Mérieux NutriSciences

Better Food. Better Health. Better World.

Food & Dietary Supplements

Nutrients determination and analiysis

An **all-inclusive** service

INDEX

FOOD & DIETARY SUPPLEMENTS

Nutrients determination and analysis

The utilization of **substances as a source of nutrients** in the production of food and dietary supplements must be safe and controlled.

In order to **protect consumers against potential health risks**, the European Commission has established harmonized rules - Directive 2020/46/EC is the main legislation - that list a number of substances known or suspected to have adverse effects on health and the **use of which is therefore controlled**. For example, the consumption of minerals or vitamins excessive amounts may cause adverse health reactions.

Nutrients usage is carried out in accordance with the following regulations:

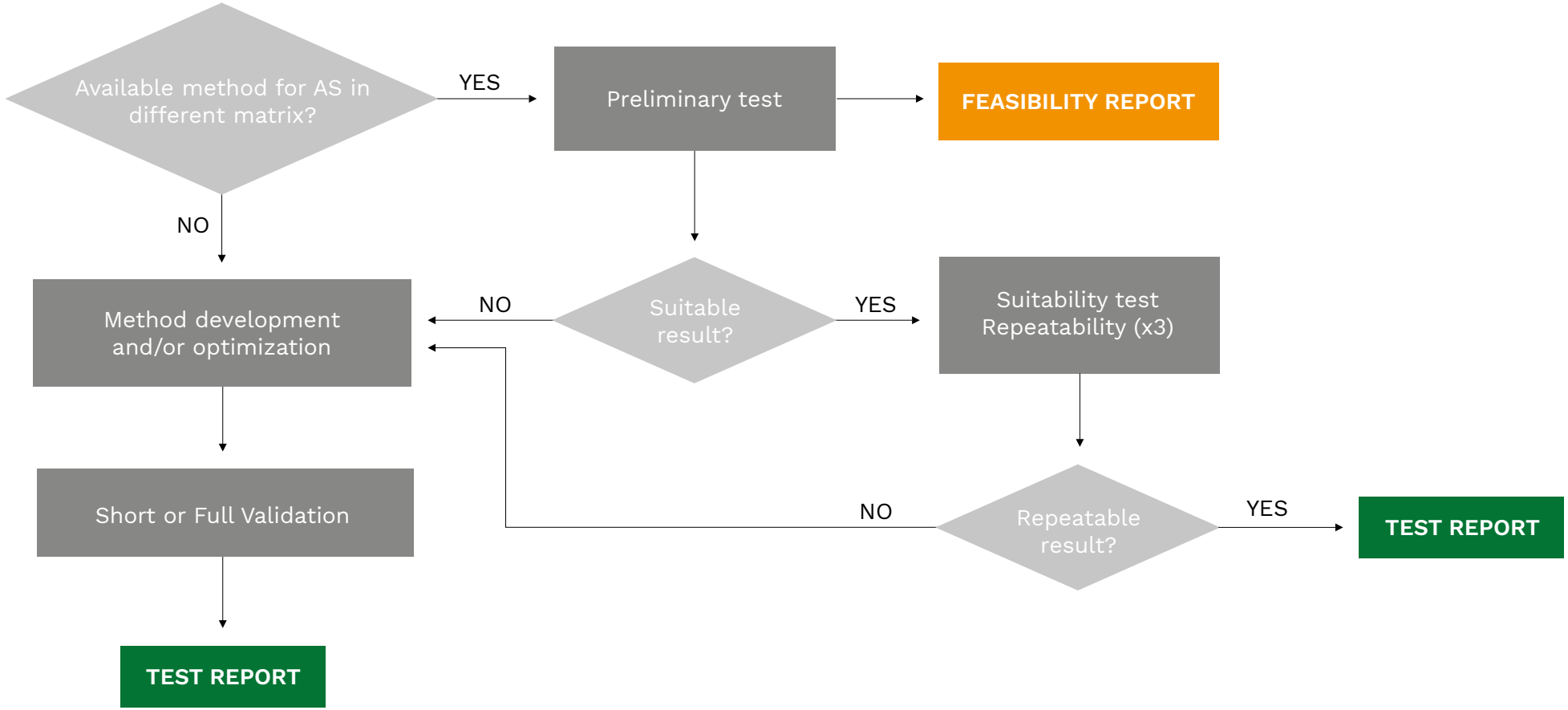
- **Vitamins and minerals**: according to commission regulation (EC) 1170/2009 Annex II
- **Botanicals**: *compendium of Botanicals*
- **Other substances than vitamins**: according to regulation (EC) 1925/2006 for the added amount which needs to be respected, as amino acids, organic acids, enzymes (as coenzyme Q10, bromelain)

