

POTASIO p-AMINO BENZOATO (POTABA) (USP)

PRODUCT CODE: 1467	CAS Nº: 138-84-1	ANALYSIS Nº: 168/22
MANUFACTURER BATCH: SP-1018.22.0003	CERTIFICATE ID: 35.507	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2022	
METAPH BATCH: 0050722	EXPIRY DATE: 30/05/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Assay	98.5 - 101.0 %	99.7 %
Limit of aniline and p-toluidine		
Aniline	=< 10 ppm	< 10 ppm
p-Toluidine	=< 20 ppm	< 20 ppm
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	8.4
Loss on drying	=< 1.0 %	< 0.01 %
Residual solvents		(*) (**)
Isopropyl alcohol	=< 5000 ppm	4003 ppm

COMPLIES WITH

USP 2022

REMARKS

(#) Individual unspecified impurities detailed underneath:

TR (2.79 min) = 0.001 %

TR (3.26 min) = 0.001 %

TR (14.80 min) = 0.003 %

Potassium p-aminobenzoate is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(*) Data adapted from the certificate of analysis of the manufacturer.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

All methods of analysis are validated by official pharmacopeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

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

Analysis date: 28/09/2022
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

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

