

Ciserano, 03/12/2020				
ANALYSIS No. F812/2020		BATCH No. 108120009		
Manufacturing date: September 2020		Retest date: September 2025		Batch size: 381,00 Kg
PRODUCT		KETOPROFEN USP / PH. EUR. CAS N. 22071-15-4		
Physical State: crystalline powder Colour: white or almost white Odour: odourless or almost odourless Solubility: Practically insoluble in Distilled Water; freely soluble in Ethanol 96%, Methylene Chloride and Acetone.		Molecular weight: 254.28 Formula : C16H14O3 Method No. 1081/1		
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. spectrum	Positive	Positive	Positive	
Specific absorbance (255 nm)	668		min. 615 max. 680	
Ultraviolet Abs. (USP) difference	0.45 %	n.m.t. 3.0%		
Appearance of the solution				
Clarity	Clear		Clear	
Colour	n.m.t. yellow degree 6		n.m.t. yellow degree 6	
Loss on drying	0.01 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.019 %	n.m.t. 0,2%	n.m.t. 0,1%	
Melting point				
USP method	94.7 °C - 95.2 °C	min. 92.0°C max. 97.0°C		
Ph. Eur. method	95.2 °C		min. 94°C max. 97°C	
ASSAY on the dried basis				
NaOH 0,1N	99.38 %	min. 98,5% max. 101,0%	min 99,0% max 100,5%	
HPLC	99.9 %			min. 98,0% max. 102,0%

Qualified Person

Quality Control Manager

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Related substances (HPLC)				
Labelled Impurities				
Carboxyl Ceba	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,1%
Ketoamide	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,10%
Demethyl Keto	0.040 %	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,10%
Methyl Keto	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,1%
3-acetilbenzophenone	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,1%
Ketonitrile	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,1%
Other Impurities				
Ceba	Not detectable	n.m.t 0,2%	n.m.t. 0,10%	n.m.t. 0,10%
Unknown impurity max	0.01 %	n.m.t.0,10%	n.m.t.0,10%	n.m.t.0,10%
Total Impurities	0.05 %	n.m.t. 1,0%	n.m.t. 0,4%	n.m.t. 0,4%
GLC				
Dicyclohexylamine content	Not detectable			n.m.t. 50 ppm
Specific rotation (in-house)	0.002 °			min. -1° max. +1°
Specific rotation (USP)	-0.577 °	min. -1° max. +1°		min. -1° max. +1°
Foreign substances	n.m.t. 10 ppm			n.m.t. 10 ppm

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DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Bulk density	0.19 g/ml			min. 0,19 g/ml max. 0,32 g/ml
Tapped density	0.30 g/ml			min. 0,30 g/ml max. 0,50 g/ml
Particle size (Malvern - Sirocco 2000)				
d(0.1)	1.34 mcm			n.m.t. 2 mcm
d(0.5)	3.76 mcm			n.m.t. 4 mcm
d(0.9)	7.60 mcm			n.m.t. 10 mcm
RESIDUAL SOLVENTS				
Acetone	13.7 ppm			n.m.t. 250 ppm
Toluene	Not detectable			n.m.t. 250 ppm
ORGANIC VOLATILE IMP.				
Benzene	Not detectable			n.m.t. 2 ppm
Enantiomeric purity (HPLC)				
S isomer	50.2 %			min. 48% max. 52%
R isomer	49.8 %			min. 48% max. 52%

We hereby certify that the material identified above has been analysed and found in accordance with the specifications of USP and Ph. Eur..

Qualified Person

Quality Control Manager

Release date: 14/12/2020