

Product Specifications: Globules 2mm Lactose

Mod. P09 REV 3 aggiornato al 27/01/2015

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Product name:	Pillules for Homeopathic preparations
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Reference:	PH EUR Current Ed.
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Chemical properties	
Composition:	Sucrose EP grade 85% Lactose EP grade 15%
Loss on drying:	Not More Than 0,30 %
Heavy metals:	< 5ppm
Impregnation:	Use an approved method. The average for the results within a validated range
Specific Rotation:	Not Less Than +41° and Not More Than +61°
Residual of Ignition:	Not More Than 0,25% w/w

Physical properties	
Solubility in water:	Usually freely soluble in water.
Shape:	Uniform, spherical seeds
Color:	White / Off white
Odour:	Neutral
Finess 2mm:	Not less than 90 % > 1800µ , not more than 10% >2000µ ; not more than 10% <1800µ 2mm (1800-2000). The count of units must be 220 pcs/gr +/- 10%
Shelf life:	36 months (with correct preservation)
Description:	Hard, brittle, free-flowing, spherical masses. Usually white or almost white

Microbiological properties	
TAMC:	Not More Than 10 ² cfu:
TYMC:	Not More than 10 ¹ cfu:
Escherichia coli:	Absent
Staphylococcus aureus:	Absent
Pseudomonas aeruginosa:	Absent
Salmonella:	Absent

Prepared by: (Fabrizio Castelli)
Signature Emilio Castelli s.a.s.

Date 27.01.2015

For acceptance :
Signature and Company Stamp

Date _____

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Product name:	Pillules for Homeopathic preparations
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Reference:	PH EUR Current Ed.
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Chemical properties	
Composition:	Sucrose EP grade 100%
Loss on drying:	Not More Than 0,30 %
Heavy metals:	< 5ppm
Impregnation:	Use an approved method. The average for the results within a validated range
Specific Rotation:	Not Less Than +41° and Not More Than +61°
Residual of Ignition:	Not More Than 0,25% w/w

Physical properties	
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Escherichia coli:	Absent
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Product Specifications: lactose Granules 4mm

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Impregnation:	Use an approved method. The average for the results within a validated range
Specific Rotation:	Not Less Than +41° and Not More Than +61°
Residual of Ignition:	Not More Than 0,25% w/w

Physical properties	
Solubility in water:	Usually freely soluble in water.
Shape:	Uniform, spherical seeds
Color:	White / Off white
Odour:	Neutral
Finess 4mm:	Not less than 90 % > 3800µ , not more than 10% >4000µ ; not more than 10% <3800µ 4mm (3800-4000). The count of units ,must be 20 pcs/gr +/- 10%
Shelf life:	36 months (with correct preservation)
Description:	Hard, brittle, free-flowing, spherical masses. Usually white or almost white

Microbiological properties	
TAMC:	Not More Than 10 ² cfu:
TYMC:	Not More than 10 ¹ cfu:
Escherichia coli:	Absent
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Pseudomonas aeruginosa:	Absent
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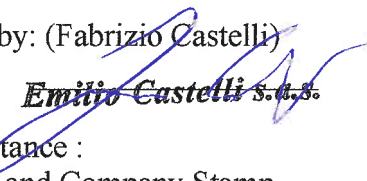
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Specific Rotation:	Not Less Than +41° and Not More Than +61°
Residual of Ignition:	Not More Than 0,25% w/w

Physical properties	
Solubility in water:	Usually freely soluble in water.
Shape:	Uniform, spherical seeds
Color:	White / Off white
Odour:	Neutral
Finess (2mm):	Not less than 90 % > 3800µ , not more than 10% >4000µ ; not more than 10% <3800µ 4mm (3800-4000). The count of units ,must be 20 pcs/gr +/- 10%
Shelf life:	36 months (with correct preservation)
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