

**Product Specifications: Globules 2mm Lactose**

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

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

<b>Physical properties</b>	
<b>Solubility in water:</b>	Usually freely soluble in water.
<b>Shape:</b>	Uniform, spherical seeds
<b>Color:</b>	White / Off white
<b>Odour:</b>	Neutral
<b>Finess 2mm:</b>	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%
<b>Shelf life:</b>	36 months (with correct preservation)
<b>Description:</b>	Hard, brittle, free-flowing, spherical masses. Usually white or almost white

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

Specs updated on: 08/07/2016

Prepared by:  
Signature \_\_\_\_\_

Date \_\_\_\_\_

For acceptance :  
Signature and Company Stamp  
\_\_\_\_\_

Date \_\_\_\_\_

## Product Specifications: Globules 2mm

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

Physical properties	
<b>Solubility in water:</b>	Usually freely soluble in water.
<b>Shape:</b>	Uniform, spherical seeds
<b>Color:</b>	White / Off white
<b>Odour:</b>	Neutral
<b>Fineness 2mm:</b>	Not less than 90 % > 1800µ , not more than 10% >2000µ ; not more than 10% <1800µ 2mm (1800-2000) The count of units must be 210-230 pcs/gr
<b>Shelf life:</b>	36 months (with correct preservation)
<b>Description:</b>	Hard, brittle, free-flowing, spherical masses. Usually white or almost white

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

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Prepared by:

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**Product Specifications: lactose Granules 4mm**

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<b>Heavy metals:</b>	< 5ppm
<b>Impregnation:</b>	Use an approved method. The average for the results within a validated range
<b>Specific Rotation:</b>	Not Less Than +41° and Not More Than +61°
<b>Residual of Ignition:</b>	Not More Than 0,25% w/w

Physical properties	
<b>Solubility in water:</b>	Usually freely soluble in water.
<b>Shape:</b>	Uniform, spherical seeds
<b>Color:</b>	White / Off white
<b>Odour:</b>	Neutral
<b>Fineness 4mm:</b>	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%
<b>Shelf life:</b>	36 months (with correct preservation)
<b>Description:</b>	Hard, brittle, free-flowing, spherical masses. Usually white or almost white

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

Specs updated on: 08/07/2016

Prepared by:  
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**Product Specifications of: Granules 4mm**

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<b>Physical properties</b>	
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<b>TYMC:</b>	Not More than 10 <sup>1</sup> cfu:
<b>Escherichia coli:</b>	Absent
<b>Staphylococcus aureus:</b>	Absent
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<b>Salmonella:</b>	Absent

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