SO <sub>4</sub> )	0.02 %	<0.02 %
Water (H <sub>2</sub> O)	4.5-5.5 %	5.28 %
Heavy metals (as Pb)	0.0005 %	<0.0005 %
Microbial limits:		
Aerobics	100 cfu/g	<100 cfu/g
Yeasts and molds	50 cfu/g	<50 cfu/g
Escherichia coli	absence	absence
Salmonella	absence	absence
As	0.0001 %	<0.0001 %
Cu	0.0005 %	<0.0005 %
Fe	0.0005 %	<0.0005 %
Ni	0.0005 %	<0.0005 %

Product obtained from animal milk with collection in the same conditions that the milk obtained for human consumption.

For industrial use we recommend to check out when received.

Panreac Química S.A.  
Technical Department. Quality Control.

J. Puigdengolas


