## Chemische Werke Hommel GmbH & Co. KG

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## **Specification**

Concerning Product:		
Article number	66905235CPUL	
Trade name / designation / denomination	Calciumgluconat Monohydrat, USP, FCC, E	
CAS number	66905-23-5	
Other names / synonyms	•Calcium gluconate monohydrate; •Calcium gluconate monohydrate injectable;	

Parameter	Specification	Unit
Organoleptic test		
Appearance	white, fine powder	
Flavor and taste	characteristic	
Odour	odoless	
Physical parameter		•
Loss on drying	≤ 2,0	%
Molar mass	≤ 448,39	g/mol
pH value	5% solution 6,0 - 8,0	%
Reducing substances	≤ 1,0	%
Solubility	in Water: soluble, in ethanol unsoluble	
Identity	•	
Assay	≥ 98,5	%
Identification	A, B: complies	
Impurities	•	1
Heavy Metals (as Pb)	≤ 20	ppm
Oxalate (as anhydros Oxalic Acid)	≤ 0,01	%
Phosphate (PO4)	≤ 0,01	%
Sulphates (SO <sub>4</sub> )	≤ 0,05	%
Elemental Impurities		
Arsenic (As)	≤ 3	ppm
Chlorides (CI)	≤ 0,07	%
Iron (Fe)	≤ 5	ppm
Lead (Pb)	≤ 2	ppm
Microbiological data		
Escherichia Coli.	negative	
Salmonella	negative	
Staphylococcus Aureus	negative	
Total Plate Count	≤ 10000	KBE/g
Yeast and Mould	≤ 1000	KBE/g
Particle size distribution		
Particles	< 80 Mesh ≤ 100	%

## **Supplemental information:**

Waltrop, 13. Mar. 2020

Complies with monographie: USP, FCC, E 578

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Waltrop, 13. Mar. 2020

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