



TECHNICAL DATA SHEET

1467-TDS-ENG-2024

POTASIO p-AMINOENZOATO (POTABA) (USP)		
DESCRIPTION DCI: POTASSIUM AMINOENZOATE		DESCRIPTION DOE: AMINOENZOATO POTASIO
CAS N°: 138-84-1	EC N°: 205-338-4	AEMPS CODE: 254PK
MOL. WEIGHT: 175.23	MOL. FORMULA: C7H6KNO2	ARTICLE CODE: 1467

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Identification A	Complies
Identification B	Complies
Identification C	Complies
Assay	98.0 - 102.0 %
Limit of aniline and p-toluidine	
Aniline	=< 10 ppm
p-Toluidine	=< 20 ppm
Organic impurities	
Benzocaine	=< 0.2 %
4-Nitrobenzoic acid	=< 0.2 %
Unspecified impurities	=< 0.10 %
pH	8.0 - 9.0
Loss on drying	=< 1.0 %

COMPLIES WITH

USP 2024

STORAGE

Store in a cool place. Keep the container tightly closed in a dry, well-ventilated place away from sunlight.

REMARKS

Potassium p-Aminobenzoate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.