

1604000001



ANGELINI

Certificate of Analysis n° 37160

TRAZODONE HYDROCHLORIDE

Product Code:	529647	QC Code:	529647		
Batch:	0900001507	Production Date:	26/01/2016	Expiry date:	01/2021
Batch size:	452.8 Kg				

Test	Acceptance criteria			Result	
Release analysis					
DESCRIPTION	White/Off white crystalline powder, odorless			White. Odourless	
IDENTIFICATION	FT- I R. spectrum as per current USP <197A>			Complies	
MELTING RANGE	≥ 231.0	≤ 234.0	C*	231.9 233.0	C*
APPEARANCE OF SOLUTION					
Colour	Less than matching fluid			Complies	
Opalescence	Less than matching fluid			Complies	
pH of 1% SOLUTION	≥ 3.90	≤ 4.50		4.19	
IONIC CHLORIDE	≥ 8.38	≤ 8.98	%	8.67	%
SULPHATES as Na2SO4	< = 0.05%			Complies	
HEAVY METALS	< = 0.002%			Complies	
RESIDUE ON IGNITION	≥ 0.00	≤ 0.20	%	0.03	%
LOSS ON DRYING	≥ 0.00	≤ 0.50	%	0.03	%
ASSAY (Potentiometric)	≥ 99.0	≤ 101.0	%	99.3	%
RESIDUAL SOLVENTS					
Acetone	≥ 0	≤ 500	p.p.m.	189	p.p.m.
Isobutyl Alcohol	≥ 0	≤ 500	p.p.m.	45	p.p.m.
3-CHLOROANILINE	< 100 p.p.m.			Complies	
BIS-CHLOROETHYLAMINE	< = 2.5 p.p.m.			< 0.02	
A.F.2335	< = 2.5 p.p.m.			0.3	
ASSAY (H.P.L.C.)	≥ 99.0	≤ 101.0	%	100.6	%
CHROMATOGRAPHIC PURITY					
AF1074	≥ 0.00	≤ 0.10	%	0.01	%
AF1814	≥ 0.0	≤ 0.1	%	0.0	%
AF1172	≥ 0.0	≤ 0.1	%	0.0	%
AF2066	≥ 0.00	≤ 0.10	%	0.01	%
AF1576	≥ 0.00	≤ 0.10	%	0.01	%
AF2320	≥ 0.0	≤ 0.1	%	0.0	%
AF2672	≥ 0.0	≤ 0.1	%	0.0	%
AF2673	≥ 0.0	≤ 0.1	%	0.0	%
AF2675	≥ 0.0	≤ 0.1	%	0.0	%
AF1575	≥ 0.0	≤ 0.1	%	0.0	%
unknown impurity	<=0.10%			Complies	
Total impurities	≥ 0.0	≤ 0.7	%	0.1	%
PARTICLE SIZE					

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A.C.R.A.F. S.p.A. Società a socio unico e sotto la direzione e coordinamento di Finaf S.p.A.
 Headquarters: Via Amelia, 70 00181 Roma ITALIA
 Manufacturing site: Via Guardapasso 1 04011 Aprilia (LT) ITALIA

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Issued: 19/02/2016



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Batch:	0900001507	Production Date:	26/01/2016	Expiry date:	01/2021
Batch size:	452.8 Kg				

Test	Acceptance criteria	Result
Through a 40 mesh sieve	$\geq 98\%$	Complies
Through a 80 mesh sieve	$\geq 95\%$	Complies
SOLUBILITY		
1.5% w/v in purified water	Total	Complies
3% w/v in chloroform	Total	Complies
TAPPED DENSITY	≥ 0.50 ≤ 0.65 g/mL	0.57 g/mL
FILTER TEST	No contamination	Complies

The lot complies with specification

APPROVED

Aprilia, 19/02/2016

Approved by Tania Messina

Quality Control Manager

We hereby certify that this batch of product has been manufactured, packed and controlled in full compliance with Good Manufacturing Practice (GMP). The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

RELEASED

Aprilia, 19/02/2016

Released by Emilia Imbriani

Quality Manager

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