



SPECIFICATIONS

TAP[®] TARTARIC ACID PELLETS (USP/NF / JP / Ph. EUR)

Type	TAP 200	TAP 400	TAP 500	TAP 600	TAP 700	Test Method
Appearance	White or nearly white or beige particles					Visual
Physical Parameters						
Particle Size	100 – 200 µm	300 – 500 µm	400 – 600 µm	500 – 710 µm	600 – 800 µm	Ph. EUR
	≥ 75 %					
Bulk Density	0.80 - 1.1 g/ml (Standard Types) 0.90 - 1.1 g/ml (Customized Types TAP 425-500 / TAP 850-1000) (for information only)					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					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
Sulfate	no turbidity					USP/NF
Arsenic	≤ 1 ppm					JP
Assay	99.7 to 100.5 %					USP/NF
Microbiological Parameters						
TAMC	< 1000 CFU/g					Ph. EUR / USP/NF / JP
TYMC	< 100 CFU/g					Ph. EUR / USP/NF / JP
E. coli	absence in 1 g sample					Ph. EUR / USP/NF / 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

TAP is a proprietary registered mark belong to third parties and not to Pharmatrans

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