



QUALITY MANAGEMENT
SYSTEM
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016
CERTIFIED BY CERTIQUALITY

COMPANY INSPECTED BY CERTIQUALITY
FOR THE COMPLIANCE TO
GMP
CODE OF FEDERAL REGULATION,
TITLE 21, VOLUME 2, PART 11



ANALYTICAL SPECIFICATIONS TO ISSUE

CERTIFICATE OF ANALYSIS / CONFORMITY PRODUCT

Product: **PKU EASY MICROTABS US-PACKAGES**

Batch number: **M03910**

Sale code: **9I00196902**

Sale pieces: **308**

Manufacturing date: **04/2023**

Expiry date: **10/2024**

Dosage form: **Tablets**

Class: **Food for special medical purposes**

TESTS	REFERENCES	RESULTS
Appearance/organoleptic characteristics	Light-yellow tablets	Conforms
Uniformity of mass	Eur Ph Current Edition	Conforms
Microbiological controls		
TAMC (Total Aerobic Microbial Count)	$\leq 5 \times 10^4$ CFU/g	40.000 CFU/g
TYMC (Total Yeasts Moulds Count) (2)	$\leq 5 \times 10^2$ CFU/g	50 CFU/g
Bile-tolerant gram negative bacteria	$\leq 2 \times 10^2$ CFU/g	< 10 CFU/g
Salmonella spp	Absent/25g	Absent/25g
Escherichia coli (1)	Absent/g or < LQ	< LQ
Listeria monocytogenes	Absent/25g	Absent/25g
Chemical controls		
Phenylalanine *	< 0.01 g/100g	< 0,002 g/100g

We declare that the product was manufactured under strict standards set (LD 193/2007, Reg. CE 178/2002, Reg. CE 852/2004 and Reg. UE 609/2013) and the Technical Specifications in force where applicable. Raw data have been verified by QC Manager.

(1) LQ = 10 CFU/g (ISO 16649 – 2:2001)

(2) Yeast: 50 CFU/g; Mould: < 10 CFU/g

* Analysis performed by external laboratories

Printing Date

08/06/2023

On approval

Date

Signature

Batch Release QP

Dr C. Berto