The choice of nutrients and substances with a nutritional or physiological effect and their dosages shall be weighted according to:

- Pre-determined nutritional or physiological objective
- Population group for which the supplement is intended
- Any negative interactions, additive or synergistic effects between components, which may have an impact on the product efficacy or safety

FEASIBILITY STUDY

Feasibility study, testing decision tree



The results reported in the Feasibility Report cannot be used for the evaluation of the stability or for batch release or for a regulatory scope unless there are justified reasons to consider them reliable under the responsibility of the Sponsor.

Vitamins

VITAMINS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
D,L-5-Methyltetrahydrofolate	I.M.	HPLC-DAD	0,002%
Choline	I.M.	SPTF-UV	100 mg/kg
Vitamin A (Retinyl Acetate)	I.M.	HPLC-DAD	0,002%
Vitamin A (Retinol)	I.M.	HPLC-DAD	0,0002%
Vitamin B1 (Thiamine)	I.M.	HPLC-DAD	0,002%
Vitamin B1 (Thiamine)	I.M.	HPLC-MSMS	0,00001%
Vitamin B12 (Cyanocobalamin)	I.M.	HPLC-DAD	0,002%
Vitamin B12 (Cyanocobalamin)	I.M.	HPLC-MSMS	0,000005%
Vitamin B2 (Riboflavin)	I.M.	HPLC-DAD	0,002%
Vitamin B2 (Riboflavin)	I.M.	HPLC-MSMS	0,00003%
Vitamin B2 (Riboflavin 5-monophosphate)	I.M.	HPLC-DAD	0,002%
Vitamin B3 (Nicotinic Acid)	I.M.	HPLC-DAD	0,0015%
Vitamin B3 (Nicotinic Acid)	I.M.	HPLC-MSMS	0,000002%
Vitamin B3 (Nicotinamide)	I.M.	HPLC-DAD	0,0015%

I.M. = Internal Method

VITAMINS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Vitamin B3 (Nicotinamide)	I.M.	HPLC-MSMS	0,000002%
Vitamin B5 (D-Panthenol)	I.M.	HPLC-DAD	0,0025%
Vitamin B5 (Pantothenate)	I.M.	HPLC-DAD	0,0025%
Vitamin B5 (Pantothenate)	I.M.	HPLC-MSMS	0,00005%
Vitamin B6 (Pyridoxine)	I.M.	HPLC-DAD	0,001%
Vitamin B6 (Pyridoxine)	I.M.	HPLC-MSMS	0,00003%
Vitamin B8 (Biotin)	I.M.	HPLC-DAD	0,0025%
Vitamin B8 (Biotin)	I.M.	HPLC-MSMS	0,00003%
Vitamin B9 (Folic Acid)	I.M.	HPLC-DAD	0,001%
Vitamin B9 (Folic Acid)	I.M.	HPLC-MSMS	0,000009%
Vitamin C (L-ascorbic acid)	I.M.	HPLC-DAD	0,008%
Vitamin D2	I.M.	HPLC-MSMS	0,2 mg/kg
Vitamin D3 (Cholecalciferol)	I.M.	HPLC-DAD	0,001%
Vitamin D3 (Cholecalciferol)	I.M.	HPLC-MSMS	0,00002%
Vitamin E (DL-alpha-tocopherol)	I.M.	HPLC-DAD	0,0015%
Vitamin E (DL-tocopheryl acetate)	I.M.	HPLC-DAD	0,025%
Vitamin K1 (Phylloquinone)	I.M.	HPLC-DAD	0,001%

