

CLORANFENICOL (EUR. PH.)

PRODUCT CODE: 412	CAS Nº: 56-75-7	ANALYSIS Nº: 111/23
MANUFACTURER BATCH: DY0092200140	CERTIFICATE ID: 38.188	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 26/06/2022	
METAPH BATCH: 0250423	RETEST DATE: 25/06/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White, greyish-white or yellowish-white, fine, crystalline powder or fine crystals, needles or elongates plates	Fine white crystalline powder
Solubility	Slightly soluble in water, freely soluble in alcohol and in propylene glycol	Complies (*)
Identification A	Complies	Complies
Acidity or alkalinity	=< 0.1 mL of 0.02 M HCl or NaOH	0.02 mL of 0.02 M NaOH
Specific optical rotation	+18.5 / +20.0	+19.1
Related substances		
Impurity A	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Chlorides	=< 100 ppm	< 100 ppm
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	97.5 - 102.0 %	101.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

CHLORAMPHENICOL is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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 and dry place. Protect from light.

Analysis date: 24/07/2023
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000471
 NORTHEAST PHARMACEUTICAL GROUP Co. Ltd.
 19th floor, Block B, Chamber of Commerce
 Headquarter Mansion
 No.51, The Youth Street, Shenhe District

