



To whom it may concern:

IJsselstein, the Netherlands August 1st 2023

Certificate of Analysis

APIRx pharmaceuticals hereby certifies that the following dietary food supplement Wellness Gum Extra Strength is produced in the European Union in compliance with the HACCP and EU guidelines and regulations: 852/2004, 178/2002,169/2004 and sold in the USA and Europe. The consumption of the product does not harm the human being and the nutritional components mentioned beneath are approve for use in human being.


Product: Wellness Gum Extra
Strength; Weight 1.8 g per gum.

Ingredients	Weight %
Gumbase	33,000%
Xylitol (E967)	19,100%
Sorbitol (E420)	13,500%
Mannitol (E421)	9,000%
Isomalt (E953)	8,000%
Flavors (natural and synthetic)	5,440%
Arabic gum (E414)	4,200%
Magnesium salt of fatty acids (E470B)	3,600%
Hemp oil (from which 0,56% CBD)	2,500%
THC	0,000%
Titanium dioxide (E171)	0,580%
Talc (E553B)	0,560%
Silicon dioxide (E551)	0,210%
Sucralose (E955)	0,090%
Soy lecithin (E322)	0,063%
Hydroxypropyl methylcellulose (E464)	0,049%
Acesulfame K (E950)	0,047%
Tocopherol (E306)	0,031%
Carnauba Wax (E903)	0,013%
Thaumatococin (E957)	0,009%
Coloring agent (E133)	0,004%

Total


100,00%

Lekhram Changoer MSc BSc
QA & Safety Director

FOOD QUALITY MANAGEMENT SYSTEM		SCH-MG-ST-00	
	Technical Specification Finished Product	Rev. 01 of 2018	Pag. 1/4

PRODUCT NAME: WELLNESS GUM EXTRA STRENGHT 50	
PRODUCER: MD'E Gum Srl – via Tevere, 16 – Castelnuovo Vomano (TE) - I	
OWNER/DISTRIBUTOR: APIRx Pharmaceuticals BV - NL	
CATEGORY: food supplement with Hemp oil. DOSAGE FORM: chewing gum of 1,8 g, peppermint flavor. Net weight: 54 g.	
DESCRIPTION: round shaped chewing-gum, swelling, Ø 16 mm, coated, white color, average weight: 1,8 g ± 5%.	
COMPOSITION	Bulking agent: gum base [gum base; natural and synthetic flavours; anti-caking agent: talc; emulsifier: soy lecithin (E322); antioxidant: tocopherol (E306)]; sweeteners: xylitol, isomalt, sorbitol, mannitol; flavors (natural and synthetics); anti-caking agents: magnesium salts of fatty acids, talc, silicon dioxide; coating agents: arabic gum, flavours, rice starch, maltodextrin, polyvinylpyrrolidone, trehalose dehydrate, Spirulina extract, carnauba wax; Hemp oil (Cannabis sativa L., semen) oil (support: silicon dioxide, hydroxypropyl methylcellulose); sweeteners: sucralose, acesulfame K, thaumatin.
FIRST PACKAGING: blister coupled clear PVDC – AL; serigraphy color: black. Sale blister: 1 blister with 10 chewing gums. SECONDARY PACKAGING: NA	
PHYSICAL-CHEMICAL PARAMETERS	
COATED APPEARANCE/COLOUR	White
CORE APPEARANCE/COLOUR	White to cream
UNCOATED WEIGHT	1,25 g (1,18 g ÷ 1,31 g)
COATED WEIGHT	1,8 g (1,89 g ÷ 1,71 g)
UNCOATED DIAMETER	15 mm (15,75 mm ÷ 14,25 mm)
UNCOATED THICKNESS	7,5 mm (7,8 mm ÷ 7,1 mm)
WATER ACTIVITY (aW) – on the semi-finished product	< 0,500

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FOOD QUALITY MANAGEMENT SYSTEM		SCH-MG-ST-00	
	Technical Specification Finished Product	Rev. 01 of 2018	Pag.2/4


MOISTURE CONTENT (%) – on the semi-finished product	< 5%
MICROBIOLOGICAL PARAMETERS	
CONTAMINANTS	
AEROBIC MESOPHILIC BACTERIAL COUNT	<1 X 10 ⁴ CFU/g
YEAST AND MOULDS	<1 X 10 ² CFU/g
Staphylococcus aureus (**)	Not present/1 g
ENTEROBACTERIACEAE (**)	<10 CFU/g
E. coli	Not present/1 g
Salmonella spp (**)	Not present/25 g
CHEMICAL PARAMETERS	
Content uniformity on 100 g	NA
Uniformity on CFT	NA

NA: Not Applicable

(**) Random verified parameters based on internal sampling plan.

