

SPECIFICATION / TAP[®]

Tartaric Acid Pellets, 100 % pelletized Tartaric Acid Ph. Eur., USP/NF, JP

	TAP 400	TAP 500	TAP 600	TAP 700	Test method
Description					
Appearance	White or nearly white or beige particles				visual
Physical Parameters					
Particle size distribution	300 – 500 µm	400 – 600 µm	500 – 710 µm	600 – 800 µm	Ph. Eur.
	≥ 75 %	≥ 75 %	≥ 75 %	≥ 75 %	
Bulk density	0.8 – 1.1 g/ml	0.8 – 1.1 g/ml	0.8 – 1.1 g/ml	0.8 – 1.1 g/ml	Ph. Eur.
Identification					
A Solution strongly acidic	strongly acidic				Ph. Eur.
B Reactions of tartrates	positive				Ph. Eur. / USP/NF
C Infrared Absorption	IR-spectrum (ATR) equivalent reference standard				USP/NF
Chemical Parameters					
Appearance of solution	Clear and not more intensely colored than the reference solution Y ₆				Ph. Eur.
Water content	≤ 0.5 %				Ph. Eur.
Loss on drying	≤ 0.5 % (for information only)				USP/NF
Calcium	≤ 200 ppm				Ph. Eur.
Chloride	≤ 100 ppm				Ph. Eur.
Specific optical rotation	+ 12.0 to 12.8 °				Ph. Eur. / USP/NF
Limit of oxalate	no turbidity				USP/NF
Residue on ignition	≤ 0.05 %				Ph. Eur. / USP/NF / JP
Sulfate	no turbidity				USP/NF
Arsenic	≤ 1 ppm				JP
Assay	99.7 to 100.5 %				USP/NF
Microbiological Parameters					
TAMC	< 10 ³ CFU/g				USP / Ph. Eur. / JP
TYMC	< 10 ² CFU/g				USP / Ph. Eur. / JP
E.coli	absence in 1 g sample				USP / Ph. Eur. / JP

Organic solvents in accordance to Ph.Eur., 5.4 and USP <467> (CPMP/ICH/283/95) are not used neither by manufacturing of TAP[®] nor by cleaning of equipment.

The starting material of TAP[®] is exclusively of vegetable origin. A contamination with animal material by manufacturing, storage or shipment in the original closed containers will not occur. Therefore, all types of TAP[®] are free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). All types of TAP[®] comply with the requirements of EMA/410/01 rev.3