



CLORAL HIDRATO (EUR. PH.)

PRODUCT CODE: 0411		CAS Nº: 302-17-0	ANALYSIS Nº: 318/24
MANUFACTURER BATCH:	10224/2409B071	CERTIFICATE ID:	44.465
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/09/2024
METAPH BATCH:	0051224	RETEST DATE:	30/09/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless, transparent crystals	Colourless, transparent crystals
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	3.5 - 5.5	4.6
Chloral alcoholate	Complies	Complies
Chlorides	<= 100 ppm	< 5 ppm
Non-volatile residue	<= 0.1 %	0.08 %
Assay	98.5 - 101.0 %	98.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

Chloral Hydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

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

Manufacturer: 40000329
CHEMISCHE FABRIK BERG GmbH
MAINTHALSTRASSE, 3
06749 BITTERFELD
WOLFEN (Alemania)