

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

PRODUCT CODE: 1467	CAS Nº: 138-84-1	ANALYSIS Nº: 086/24
MANUFACTURER BATCH: SP-1018.22.0003	CERTIFICATE ID: 41.680	
SUPPLIER BATCH: 0050722	MANUFACTURING DATE: 01/05/2022	
METAPH BATCH: 0380324	EXPIRY DATE: 30/05/2027	

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 %	99.5 % (*)
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 %

COMPLIES WITH

USP 2024

REMARKS

(#) Unspecified impurities detailed underneath:

RT (2.79 min) = 0.001 %

RT (3.26 min) = 0.001 %

RT (14.80 min) = 0.003 %

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.

(*) 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: 23/04/2024

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)