



Boehringer Ingelheim
Bidachem

Certificate of analysis
KETOPROFEN

Nr° 29958

Product :

Batch n°:

12051089

Tests	Results	Specifications
Appearance:	conforms	A white or almost white crystalline powder.
Solubility:	conforms	Practically insoluble in water, freely soluble in acetone, in alcohol and in methylene chloride.
Identification:		
IR Spectrum:	conforms	Conforms to reference spectrum
Clarity of solution (10% in acetone):	conforms	Not more than refer. suspen. I
Color of solution (10% in acetone):	conforms	Not more than reference solution Y6
Heavy metals:	conforms	Not more than 10 ppm
Loss on drying:	0,06 %	Not more than 0,5 %
Sulphated ash:	0,01 %	Not more than 0,1%
Potentiometric assay (0.1 N NaOH):	100,0 %	99,0 – 100,5 % (on dried substance)
Related substances (HPLC):		
Imp. A:	≤ 0,05 %	Not more than 0,2 %
Imp. C:	≤ 0,05 %	Not more than 0,2%
Imp. B:	0,10 %	Not more than 0,2%
Imp. D:	0,08 %	Not more than 0,2%
Imp. E:	≤ 0,05 %	Not more than 0,2%
Imp. F:	≤ 0,05 %	Not more than 0,2%
Max Unspecified Imp.:	≤ 0,05 %	Not more than 0,10%
Total impurities (excluding imp. A and imp. C):	0,18 %	Not more than 0,4%
Residual solvents (GC-HS):		
Toluene:	583 ppm	Not more than 890 ppm
Benzene:	< 2 ppm	Not more than 2 ppm

This product corresponds to:

Ph.Eur. latest Ed.

Manufacturing date:

June 2012

Retest date:

June 2017

Internal Code: 163050

Analytical release date: 13 June 2012

BIDACHEM s.p.a
Quality Control
Manager


Dr. T. De Quarti