PHARMATRANS SANAQ AG
PHARMACEUTICALS BIRSIGSTRASSE 79 TEL. +41 61 225 90 00
CH-4011 BASEL FAX +41 61 225 90 01
info@pharmatrans-sanaq.com

Specification TAP 400

Characters	Specification	Test Method
Appearance	White or nearly white particles	Visual
Identification	conform	USP „Tartaric Acid“
Physical Parameters	Specification	Test Method
Particle size distribution	p3 (300 µm, 500 µm) ≥ 85 %	IPC
Bulk density	g/ml (information)	Ph.Eu 2.9.15
Identity		
Identification A	conform	USP <191>
Identification B	conform	USP <191>
Chemical Parameters		
Specific optical rotation	Between +12.0° and +12.8°	USP <781S>
Loss on drying	≤ 0.5 %	USP <731>
Oxalic acid	Not turbidity	USP „Tartaric Acid“
Sulphates	Not turbidity	USP <221>
Heavy metals	≤ 10 ppm	USP <231> Method II
Residue on ignition	≤ 0.1 %	USP <281>
Organic Volatile Impurities	Conform	USP <467>
Assay		
Dried substance	99.7 to 100.5 %	USP „Tartaric Acid“
MIcrobiological Limits	Specification	Test Method
Total viable aerobic count (CFU/g)	$< 10^3$	Ph.Eu 2.6.12
Fungi / Moulds and yeasts (CFU/g)	$< 10^2$	Ph.Eu 2.6.12
Eschericha coli	Absence in 1 g sample	Ph.Eu 2.6.13

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Specification TAP 200

Characters	**Specification**	**Test Method**
Appearance	White or nearly white particles	Visual
Identification	conform	USP „Tartaric Acid“
Physical Parameters	Specification	Test Method
Particle size distribution	p3 (100 µm, 350 µm) ≥ 85 %	IPC
Bulk density	g/ml (information)	Ph. Eur 2.9.15
Identity		
Identification A	conform	USP <191>
Identification B	conform	USP <191>
Chemical Parameters		
Specific optical rotation	+12.0° and +12.8°	USP <781S>
Loss on drying	≤ 0.5 %	USP <731>
Oxalic acid	no turbidity	USP „Tartaric Acid“
Sulphates	no turbidity	USP <221>
Heavy metals	≤ 10 ppm	USP <231> Method II
Residue on ignition	≤ 0.1 %	USP <281>
Organic Volatile Impurities	Conform	USP <467>
Assay		
Dried substance	99.7 to 100.5 %	USP „Tartaric Acid“
Microbiological Limits	Specification	Test Method
Total viable aerobic count [CFU/g]	$< 10^3$	Ph. Eur 2.6.12
Fungi / Moulds and yeasts [CFU/g]	$< 10^2$	Ph. Eur 2.6.12
Escherichia coli	absence in 1 g sample	Ph. Eur 2.6.13