



TARTARIC ACID PELLETS

Functional Starter Pellets as pH modifier

Pelletized Tartaric Acid (Ph. Eur., USP/NF, JP)

Description

TAP are highly spherical starter pellets consist of 100 % Tartaric Acid and act as a pH modifier in extended release formulations of weakly basic drugs. These drugs typically show bad solubility in higher pH environment such as in the in the lower intestinal tract which can be enhanced by use of TAP as a starter core.

Product Types

TAP 200*	100 - 350 μ m
TAP 400	300 - 500 μ m
TAP 425-500*	425 - 500 μ m
TAP 500	400 - 600 μ m
TAP 600	500 - 700 μ m
TAP 700	600 - 800 μ m

*on demand



Summary

- » Ready-made spherical particles
- » Defined Particle size and shape
- » 100 % pelletized Tartaric Acid (Ph. Eur., USP/NF, JP), no binders



SPECIFICATION

	TAP400	TAP 500	TAP 600	TAP 700	Test Method
Description					
Appearance	White or nearly white particles				visual
Physical Parameters					
Particle size distribution	300 – 500 µm ≥ 75 %	400 – 600 µm ≥ 75 %	500 – 710 µm ≥ 75 %	600 – 800 µm ≥ 75 %	Ph. Eur.
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 Tartrate	positive				Ph.Eur. / USP/ NF
C Infrared Absorption	IR-spectrum equivalent reference standard				USP/ NF
Chemical Parameters					
Appearance of solution	Clear and not more intensely colored than the reference 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	≤ 150 ppm				Ph.Eur. / USP/ NF / JP
Heavy metals	≤ 10 ppm				Ph.Eur. / USP/ NF / JP
Arsenic	≤ 1 ppm				JP
Assay	99.7 to 100.5 %				USP/ NF
Microbiological Parameters					
TAMC	< 10 ³ CFU/g				Ph.Eur. / USP/ JP
TYMC	< 10 ² CFU/g				Ph.Eur. / USP/ JP
E.coli	absence in 1 g sample				Ph.Eur. / USP/ 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 sealed containers is strictly excluded. Therefore the product is absolutely unobjectionable in terms of BSE/TSE risk and according to Ph. Eur., 5.2.8 no BSE/TSE certificate has to be issued by the manufacturer/supplier.