



ANGELINI

2105000433

Certificate of Analysis n° 78510

TRAZODONE HYDROCHLORIDE

Product Code:	529647	QC Code:	529647	
Batch:	0900002317	Production Date:	06/10/2020	Expiry date:
Batch size:	460.0 Kg			10/2025

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*	231.9 233.1	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	%	8.64	
SULPHATES as Na2SO4	<= 0.05%			Complies	
HEAVY METALS	<= 0.002%			Complies	
RESIDUE ON IGNITION	≥ 0,00	≤ 0,20	%	0.02	
LOSS ON DRYING	≥ 0,00	≤ 0,50	%	0.03	
ASSAY (Potentiometric)	≥ 99,0	≤ 101,0	%	99.9	
RESIDUAL SOLVENTS					
Acetone	≥ 0	≤ 500	p.p.m.	212	
Isobutyl Alcohol	≥ 0	≤ 500	p.p.m.	40	
3-CHLOROANILINE	< 100 p.p.m.			Complies	
BIS-CHLOROETHYLAMINE	<= 2.5 p.p.m.			<0.02	
A.F.2335	<= 2.5 p.p.m.			1.4	
ASSAY (H.P.L.C.)	≥ 99,0	≤ 101,0	%	99.4	
CHROMATOGRAPHIC PURITY					
AF1074	≥ 0,00	≤ 0,10	%	<=0.05%	
AF1814	≥ 0,0	≤ 0,1	%	<=0.05%	
AF1172	≥ 0,0	≤ 0,1	%	<=0.05%	
AF2066	≥ 0,00	≤ 0,10	%	<=0.05%	
AF1576	≥ 0,00	≤ 0,10	%	<=0.05%	
AF2320	≥ 0,0	≤ 0,1	%	<=0.05%	
AF2672	≥ 0,0	≤ 0,1	%	<=0.05%	
AF2673	≥ 0,0	≤ 0,1	%	<=0.05%	
AF2675	≥ 0,0	≤ 0,1	%	<=0.05%	
AF1575	≥ 0,0	≤ 0,1	%	<=0.05%	
	≥ 0,0	≤ 0,1	%	<=0.05%	

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: 10/05/2021



ANGELINI

Certificate of Analysis n° 78510

TRAZODONE HYDROCHLORIDE

Product Code:	529647	QC Code:	529647		
Batch:	0900002317	Production Date:	06/10/2020	Expiry date:	10/2025
Batch size:	460.0 Kg				

Test	Acceptance criteria			Result	
unknown impurity	$\geq 0,00$	$\leq 0,10$	%	$\leq 0,05\%$	%
Total impurities	$\geq 0,0$	$\leq 0,7$	%	0.0	%
PARTICLE SIZE					
Through a 40 mesh sieve	$> = 98\%$			Complies	
Through a 80 mesh sieve	$> = 95\%$			Complies	
SOLUBILITY					
1.5% w/v in purified water	Total			Complies	
3% w/v in chloroform	Total			Complies	
TAPPED DENSITY	$\geq 0,50$	$\leq 0,65$	g/mL	0.52	g/mL
FILTER TEST	No contamination			Complies	

The lot complies with specification

APPROVED

Aprilia, 10/05/2021

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, 10/05/2021

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 00181 Roma ITALIA
Manufacturing site: Via Guardapasso 1 04011 Aprilia (LT) ITALIA

Page 2 of 2

Issued: 10/05/2021