

Certificate of analysis

Manufacturing site

Stab. Mereto di Tomba
Via XXIV Maggio 40
33036 Mereto di Tomba UD
Italy
+39 0432 866711

Issued QP

12.02.2016

Code

500470

Ref. DDT.

80002230

Ref. Order

7614/2015

Batch Nr.

1601949

Mfg. date 08.02.2016

Retest date 08.02.2021

Analysis nr. 40000009872

Buyer 10038

ACEF SPA
VIA UMBRIA
29017 FIORENZUOLA D'ARDA PC
Italy

End User 10038

ACEF SPA

Product

ZONISAMIDE

TEST	UM	SPECIFICATIONS	REFERENCES	RESULTS
Description	-	white to off-white crystalline powder	Visual test	Conform to description
Identification (IR)	-	Corresponding to WS	EP	Corresponding to WS
Identification (HPLC)	-	Corresponding to WS	Company	Corresponding to WS
Water content (KF)	%	max 0,5	EP	0,1
Sulphated ash	%	max 0,1	EP	0,0
Melting point	°C	162,0 - 166,0	EP	164,6
Heavy metals	µg/g	max 10	EP	< 10
Chlorides	µg/g	max 500	EP	< 500
Assay (HPLC)	%	98,0 - 102,0	Company	99,7
Unspecified impurities (HPLC)	%	max 0,10	Company	< 0,02
Total impurities (HPLC) (except ZON3)	%	max 0,3	Company	0,0
ZON3 content (HPLC - skip test)	ppm	max 3	Company	< 3
Triethylamine residue (GC)	%	max 0,1	Company	0,0
Acetonitrile residue (GC)	µg/g	max 410	Company	165
Dichloromethane residue (GC)	µg/g	max 500	Company	< 100
Ethyl Acetate residue (GC)	µg/g	max 500	Company	< 100
2-Propanol residue (GC)	µg/g	max 500	Company	< 100
Toluene residue (GC)	µg/g	max 500	Company	< 100

Name and Surname: Andrea Deison

Title: Quality Control

Approved

Date: 11.02.2016 10:46:09

Name and Surname: Beatrice Bramanti

Title: Quality Assurance

Approved

Date: 11.02.2016 14:23:05