

Art.: 5105
Ch.: 24002832

E-mail: procos@procos.it
www.procos.it

Sample Nr.	210241623	Manufacturing Date	14/09/2023	Retest Date	14/09/2028
Code Q3	Lot/Batch 0000390343	Description 5-ALA	Product Class FERT CLASSE A		
Tests	Results	Units	Specification		
CHARACTERS					
APPEARANCE	Complies to specification	-	White to off-white crystals		
C-USP<197> - C-EP 2.2.24.					
IR IDENTIFICATION	Complies to specification	-	Complies to Note A		
IDENTIFICATION HPLC Q3T					
RETENTION TIME	Complies to specification	-	Complies to Note B		
C-USP<191> - C-EP 2.3.1. METHOD A					
CHLORIDE IDENTIFICATION	Complies to specification	-	Forms white precipitate		
C-USP<855> - C-EP 2.2.1.					
CLARITY OF SOLUTION	Complies to specification	-	Clear		
C-USP<631> - C-EP 2.2.2.-Q3					
COLOR OF SOLUTION	Complies to specification	-	Not more intensely colored than B7 or Y7		
C-USP<741> - C-EP 2.2.14. - Q3					
MELTING POINT	154	°C	Between 151°C and 155°C		
C-USP<791> - C-EP 2.2.3.					
pH	2.7	pH	Between 2.5 and 2.9		
RELATED SUBSTANCES HPLC Q3-A					
IMPURITY A	Not Detected	%	NMT 0.10%		
RELATED SUBSTANCES HPLC Q3-B					
IMPURITY C	Not Detected	%	NMT 0.10%		
IMPURITY D	Not Detected	%	NMT 0.10%		
IMPURITY E	Not Detected	%	NMT 0.10%		
IMPURITY F	Not Detected	%	NMT 0.10%		
Each individual unspecified impurity	Not Detected	%	NMT 0.10%		
TOTAL RELATED SUBSTANCES Q3	Not Detected	%	NMT 0.10%		
Sum of all specified impurities	Not Detected	%	NMT 0.50%		
Sum of all unspecified impurities	Not Detected	%	NMT 0.50%		
Total impurities	Not Detected	%	NMT 0.50%		
ASSAY HPLC Q3T	Not Detected	%	NMT 0.5%		

E-mail: procos@procos.it
www.procoss.it

Sample Nr.	210241623	Manufacturing Date	14/09/2023	Retest Date	14/09/2028
Code Q3	Lot/Batch 0000390343	Description 5-ALA	Product Class FERT CLASSE A		
Tests	Results	Units	Specification		
ASSAY (dried basis)	99.4	%	Between 98.0% and 102.0%		
LOD Q3 (C-EP 2.2.32.)					
LOSS ON DRYING	0.07	%	NMT 0.5%		
KF Q3 (C-USP<921>METHOD I-C-EP 2.5.12.)					
WATER	0.20	%	NMT 0.5%		
C-USP<281> - C-EP 2.4.14.					
RESIDUE ON IGNITION/SULPHATED ASH	0.00	%	NMT 0.10%		
GC Q3SR-A					
Methanol	Not Detected	ppm	NMT 3000 ppm		
Acetone	606	ppm	NMT 5000 ppm		
Dichloromethane	Not Detected	ppm	NMT 600 ppm		
Diisopropyl ether	Not Detected	ppm	NMT 1700 ppm		
GC Q3SR-B					
N,N-dimethylformamide	Not Detected	ppm	NMT 880 ppm		
GC Q3SR-C					
Benzene	Not Detected	ppm	NMT 2 ppm		
C-USP<1111> - C-EP 5.1.4./2.6.12.-Q3					
Total combined Yeasts and Molds Count	<5	UFC/g	NMT 10 CFU/g		
Total Aerobic Microbial Count	<10	UFC/g	NMT 100 CFU/g		
Notes					
A: IR IDENTIFICATION (5-ALA)	The IR spectrum of the sample conforms with that of the reference standard The retention time of the major peak in the chromatogram of the test solution must conform with that of the standard solution as given under the test of Assay (by HPLC) Pharmaceutical Active Ingredient 5-Aminolevulinic acid methyl ester 2,5-Bis-(beta-carboxyethyl)-pyrazine Phthalic acid 5-N-(Phthaloyl)-aminolevulinic acid methyl ester 5-N-(Phthaloyl)-aminolevulinic acid PRODUCT COMPLIES WITH PROCOS SPECIFICATIONS				
B: RETENTION TIME (5-ALA)					
FERT					
5-ALA IMPURITY A					
5-ALA IMPURITY D					
5-ALA IMPURITY C					
5-ALA IMPURITY E					
5-ALA IMPURITY F					
PROCOS CLASS					

E-mail: procos@procos.it
www.procospa.it

Sample Nr.	210241623	Manufacturing Date	14/09/2023	Retest Date	14/09/2028
Code	Lot/Batch	Description	Product Class		
Q3	0000390343	5-ALA	FERT CLASSE A		

Lot Released : Complies with all specifications of the testing instruction and with GMP standard.

Cameri, September 21, 2023
Procospa
Quality Control

Authorized Person

TIZIANO RUFFILLI

Tiziano Ruffilli