I.M. = Internal Method

VITAMINS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Vitamin K1 (Phylloquinone)	I.M.	HPLC-FLD	0,000015%
Vitamin K2 (Menaquinone 4)	I.M.	HPLC-DAD	0,001%
Vitamin K2 (Menaquinone 4)	I.M.	HPLC-FLD	0,00002%
Vitamin K2 (Menaquinone 7)	I.M.	HPLC-DAD	0,0002%
Vitamin K2 (Menaquinone 7)	I.M.	HPLC-FLD	0,00002%
Vitamin K3	I.M.	GC	0,3 mg/kg

I.M. = Internal Method

Minerals \ Cations

MINERALS \ CATIONS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Boron	I.M.	ICP-OES	0,0003%
Calcium	I.M.	ICP-OES	0,025%
Chromium	I.M.	ICP-OES	0,0001%
Copper	I.M.	ICP-OES	0,0002%
Iodine	UNI	ICP-MS	0,0001%
Iodine	I.M.	TITR	0,02%
Iron	I.M.	ICP-OES	0,006%
Magnesium	I.M.	ICP-OES	0,025%
Manganese	I.M.	ICP-OES	0,0001%
Molybdenum	I.M.	ICP-OES	0,0002%
Phosphorus (as P)	I.M.	ICP-OES	0,001%
Potassium	I.M.	ICP-OES	0,025%
Selenium	I.M.	ICP-OES	0,001%
Silica	I.M.	ICP-MS	Liquids > 1.3 mg/Kg - Solids > 10.3 mg/Kg

I.M. = Internal Method

VITAMINS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Silver	I.M.	ICP-OES	0,000005%
Sodium	I.M.	ICP-OES	0,025%
Zinc	I.M.	ICP-OES	0,0002%

AMINOACIDS DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
5-Hydroxytryptophan	I.M.	HPLC-DAD	0,005 g/100g
Aminoacids (after hydrolysis)	I.M.	IC	0,01 g/100g
Carnitine	I.M.	HPLC-UV	100 mg/Kg
Free Aminoacids (Full profile)	I.M.	IC	10 mg/kg
O-Acetyl-L-carnitine hydrochloride	I.M.	HPLC-DAD	0,025 g/100 g
Sulfur Aminoacids (after hydrolysis)	I.M.	IC	0,01 g/100g
Tryptophan	I.M.	HPLC-FLD	5 mg/Kg - 45 mg/Kg

I.M. = Internal Method

Other active substances

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Alkaloyds			
Berberine chloride	I.M.	HPLC-DAD	0,01%
Caffeine	I.M.	HPLC-DAD	0,005%
Capsaicinoids	AOAC 995.03 1998	HPLC	10 SHU / 10 mg/kg
Piperine	I.M.	HPLC-DAD	0,005%
Synephrine	I.M.	HPLC-DAD	0,008%
Theobromine	I.M.	HPLC-DAD	0,001%
Carotenoids			
ß-Carotene	I.M.	HPLC-DAD	0,003%
Lutein	I.M.	HPLC-DAD	0,003%
Zeaxantin	I.M.	HPLC-DAD	0,003%
Catechins			
Catechins (catechin, epicatechin, epigallocatechin, epigallocatechin gallate, epicatechin gallate, gallocatechin gallate, catechin gallate, total catechins)	I.M.	HPLC	0.01%
Epigallocatechin gallate (EGCG)	I.M.	HPLC-DAD	0,002%

