

The Testing laboratory of the Quality Control Department
of SC "BALKAN PHARMACEUTICALS" SRL

Nr. LÎ - 138 din 19.07.2024

Accreditation standard:

Level 3: SM EN ISO/ IEC 17025:2018

Legal address: 7/A, Industrialia street, Singera, Chisinau mun., MD-2091

1. Tests carried out in permanent premises ¹: 7/A, Industrialia street, Singera, Chisinau mun., MD-2091.

(address)

Nr.	Type/Name of the test	Material / product	Normative document/ internal standard/reference
1. MICROBIOLOGICAL TESTS			
1.1	Sterility test	Sterile raw materials and sterile dosage forms	European Pharmacopoeia, 2.6.1 SOP – 06 – 027, ed.5 from 01.04.2024.
1.2	Determination of the Total aerobic microbial count	Raw materials and non-sterile dosage forms	European Pharmacopoeia, 2.6.12
		Dietary supplements	SOP – 06 – 029, ed. 5, from 22.12.2023
1.3	Determination of the Total combined yeasts/ mould count	Raw materials and non-sterile dosage forms	European Pharmacopoeia, 2.6.12
		Dietary supplements	SOP – 06 – 029, ed. 5, from 22.12.2023
1.4	Determination of the Escherichia coli	Non-sterile dosage forms	European Pharmacopoeia, 2.6.12, 2.6.13, 4.2
		Dietary supplements	COΠ – 06 – 031, ed. 2, from 01.06.2021
1.5	Determination of the Bile-tolerant gram-negative bacteria	Non-sterile dosage forms	European Pharmacopoeia, 2.6.12, 2.6.13, 4.1
		Dietary supplements	COΠ – 06 – 031, ed. 2, from 01.06.2021

2. Tests carried out at the client's Conformity Assessment Body

Nr.	Type/Name of the test	Material / product	Normative document/ internal standard/reference
1. SAMPLING			
1.1	Sampling	Raw materials and medicinal forms for human use	FP – 06 – 001, ed. 7 from 24.11.2023
		Dietary supplements	ΦΠ – 06 – 004, ed. 3 from 29.09.2021

Approved:

Director MOLDAC

Iurie FRIPTULEAC

Signature _____ **Date** _____

¹ All locations where the Testing Laboratory carries out testing activities will be specified by the Conformity Assessment Body.