

## Certificate of Analysis

**Productname:** Tryptophanum apyrogeen  
**Number of analysis/Inspection Code:** 1 / KEUR-187794B  
**Batchnumber:** 20I30-F01-375614  
**Reference code / No.:** 3968 / 191820  
**Analysed according to:** PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline or amorphous powder	Conform Conform		
Fermentation	According to Fermentation products Ph. Eur.	Conform		Data producer
Identification A	-33,0 - -30,0	Conform		Specific optical rotation
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=JB6	Conform		1% m/V in HCl 1M
Specific optical rotation	-33,0 - -30,0	-31,5		1%m/V; dried
Ninhydrin-positive substances	Conform	Conform		HPLC
Any ninhydrin-positive substance	<=0,2	<0,2	%	
Total	<=0,5	<0,5	%	
Impurity A and other rel. subst.	Conform	Conform		HPLC
Impurity A	<=10	4	ppm	
Sum imp. < RT Tryptophan	<=100	33	ppm	
Sum imp. RT>Tr <1,8 RT N-Ac Tr	<=300	<3	ppm	
Chlorides	<=200	Conform	ppm	
Sulphates	<=300	Conform	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=20	Conform	ppm	
Loss on drying	<=0,5	0,0	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay L-Tryptophane	98,5 - 101,0	99,8	%m/m	Dried
Endotoxins	<6,0	Conform	IU / g	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer



Analysis performed by the authorized laboratory Proxylabs+Microb..

Release:

Paul Hofman

Pharmacist - Qualified Person

12/21/20

Expiration: 06-2022

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.