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Essential oils			
alpha-Santalol	I.M.	GC-MS	0,0005%
Anethole	I.M.	HPLC-UV	0,01 g/100g
Bisabolol	I.M.	GC-MS	0,0005%
Camphor	I.M.	GC-MS	0,0005%
Carvacrol	I.M.	GC-MS	0,0005%
Eucalyptol	I.M.	GC-MS	0,0005%
Menthol	I.M.	GC-MS	0,0005%
p-Cymene	I.M.	GC-MS	0,0005%
trans-Caryophyllene	I.M.	GC-MS	0,0005%
Verbenone	I.M.	GC-MS	0,0005%
Curcuminoids			
Bisdemethoxycurcumin	I.M.	HPLC-DAD	0,005%
Curcumin	I.M.	HPLC-DAD	0,005%
Demethoxycurcumin	I.M.	HPLC-DAD	0,005%
Curcuminoids expressed as curcumin	I.M.	HPLC-DAD	0,005%

I.M. = Internal Method

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Flavonoids			
Anthocyanins	I.M.	HPLC-DAD	0,005%
Apigenin-7-glucoside	I.M.	HPLC-DAD	0,005%
Daidzein	I.M.	HPLC-DAD	0,005%
Diosmin	I.M.	HPLC-DAD	0,005%
Apigenin-7-glucoside	I.M.	HPLC-DAD	0,005%
Galangin	I.M.	HPLC-DAD	0,005%
Hesperidin	I.M.	HPLC-DAD	0,005%
Naringin	I.M.	HPLC-DAD	0,005%
Quercetin	I.M.	HPLC-DAD	0,005%
Genistein	I.M.	HPLC-DAD	0,005%
Ginkgo flavone glycosides	I.M.	HPLC	0,01 g/100g
Isoflavones (Biochanin A, Daidzein, Formononetin, Genistein, Puerarin)	I.M.	HPLC-DAD	0,005%
Quercetin	I.M.	HPLC-DAD	0,005%
Rutin	I.M.	HPLC-DAD	0,005%
Silybin A + B	I.M.	HPLC-DAD	0,001%
Silymarin	I.M.	HPLC-DAD	0,005%
Total soluble proanthocyanidins	AOAC_2019.06	SPTF-UV	0,08%

I.M. = Internal Method

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Monacolins			
Monacolin K in the lactone form	I.M.	HPLC-DAD	0,01%
Monacolin K in acid form	I.M.	HPLC-DAD	0,01%
Sum monacolin K lactone and acid	I.M.	HPLC-DAD	0,01%
Minor monacolins	I.M.	HPLC-DAD	-
Phenols - polyphenols			
Caffeoylquinic acids	I.M.	HPLC-DAD	0,005%
Chlorogenic acid	I.M.	HPLC-DAD	0,005%
Echinacoside	I.M.	HPLC-DAD	0,003%
Gingerols	I.M.	HPLC-DAD	0,005%
Phenolic acids (4-hydroxybenzoic acid, chlorogenic acid, caffeic acid, ferulic acid, gallic acid, p-cumaric acid, protocatechuic acid, rosmarinic acid, siringic acid, vanillic acid)	I.M.	HPLC	0,01 g/100g
Polyphenols (Folin-Ciocalteau)	I.M.	SPTF-UV	0,6%
Resveratrol	I.M.	HPLC-DAD	0,0025%
Rosmarinic acid	I.M.	HPLC-DAD	0,001%

I.M. = Internal Method

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Other			
(1-3) (1-6) ß-glucans	I.M.	ENZYMATIC	0,3 g/100g
Acidic composition in *Serenoa*	EP 04/2019:1848 CORRECTED 10.0	GC	-
Alpha lipoic acid	I.M.	HPLC-DAD	0,04%
Andrographolide	I.M.	HPLC-UV	0,1 g/100g
Asiaticoside (Centella extract)	EP 01/2016:1498	HPLC-UV	0,01 g/100g
Boswellic acids expressed as beta-boswellic acid	I.M.	HPLC-DAD	0,005%
Bromelin	I.M.	ENZYMATIC	0,065 GDU/g
ß-galactosidase activity	I.M.	ENZYMATIC	-
ß-sitosterol	I.M.	HPLC-DAD	0,005%
Cannabidiol	I.M.	HPLC-MSMS	0,1 g/100g
Carnosic acid	I.M.	HPLC-DAD	0,015%
Carnosol	I.M.	HPLC-DAD	0,01%
Citicoline Monosodium Salt	I.M.	HPLC-DAD	0,20 g/100g
Citrulline	I.M.	SPTF	0,6 ug/mL
Coenzyme Q10	I.M.	HPLC-DAD	0,005%
Coumarin	I.M.	HPLC-UV	1 mg/kg

