

Ciserano, 16/10/2014		Page 1 / 3		
ANALYSIS No. F228/2014		BATCH No. 108114005		
Manufacturing date: July 2014		Retest date: July 2019		Batch size: 252,00 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>I.R. spectrum</i>	Positive	Positive	Positive	
<i>Specific absorbance (255 nm)</i>	677		min. 615 max. 680	
<i>Ultraviolet Abs. (USP) difference</i>	2.08 %	n.m.t. 3%		
Appearance of the solution	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	0.080 %	n.m.t. 0,2%	n.m.t. 0,1%	
Melting point				
<i>USP method</i>	94.7 °C - 95.6 °C	min. 92°C max. 97°C		
<i>Ph. Eur. method</i>	95.6 °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>	100.1 %			min. 98,0% max. 102,0%

Qualified Person

Quality Control Manager

Ciserano, 16/10/2014				
ANALYSIS No. F228/2014		BATCH No. 108114005		
Manufacturing date: July 2014		Retest date: July 2019		Batch size: 252,00 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 : C ₁₆ H ₁₄ O ₃		
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
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	0.002 %	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,10%
Demethyl Keto	Not detectable	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,10%
Methyl Keto	0.010 %	n.m.t 0,2%	n.m.t. 0,2%	n.m.t. 0,1%
3-acetilbenzophenone	0.010 %	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	0.07 %	n.m.t. 1%	n.m.t. 0,4%	n.m.t. 0,4%
GLC				
Dicyclohexylamine content	8.0 ppm			n.m.t. 50 ppm
Specific rotation (in-house)	0.011 °			min. -1° max. +1°
Specific rotation (USP)	-0.058 °	min. -1° max. +1°		min. -1° max. +1°
Foreign substances	n.m.t. 10 ppm			n.m.t. 10 ppm

Qualified Person

Quality Control Manager

Ciserano, 16/10/2014				
ANALYSIS No. F228/2014		BATCH No. 108114005		
Manufacturing date: July 2014		Retest date: July 2019		Batch size: 252,00 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
Bulk density	0.20 g/ml			min. 0,19 g/ml max. 0,32 g/ml
Tapped density	0.32 g/ml			min. 0,30 g/ml max. 0,50 g/ml
Particle size (Malvern - Scirocco 2000)				
d(0.1)	0.70 mcm			n.m.t. 2 mcm
d(0.5)	4.00 mcm			n.m.t. 4 mcm
d(0.9)	9.99 mcm			n.m.t. 10 mcm
RESIDUAL SOLVENTS				
Acetone	7.1 ppm			n.m.t. 250 ppm
Toluene	2.7 ppm			n.m.t. 250 ppm
ORGANIC VOLATILE IMP.				
Benzene	Not detectable			n.m.t. 2 ppm
Enantiomeric purity (HPLC)				
S isomer	49.6 %			min. 48% max. 52%
R isomer	50.4 %			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: 21/10/2014

Quality Control Manager