METAPHARMACEUTICAL IND SL
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PARACETAMOL CRISTAL (EUR. PH.)

PRODUCT CODE: 1381	CAS Nº: 103-90-2	ANALYSIS Nº: 018/25	
MANUFACTURER BATCH:	CW-2312235C	CERTIFICATE ID:	44.839
SUPPLIER BATCH:	24F21-F240164	MANUFACTURING DATE:	01/12/2023
METAPH BATCH:	0180125	EXPIRY DATE:	30/11/2028

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Identification B	Complies	Complies (*)
Related substances		
Impurity K	=< 50 ppm	3 ppm
Impurity J	=< 10 ppm	0 ppm
Unspecified impurities	=< 0.05 %	< 0.03 %
Total impurities	=< 0.2 %	< 0.03 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	0.1 %
Assay	99.0 - 101.0 %	99.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

PARACETAMOL 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. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed in a fresh, dry, well-ventilated place and protected from light.

Analysis date: 29/01/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001470
LIANYUNGANG KANGLE PHARMACEUTICAL CO. LTD.
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