



PHARMATRANS SANAQ AG

PHARMACEUTICALS

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SPECIFICATION

SUGAR SPHERES¹⁾

(Ph. Eur. – Current Ed., USP38NF33)

Product name: SUGAR SPHERES SANAQ

Origin: Italy

DETERMINATIONS

SPECIFICATIONS

COLOUR

White to off white

IDENTIFICATIONS

A. C.C.M.
B. Starch identification
C. Reaction with the c
upritartric solution

Examined solution
similar to the testimony A
Blue coloring
Orange precipitate

GRANULOMETRY

Sucrose content:

NLT 75.0 %

Starch content:

8.5 % - 25.0 %

LOD

≤ 4.0 %

Friability

NMT 4 %

Heavy metals

< 5 ppm

Residue on ignition /
Sulphated Ash:

< 0.20 %

Microbiological contamination

Total viable aerobic

Microbial count

Yeast and Molds

Escherichia coli

Salmonella

Pseudomonas aeruginosa

Staphylococcus aureus

NMT 10³ cfu/ g

NMT 10² cfu/ g

absence / g

absence / 10 g

absence

absence

CONFORM

Ph. EUR, USP-NF & JP current Ed.

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¹⁾Based on the original figures given by the manufacturer. This certificate is valid without signature.