FALEXIN MONOHYDRATE



## entrient Pharmaceuticals Spain S.A.

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## Certificate of Analysis

ALEXIN MONOTHERATE			
JRILEX ® COMPACTED		Batch/lot: B428019 Expiration Date: Sep 2024	Batch/lot size: 3000 KG
anufacturing date: Oct 2020			Release Date: 06-Nov-2020
Tests	Specifications	Units	Results
pearance	White-almost white powde	er with granules	Complies
lubility	Conforms with test		Complies
entification (IR)	Conforms with test		Complies
ystallinity	Crystalline		Complies
1	4,0 to 5,5		5,0
pecific opt. rotation, anhydrous basis	149 to 158	deg	156
ater content by KF	4,0 to 8,0	%w/w	6,3
ssay, anhydrous basis1	97,0 to 102,0	%w/w	99,8
elated Substances:7-ADCA	< = 1,0	%w/w	0,05
slated Substances: PHENYLGLYCINE	< = 1,0	%w/w	0,02
elated Substances: PG-AMIDE	< = 0,5	%w/w	< 0,02
el. Subs.: Delta-2-Cephalexin	< = 1,0	%w/w	< 0,02
el. Subst.: CEX-piperazine+ degradants	< = 1,0	%w/w	0,07
al. Subst.: ANY OTHER IMPURITY	< = 1,0	%w/w	0,04
elated Substances: TOTAL IMPURITIES	< = 3,0	%w/w	0,23
alk Density	> = 0,45	g/ml	0,60
apped Density	> = 0,75	g/ml	0,81
Jiphated Ash	< = 0.2	%w/w	Complies if tested**

harmacopoeia quality: Complies with the current editions: Ph.Eur, BP, USP, IP\*.

< 0,20

lanufactured according to ICH Q7 GMP for APIs.

I,N-Dimethylaniline is not used in the manufacturing process of this product or present in any of the raw materials.

Expiry date is 2 years for IP grade as per Indian D&C Act.

our sales order#: 107826 oustomer order#: A-2210074

hip-to SIEMSGLUSS IBERICA S.A., Parcela 6, Nave 2, , 08620, Sant Vicenc Dels Horts

Barcelona), ES

esidual Acetone

\* Checked at regular intervals

Release Specification

ate of Issue: St. Perpetua de Mogoda, February 10, 2021

COA approved with Digital Signature by Judit Fuentes. QA Technician, 15:10:13, 10.02.2021

Complies if tested\*\*

%w/w

ne material covered by this delivery is produced in accordance with Centrient Pharmaceuticals manufacturing specifications currently in force for this product grade. Centrient Pharmaceuticals rtifies that the material supplied conforms to the performance typical for this grade and product description, and has been monitored in accordance with the internal quality control routines reployed in our company, however, the buyer must check the suitability of this grade for the actual application. This certificate does not release the recipient from his obligation to carry out his ual incoming goods checks. The applicability of any other general terms and conditions is explicitly rejected and superseded by our General Terms and Conditions of Sale as mentioned on our absite www.centrient.com