

## POTASIO p-AMINO BENZOATO (POTABA) (USP)

PRODUCT CODE: 1467	CAS Nº: 138-84-1	ANALYSIS Nº: 081/25
MANUFACTURER BATCH: SP-1018.23.0002	CERTIFICATE ID: 45.783	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 30/07/2023	
METAPH BATCH: 0330325	EXPIRY DATE: 30/07/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	Almost white powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Assay	98.0 - 102.0 %	100.1 %
Limit of aniline and p-toluidine		
Aniline	=< 10 ppm	1.2 ppm
p-Toluidine	=< 20 ppm	Not Detected
Organic impurities		
Benzocaine	=< 0.2 %	Not Detected
4-Nitrobenzoic acid	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
pH	8.0 - 9.0	8.5
Loss on drying	=< 1.0 %	0.08 %

### COMPLIES WITH

USP 2025

### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

All data controlled by Metapharmaceutical Industrial SL.

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.

### STORAGE

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

Analysis date: 21/05/2025  
 Signature: Albert Sánchez López (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000619  
 SP QUIMICA, S.A.  
 Ctra. Reus - Vinyols, Km. 4,1  
 43330 Riudoms  
 TARRAGONA(España)

