



SPECIFICATIONS

Calcium Carbonate Spheres SANAQ[®] (USP-NF / Ph. EUR)

| Type | 75 | 106 | 150 | 300 | 500 | 710 | Test method |
|---|---|---------------|---------------|---------------|---------------|---------------|-------------------|
| Appearance | Hard, brittle, free flowing, white colour spherical masses | | | | | | |
| Odor | odorless | | | | | | |
| Solubility | Practical insoluble in water, absolute ethanol, acetone and toluene | | | | | | Ph. Eur. |
| Iodinated zink chloride solution (Ident. A) | passes | | | | | | USP-NF/Ph. Eur. |
| Degree of Polymerization (Ident. B) | n.m.t. 350 DP units | | | | | | USP-NF/Ph. Eur. |
| Particle Size Distribution | 75-212 μ | 106-212 μ | 150-300 μ | 300-500 μ | 500-710 μ | 710-850 μ | USP-NF/Ph. Eur. |
| | $\geq 85\%$ | | | | | | USP-NF/Ph. Eur. |
| Loss on drying | n.m.t. 2.0 % | | | | | | USP-NF/Ph. Eur. |
| Identification | shall responds to the testsfor calcium | | | | | | |
| Acid insoluble substance | n.m.t. 10 mg | | | | | | USP-NF/Ph. Eur. |
| Limit of magnasium and alkali | n.m.t. 5 mg | | | | | | USP-NF/Ph. Eur. |
| Salts | | | | | | | USP-NF/Ph. Eur. |
| Limit of fluoroide | n.m.t. 0.005 % | | | | | | USP-NF/Ph. Eur. |
| Lead | n.m.t. 3 ppm | | | | | | USP-NF/Ph. Eur. |
| Iron | Shall not exceed thatn that of standard solution (0.1%) | | | | | | USP-NF/Ph. Eur. |
| Heavy Metals | n.m.t. 0.002 % | | | | | | USP-NF/Ph. Eur. |
| Organic volatile impurities | Shall meet the requirement | | | | | | USP-NF/Ph. Eur. |
| Assay | Between 98.0 % to 100.5 % | | | | | | USP-NF/Ph. Eur. |
| Microbiological Parameters | | | | | | | |
| Total aerobic count | n.m.t. 100 CFU/g | | | | | | USP-NF / Ph. Eur. |
| Moulds and yeasts | Absent | | | | | | USP-NF / Ph. Eur. |
| E. coli, Pseudomonas aeruginosa | Absent | | | | | | USP-NF / Ph. Eur. |
| St. Aureus, Salmonella species | Absent | | | | | | USP-NF / Ph. Eur. |

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