

Ciserano, 13/04/2018				
ANALYSIS No. F140/2018		BATCH No. 108118004		
Manufacturing date: February 2018		Retest date: February 2023		Batch size: 419,00 Kg
PRODUCT		KETOPROFEN USP / PH. EUR. CAS N. 22071-15-4		
Physical State: crystalline powder		Molecular weight: 254.28		
Colour:	white or almost white	Formula :		C16H14O3
Odour:	odourless or almost odourless	Method No.		1081/1
Solubility:	Practically insoluble in Distilled Water; freely soluble in Ethanol 96%, Methylene Chloride and Acetone.			
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
<i>I.R. spectrum</i>	Positive	Positive	Positive	
<i>Specific absorbance (255 nm)</i>	654		min. 615 max. 680	
<i>Ultraviolet Abs. (USP) difference</i>	0.94 %	n.m.t. 3%		
Appearance of the solution				
<i>Clarity</i>	Clear		Clear	
<i>Colour</i>	n.m.t. yellow degree 6		n.m.t. yellow degree 6	
Loss on drying	0.02 %	n.m.t. 0,5%	n.m.t. 0,5%	
Sulphated ash	0.031 %	n.m.t. 0,2%	n.m.t. 0,1%	
Melting point				
<i>USP method</i>	93.7 °C - 94.8 °C	min. 92°C max. 97°C		
<i>Ph. Eur. method</i>	94.8 °C		min. 94°C max. 97°C	
Heavy metals	n.m.t. 10 ppm	n.m.t. 20 ppm	n.m.t. 10 ppm	
ASSAY on the dried basis				
<i>NaOH 0,1N</i>	99.88 %	min. 98,5% max. 101,0%	min 99,0% max 100,5%	
<i>HPLC</i>	100.0 %			min. 98,0% max. 102,0%

Qualified Person

Quality Control Manager

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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	0.05%	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	0.01%	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	0.03 %	n.m.t.0,10%	n.m.t.0,10%	n.m.t.0,10%
Total Impurities	0.10 %	n.m.t. 1%	n.m.t. 0,4%	n.m.t. 0,4%
GLC				
Dicyclohexylamine content	4.0 ppm			n.m.t. 50 ppm
Specific rotation (in-house)	-0.004 °			min. -1° max. +1°
Specific rotation (USP)	-0.405 °	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	0.21 g/ml			min. 0,19 g/ml max. 0,32 g/ml
✓ Tapped density	0.31 g/ml			min. 0,30 g/ml max. 0,50 g/ml
Particle size (Malvern - Scirocco 2000)				
d(0.1)	1.54 mcm			n.m.t. 2 mcm
d(0.5)	4.23 mcm			n.m.t. 4 mcm
d(0.9)	8.88 mcm			n.m.t. 10 mcm
RESIDUAL SOLVENTS				
✓ Acetone	13.8 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	50.6 %			min. 48% max. 52%
R isomer	49.4 %			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

Release date: 18/04/2018

Quality Control Manager