



s.p. química, s.a.

METAPHARMACEUTICAL

N DE LOTE:

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28/05/2025

DOMICILIO:

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CERTIFICATE OF ANALYSIS

Product: POTASSIUM P-AMINO BENZOATE USP
Batch nr: SP-1018.23.0002
Date: 07 September 2023

CONCEPT	SPECIFICATION	RESULTS	METHOD
Identification A	IR absorption	Complies	SPA-1018-05
Identification B	Retention time	Complies	SPA-1018-05
Identification C	Test	Complies	SPA-1018-05
Description	White, off white powder	Complies	SPA-1018-05
Assay (HPLC)	98.0 - 102.0 %	100.4%	SPA-1018-05
Loss on drying:	≤ 1.0 %	0.09%	SPA-1018-05
pH (5% w/v in water)	8.0-9.0	8.5	SPA-1018-05
Aniline	≤ 10 ppm	<10ppm	SPA-1018-05
p-Toluidine	≤ 20 ppm	<20ppm	SPA-1018-05
Benzocaine	≤ 0.2 %	<0.2%	SPA-1018-05
4-nitrobenzoic acid	≤ 0.2 %	<0.2%	SPA-1018-05
Unspecified impurities	≤ 0.10 %	<0.10%	SPA-1018-05
Isopropyl alcohol	≤ 5000 ppm	<100ppm	SPA-1018-05

OBSERVATIONS

Manufacture Date: July-23
Expiry Date: July-28
Analyst: RM

X. Bes
SP QUÍMICA, S.A.
Quality Control



MP.CC.009_4 ANEXO 6

COD: SPE-1018-05

Inscrita Reg. Mer. de Tarragona, fecha 15. 02. 85, tomo 333, libro 257, Secc. Sdades., folio 17, hoja 5.427, inscripción 1ª.
C.I.F. A - 43063379.