

DEFINITION/CHARACTERS/PRODUCTION

GRANULAC 80 is MEGGLE's brand name for a milled lactose.

GRANULAC 80 conforms to the monograph "Lactose Monohydrate" in the Ph. Eur., USP-NF and JP. The monograph has undergone pharmacopoeial harmonisation.

GRANULAC 80 conforms to the monograph "Lactose Monohydrate" in the Chinese Pharmacopoeia (ChP). Testing is performed using the methods indicated below.

GRANULAC 80 is a white or almost white, crystalline, odourless powder. It is freely but slowly soluble in water, practically insoluble in ethanol (96 per cent), chloroform and ether.

Production and release site: MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg am Inn, Germany

The management system of MEGGLE GmbH & Co. KG, Megglestr. 6-12, 83512 Wasserburg am Inn, Germany has been certified meeting the requirements of GMP and GDP according to EXCiPACT™.

Additional regulatory information is available under <https://www.meggle-pharma.com>.

IDENTIFICATION

| Method | Specification |
|------------------------------------------------------------------------------|---------------|
| Identification A/Ph. Eur. 2.2.24/Infrared absorption spectrophotometry | conforms |
| Identification B/USP-NF <201>/Thin-layer chromatographic identification test | conforms |
| Identification D/Ph. Eur. 2.5.12/Water | conforms |
| Identification (1)/ChP <0512>/HPLC | conforms |

TESTS

| | Method | Specification |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Appearance of solution | Ph. Eur. 2.2.1 Instrumental method (max 3 NTU equals "The solution S is clear") | max 3 NTU |
| Appearance of solution | Ph. Eur. 2.2.2 <i>Method II</i> | The solution is not more intensely coloured than reference solution BY ₇ |
| Absorbance: proteins and light-absorbing impurities at 400 nm | Ph. Eur. 2.2.25 | max 0.04 |
| Absorbance: proteins and light-absorbing impurities from 270 to 300 nm | Ph. Eur. 2.2.25 | max 0.07 |
| Absorbance: proteins and light-absorbing impurities from 210 to 220 nm | Ph. Eur. 2.2.25 | max 0.25 |
| Acidity or alkalinity | Ph. Eur. Lactose Monohydrate | The solution is colourless |
| Acidity or alkalinity | Ph. Eur. Lactose Monohydrate/Requirement of 0.1 M sodium hydroxide to change the colour of the indicator to pink or red | max 0.4 ml |
| Specific optical rotation (anhydrous substance) | Ph. Eur. 2.2.7 | +54.4 - +55.9 ° |
| Water | Ph. Eur. 2.5.12 | 4.5 - 5.5 % |
| Loss on drying | USP-NF <731> | max 0.5 % |
| Sulfated ash | Ph. Eur. 2.4.14 | max 0.1 % |
| Particle size distribution < 53 µm | Ph. Eur. 2.9.38/Air-entrainment method (air-jet sieving); 10 g; + 0.1 g Al ₂ O ₃ ; p = 1500 - 2500 Pa; 2 min | 20 - 42 % |

| | Method | Specification |
|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|----------------|
| Particle size distribution < 212 µm | Ph. Eur. 2.9.38/Air-entrainment method (air-jet sieving); 10 g; + 0.1 g Al ₂ O ₃ ; p = 1500 - 2500 Pa; 2 min | min 95 % |
| Heavy metals | JP <1.07> Method 1, ChP <0821 Method 1> tested with ICP-MS acc. to Ph. Eur. 5.20/USP-NF <232> and <233>/ICH Q3D | max 5 µg/g |
| Arsenic (As) | ChP <0822 Method 1> tested with ICP-MS acc. to Ph. Eur. 5.20/USP-NF <232> and <233>/ICH Q3D | max 2 µg/g |
| Assay: Lactose calculated on the anhydrous basis | ChP <0512> | 98.0 - 102.0 % |
| Related substances | ChP <0512> | max 0.5 % |

MICROBIAL CONTAMINATION

| | Method | Specification |
|-------------------------------------------|---------------------------------------|----------------|
| Total aerobic microbial count (TAMC) | Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05> | max 100 cfu/g |
| Total combined yeasts/moulds count (TYMC) | Ph. Eur. 2.6.12/USP-NF <61>/JP <4.05> | max 10 cfu/g |
| <i>Escherichia coli</i> | Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05> | absence /10 g |
| <i>Salmonella</i> spp. | Ph. Eur. 2.6.13/USP-NF <62>/JP <4.05> | absence /100 g |

STORAGE

Tight container. Storage in an unopened, originally packed MEGGLE container at room temperature under dry and odour-free conditions.

This specification was electronically released.