



ANGELINI

2004 000176

## Certificate of Analysis n° 66038

## TRAZODONE HYDROCHLORIDE

Product Code:	529647	QC Code	529647		
Batch:	0900002169	Production Date	18/09/2019	Expiry date:	09/2024
Batch size:	458.0 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°	232,0 232,9	C°
APPEARANCE OF SOLUTION					
Colour	Less than matching fluid			Complies	
Opalescence	Less than matching fluid			Complies	
pH of 1% SOLUTION	≥ 3,90	≤ 4,50		4,23	
IONIC CHLORIDE	≥ 8,38	≤ 8,96	%	8,61	%
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	%	0.10	%
ASSAY (Potentiometric)	≥ 99,0	≤ 101,0	%	99.7	%
RESIDUAL SOLVENTS					
Acetone	≥ 0	≤ 500	p.p.m.	173	p.p.m.
Isobutyl Alcohol	≥ 0	≤ 500	p.p.m.	34	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.			0.4	
ASSAY (H.P.L.C.)	≥ 99,0	≤ 101,0	%	100.4	%
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	%	0.00	%
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					

This document has been produced by an electronic system

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

Page 1 of 2

Issued 12/03/2020



ANGELINI

# Certificate of Analysis n° 66038

## TRAZODONE HYDROCHLORIDE

Product Code:	529647	QC Code	529647		
Batch:	0900002169	Production Date	18/09/2019	Expiry date	09/2024
Batch size	458.0 Kg				

Test	Acceptance criteria	Result
Through a 40 mesh sieve	> = 98%	Complies
Through a 60 mesh sieve	> = 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	0.54 g/mL
FILTER TEST	No contamination	Complies

The lot complies with specification

**APPROVED**

Aprilia, 05/03/2020

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, 12/03/2020

Released by Emilia Imbriani

Quality Manager

This document has been produced by an electronic system.

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  
00161 Roma ITALIA

Manufacturing site:

Via Guardapasso 1  
04011 Aprilia (LT) ITALIA

Page 2 of 2

Issued: 12/03/2020