

Certificate of analysis

Manufacturing site

Stab. Baranzate
Via Bissone 5
20021 Baranzate MI
Italy
+39 02 382281

Issued QP

22.10.2020

Code

500644

Ref. DDT.

80010582

Ref. Order

2020-4624

Batch Nr.

2011944

Mfg. date

18.09.2020

Retest date

17.09.2025

Analysis nr.

40000044432

Buyer

10038

ACEF S.p.A.

Via Umbria 8/14

29017 FIOREZZUOLA D'ARDA PC

Italy

End User

10038

ACEF S.p.A.

Product

DICLOFENAC SODIUM EP/USP

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	A white or slightly yellowish hygroscopic crystalline powder.	EP/USP	Conform to description
Identification : IR Spectrum	-	Positive	EP/USP	Positive
Reaction of Sodium	-	Positive	EP/USP	Positive
Identification: RT in HPLC	-	Positive	EP/USP	Positive
Appearance of solution	-	Conform	EP/USP	Conform
Absorbance of solution		max 0,050	EP/USP	0,005
Loss on drying	%	max 0,5	EP/USP	0,1
Water Content (KF)	%	max 0,5	Company	0,2
pH		7,0 - 8,5	USP	7,8
1-(2,6-diclorofenil)-2-indolinone (HPLC)	%	max 0,05	EP/USP/Company	< 0,03
Impurity E EP (HPLC)	%	max 0,10	EP/USP/Company	< 0,03
Impurity Dik/7 (HPLC)*	%	max 0,10	EP/USP/Company	< 0,03
Impurity Dik/6 (HPLC)*	%	max 0,10	EP/USP/Company	< 0,03
Each other known impurity (HPLC)	%	max 0,10	EP/USP/Company	< 0,03
Each unknown impurity (HPLC)	%	max 0,10	EP/USP/Company	< 0,03
Total impurities (HPLC)	%	max 0,3	EP/USP/Company	0,0
Assay (potentiometric)	%	99,0 - 101,0	EP/USP	99,4
Isopropanol (GC)	µg/g	max 500	Company	< 5
Ethyl acetate (GC)	µg/g	max 100	Company	22
Toluene (GC)	µg/g	max 890	Company	22
Benzene (Skip test)	-	< 2 ppm		< 2 ppm
Aniline (skip test)	ppm	max 7,5		< 7,5

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TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
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is likely to be present

*DIK/6 = N-Phenyl 2,6-Dichloroaniline

*DIK/7 = N-Chloroacetyl-N-phenyl-2,6-Dichloroaniline

Elemental impurities: none of the elemental impurity reported in ICHQ3D

is likely to be present

*DIK/6 = N-Phenyl 2,6-Dichloroaniline

*DIK/7 = N-Chloroacetyl-N-phenyl-2,6-Dichloroaniline

Name and Surname: MICHELA RAMPI

Title: Quality Control

Approved

Date: 12.10.2020 09:01:13

Name and Surname: Marina Ariu

Title: Quality Assurance

Approved

Date: 12.10.2020 12:12:39