

PROPILTIOURACILO (EUR. PH.)

PRODUCT CODE: 1505	CAS Nº: 51-52-5	ANALYSIS Nº: 110/25
MANUFACTURER BATCH: 10059/2309B544	CERTIFICATE ID: 46.276	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2023	
METAPH BATCH: 0280425	RETEST DATE: 30/09/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder or crystals	White crystalline powder
Solubility	Very slightly soluble in water, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides	
Identification B	Complies	Complies
Impurity A	= < 0.05 %	0.004 %
Related substances		
Impurity B	= < 0.2 %	Not Detected
Unspecified impurities	= < 0.10 %	< 0.05 %
Total impurities	= < 0.2 %	< 0.05 %
Loss on drying	= < 0.5 %	0.03 %
Sulfated ash	= < 0.1 %	0.04 %
Assay	98.0 - 101.0 %	100.42 %

COMPLIES WITH

European Pharmacopoeia 11.8

REMARKS

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

Propylthiouracil 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 and dry place and protected from light.

Analysis date: 30/07/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

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

