



Product Information

Omyapure® 35 - OG

Certified as suitable according to Monograph 14, European Pharmacopoeia: **R1-CEP 2001-366-Rev 01 CHEM (#)**
Meeting USP requirements and manufactured according to GMP ICH Q7a.

PRODUCTION SITE: ORGON, France (certified ISO 9001 and ISO 22000)

SHORT DESCRIPTION OF THE PRODUCT: A high purity natural calcium carbonate, manufactured from selected mineral.

CHEMICAL ANALYSIS:	CaCO ₃	99.5	%
	MgCO ₃	0.3	%
	Fe ₂ O ₃	0.02	%
	MgO	Traces	
	Acid insoluble substances	0.1	%
	Heavy metals content	10	ppm
	Calcium content	39.8	%

SPECIFIC PRODUCT DATA:	Fineness:		
	· Residue on a 45 µm sieve (ISO 787/7)	0.01	%
	· Top cut (d98%)	12	µm
	· Mean particle size (d50%)	3	µm
	· Particles < 2 µm	33	%
	Optical properties:		
	· CIE L*, a*, b* (ISO 11664-4)	962/045/32	%

GENERAL PRODUCT DATA:	Raw material density (ISO 787/10)	2.7	g/ml
	Packed bulk density (ISO 787/11)	0.8	g/ml
	pH value (ISO 787/9)	9	
	Pharma Calcium Carbonate	heavy	

MAIN APPLICATIONS:

- Pharmaceuticals
- Active pharmaceutical ingredient
 - Natural calcium source
 - Neutralising agent

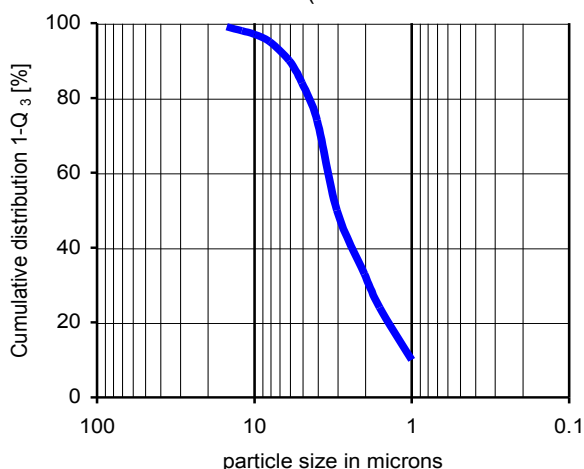
For some applications, MPG and Ca limits must be applied

STANDARD PACKAGING:

- Minimum selling unit: pallet
- BAGS (paper) of 25 kg on one-way pallet of 1250 kg, shrink-wrapped

Shelf life in dry conditions: 3 years

PARTICLE SIZE DISTRIBUTION (Malvern Mastersizer 2000):



(#) http://extranet.pheur.org/4DLink1/4DCGI/Query_CEP?vSelectName=1&vContains=1&vsubName=calcium+carbonate&SWTP=1&OK=Search

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edition : 22.11.2012
Product Information :
S08.03.01_EN_CORP\FROG I04506_E
version : 6