I.M. = Internal Method

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Ergosterol	I.M.	HPLC	5 mg/kg
Escin	I.M.	HPLC-DAD	0,005%
Forskolin	I.M.	HPLC-DAD	0,014%
Fructooligosaccharides (FOS)	AOAC 997.08 1999	HPLC	0,1 g/100g
γ-Oryzanol	I.M.	HPLC-DAD	0,005%
Ginsenosides expressed as Ginsenoside Rb1	I.M.	HPLC-DAD	0,005%
Glucosamine	I.M.	HPLC-MSMS	0,2 g/100g
Glutathione (Oxidized and Reduced)	I.M.	HPLC-DAD	0,001%
Glycyrrhizic acid ammonium salt	I.M.	HPLC-DAD	0,005%
Harpagoside	I.M.	HPLC-DAD	0,01%
Hyaluronic acid	I.M.	HPLC-MSMS	1 g/100g
Hydroxyantraquinone derivatives expressed as Sennoside B	I.M.	HPLC-DAD	0,01%
Hydroxycitric acid	I.M.	HPLC-DAD	0,03%
Hydroxytyrosol	I.M.	HPLC-DAD	0,01%
Lactoferrin	I.M.	HPLC-DAD	0,05%
Lactoferrin	I.M.	SDS PAGE	0,01%
Melatonin	I.M.	HPLC-DAD	0,005%

I.M. = Internal Method

ACTIVE SUBSTANCES DESCRIPTION	METHOD	ANALYTICAL TECHNIQUE	LOQ
Methylsulfonylmethane (MSM)	I.M.	GC-FID	0,020%
Methylsulfonylmethane (MSM)	USP-NF METHYLSULFONYLMETHANE TABLETS	GC	-
Myo Inositol (Free form)	I.M.	HPLC	2 mg/kg
N-acetyl cysteine (NAC)	I.M.	HPLC-DAD	0,005%
Octopamine hydrochloride	I.M.	HPLC-DAD	0,009%
Omega Fatty Acids (DHA and EPA)	I.M.	GC	0,5 mg/g
Palmitoylethanolamide (PEA)	I.M.	HPLC-DAD	0,07%
Parthenolide	I.M.	HPLC-DAD	0,003%
Phytosterols	I.M.	GC-FID	0,05%
Quinic Acid	I.M.	HPLC-DAD	0,1%
Salicin	I.M.	HPLC-DAD	0,005%
SAM-e (S-(5'-Adenosyl)-L-methionine p-toluenesulfonate salt)	I.M.	HPLC-DAD	0,001%
Sapogenins (Ruscogenine and Neoruscogenin)	EP 01/2017:1847	HPLC-UV	0,01 g/100g
Sesquiterpene acids expressed as Valerenic acid	I.M.	HPLC-DAD	0,005%
Tannins	EP 01/2008:20814	SPTF-UV	10 mg/kg
Terpene lactones	I.M.	HPLC-RI	0,01 g/100g
Valerenic acids expressed as valerenic acid	I.M.	HPLC-DAD	0,005%
Verbascoside	I.M.	HPLC-DAD	0,005%

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Mérieux NutriSciences

A STRONG PRESENCE IN EUROPE AND WORLDWIDE

MÉRIEUX NUTRISCIENCES OFFERS ITS SCIENTIFIC EXCELLENCE IN PHARMACEUTICAL, FOOD, CHEMICAL, BIOCIDE AND COSMETIC PRODUCTS TESTING AND CONSULTING TO ENSURE SUPPORT, OPTIMAL REACTIVITY AND FLEXIBILITY TO ITS CUSTOMERS ALL OVER THE WORLD.

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