

Certificate of analysis

Manufacturing site
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Code
 500470

Ref. DDT.
 80003029

Ref. Order
 2929/2016

Batch Nr. 1607138
Mfg. date 17.05.2016
Retest date 16.05.2021
Analysis nr. 40000012174

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	164,5
Heavy metals	µg/g	max 10	EP	< 10
Chlorides	µg/g	max 500	EP	< 500
Assay (HPLC)	%	98,0 - 102,0	Company	99,6
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	154
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

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 Approved
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