



METAPHARMACEUTICAL

N DE LOTE:

0280921

Certificate of Analysis

29/09/2021

Product name **PIROXICAM**

Product Code C8000
Batch Number 2050002904
Batch Size 348,000 KG

Manufacturing date 20/10/2020
Re-test date 11/10/2025
Certificate Nr. 890000007737

Test	Specification	M.U.	Result
DESCRIPTION: white or slightly yellow crystalline powder odorless	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (UV)	complies		complies
IDENTIFICATION (TLC Rf value)	complies		complies
WATER	<= 0,5	%	0,03
LOSS ON DRYING	<= 0,5	%	0,04
SULPHATED ASH	<= 0,1	%	0,00
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N,N-dimethylacetamide (rel.sub.HPLC)	<= 200	ppm	22
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RELATED SUBSTANCES HPLC Ph. Eur.	--	--	--
Impurity A (rel.sub. HPLC)	<= 0,20	%	0,10
Impurity B (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity D (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity G (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Impurity J (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,05)
Any other Impurity (rel.sub. HPLC)	<= 0,10	%	0,05 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,40	%	0,15
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RESIDUAL SOLVENTS:	--	--	--
-Acetone (GC)	<= 1000	ppm	< LOQ (50)
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ASSAY A: with reference to the anhydrous and solvent-free substance (HPLC)	97,0 - 103,0	%	99,4
ASSAY B (pot.) (calculated on the dried basis)	98,5 - 101,0	%	100,4
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ADDITIONAL TEST:	--	--	--
-PARTICLE SIZE (d 90)	Informative Value	µm	20,2

Andrea Rebora
QC Manager
Approved June 09, 2021

Agnese Messina
Qualified Person
Approved June 09, 2021



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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
-PARTICLE SIZE (d 50)	Informative Value	µm	12,0
-PARTICLE SIZE (d 10)	Informative Value	µm	2,0
<u>NOTE</u>			
RRT 1,38(any other impurity)			

Solubility: practically insoluble in water; soluble in methylene chloride; slightly soluble in ethanol.

Complies with: Ph.Eur. BP USP JP

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Andrea Rebora QC Manager Approved June 09, 2021	Agnese Messina Qualified Person Approved June 09, 2021
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