

PIROXICAM (EUR. PH.)

PRODUCT CODE: 1445	CAS Nº: 36322-90-4	ANALYSIS Nº: 220/24
MANUFACTURER BATCH: 2050002904	CERTIFICATE ID: 43.353	
SUPPLIER BATCH: 0280921	MANUFACTURING DATE: 20/10/2020	
METAPH BATCH: 0030924	RETEST DATE: 11/10/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellow, crystalline powder	White crystalline powder (*)
Solubility	Practically insoluble in water, soluble in methylene chloride, slightly soluble in anhydrous ethanol	Complies
Identification	Complies	Complies (*)
Related substances		
Impurity A	=< 0.2 %	0.06 %
Impurity B	=< 0.2 %	Not Detected
Impurity D	=< 0.2 %	< 0.05 %
Impurity G	=< 0.2 %	Not Detected
Impurity J	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.10 %	0.06 % (RT = 25.06 min)
Total impurities	=< 0.4 %	0.12 %
Loss on drying	=< 0.5 %	0.03 % (*)
Sulfated ash	=< 0.1 %	0.04 % (*)
Assay	98.5 - 101.0 %	100.7 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

It shows polymorphism.

Piroxicam 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

Store in an airtight container, protected from light.

Analysis date: 02/10/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000353

