



# ***INERT GRANULES and GLOBULES***

## ***CORES FOR HOMEOPATHIC FORMULATIONS***

*Product data sheet*

### ***Definition***

- ✧ Inert granules and globules for homeopathic use are solid preparations obtained from particles of sucrose or a mixture of sucrose and lactose by successive addition of both.
- ✧ Produced in accordance with the cGMP.
- ✧ Compliance with Fr. Ph.

### ***Components:***

- ✧ Either **100% sucrose**, **75% sucrose and 25% lactose** or **85% sucrose and 15% lactose**

### ***Main application:***

- ✧ Used as cores to be impregnated in the manufacture of homeopathic products.
- ✧ Intended for oral or sublingual administration.

### ***Chemical and Microbiological specifications***

- ✧ Loss on drying  $\leq 0.1 \%$
- ✧ Impregnation 90 % - 110 %
- ✧ Disintegration  $\leq 10$  min.
- ✧ Microbiological control:
  - Total viable aerobic bacteria count  $\leq 1000/g$
  - Yeast and Moulds  $\leq 100/g$
  - Escherichia coli absent /1g

### ***Particle weight specifications***

<b>20 granules or globules</b>	<b>2 mm</b>	<b>3.6 mm</b>	<b>3.8 mm</b>	<b>4 mm</b>
<b>Average weight</b>	3.5 – 4.5 mg	33 – 41 mg	38 – 47 mg	45 – 55 mg
<b>Less than 5 granules or globules must be :</b>		< 33 or > 41 mg	< 38 or > 47 mg	< 45 or > 55 mg
<b>No granules or globules must be :</b>		< 30 or > 45 mg	< 34 or > 51 mg	< 40 or > 60 mg

### ***General information***

- ✧ Packaging: 20 kg plastic buckets, tightly closed, with polyethylene liner, containing a desiccant.
- ✧ Storage conditions: in original sealed box, protected from humidity at a temperature between 15 and 30°C.
- ✧ Samples kept for 5 years and records available for the same period.
- ✧ Certificate of analysis and Material Safety Data Sheet attached to each delivery.

For further information, please contact

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