

Certificate of Analysis

Product name: **Tryptophanum apyrogen**

Batch number / Weight: **22A26-B06-217528 / 250 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22A26-B06 / INS-22-5373**

Reference Code / No.: **V01867 / 211952**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline or amorphous powder	Conform		
Identification A	-33,0 - -30,0	C		
Identification B	Conform	Conform		
Appearance of solution	Clear / <=JB6	Conform		
Specific optical rotation	-33,0 - -30,0	-30,8		
Ninhydrin-positive substances	Conform	Conform		
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Impurity A and other rel. subst.	Conform	Conform	%	
Impurity A	<=10	<3,5	ppm	
Sum imp. < RT Tryptophan	<=100	12,1	ppm	
Sum imp. > RT Tryptophan	<=100	24,0	ppm	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=20	<20	ppm	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,08	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Tryptophane	98,5 - 101,0	100,1	%m/m	
Endotoxins	<6,0	<6,0	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 3000	<3000	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

29-08-2022

Expiration: 27-04-2024

Conclusion: APPROVED

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