STATEMENTS REGARDING ALLERGENS	
GLUTEN	GLUTEN FREE – This product can be considered gluten free because the concentration is less than <20 ppm (Reg. (CE) No. 41/2009).
LACTOSE	The product does not contain lactose.
ALLERGENS	This product is manufactured in a facility that holds and works all allergens listed in Annex II of Reg. (UE) No. 1169/2011. Allergen: soy derivatives.
OTHER STATEMENTS	
GMO	This product complies with Reg. (EC) N.1829 / 2003 and N.1830 / 2003 and can be declared GMO-free.


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FOOD QUALITY MANAGEMENT SYSTEM		SCH-MG-ST-00	
	Technical Specification Finished Product	Rev. 01 of 2018	Pag.3/4

BSE/TSE	This product complies with Reg. (EC) No 999/2001 and subsequent mod. and int. Up to Reg. (EU) No 27/2016. The product DOES NOT CONTAIN NOT DRIFT and from the risk of transmission of spongiform encephalopathy (BSE / TSE).
PESTICIDES	This product complies with Reg. (EC) No. 839/2008 and No. 310/2011. The product is NOT contaminated by pesticides and DOES NOT CONTAIN contaminated materials.
PAH	This product complies with Reg. (CE) N. 1933/2015. The product is NOT contaminated with polycyclic aromatic hydrocarbons and DOES NOT CONTAIN contaminated materials.
HEAVY METALS	This product complies with Reg (EC) 78/2005, N.1881 / 2006 and No 629/08 concerning the presence of heavy metals. The product MEETS THE LIMITS set for lead, cadmium, mercury, arsenic.
MYCOTOXIN	This product complies with Reg. (EC) N.1881 / 2006 and succ. mod. and int. In the field of mycotoxins. The product DOES NOT CONTAIN and DOES NOT CONTAIN contaminated materials.
IRRADIATION	This product is in compliance with Reg. (EC) No. 2/1992 and No. 3/1999. The product is NOT SUFFERED irradiation / ionization processes, nor has it been made with raw materials that have undergone such processes.
MOCA	The materials in contact with the product comply with Reg. EC 10/2011 (plastics and articles intended to come into contact with food) and with the EC Reg. 1935/2004 (materials and objects intended to come into contact with food).
CERTIFICATIONS	This product has no Kosher Certification, Halal, Organic.

OTHER INFORMATIONS	
INTENDED USE	Food supplement with Hemp oil.
CLAIMS (Reg. UE 432/2012)	NA
HOW TO USE	It is suggested to take 1 gum daily when necessary.
STORAGE CONDITIONS	Store in a cool (<25°C) and dry place and away from the heat and the sun.
MODE OF TRANSPORT	Ordinary and room temperature transport. Expected delivery time may depend on the place of destination.
MINIMUM SHELF LIFE	24 months (from production date and in the final packaging)

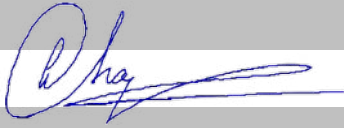
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FOOD QUALITY MANAGEMENT SYSTEM		SCH-MG-ST-00	
	Technical Specification Finished Product	Rev. 01 of 2018	Pag.4/4

INSTRUCTIONS AND PRECAUTIONS	<ul style="list-style-type: none"> Keep out of reach of children under the age of Foods supplements are not intended to substitute a varied balanced diet and a healthy lifestyle. Do not exceed the recommended dose. The expiry date refers to the product unopened form and stored correctly. The product contains polyols therefore an excessive consumption may cause a laxative effect. 																													
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R&D Dept.
QC Lab.
29/07/2020

Date	Version	Description of changes
29/07/2020	Rev. 00	First issue
27/08/2020	Rev. 01	Second issue
01/09/2020	Rev. 02	Third issue

Customer approval	
Name	
Signature	
Title	
Date	

Note: We kindly ask to you to stamp, sign this present document and returned it to us within six (6) days. After this period we will consider it accepted and approved.

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