



S.I.I.T. S.r.l. UNIPERSONALE

Innovative Healthcare Products Contract Development & Manufacturing

CERTIFICATE OF ANALYSIS

Certificate N° **1_2211654**

Product Code: **06007100**

Customer **DELTA MEDICAL PROMOTIONS AG**

Product **ZEST MULTIVITAMIN, tablets#60**

Batch N° **NW512**

Expiry Date **10/2025**

Test	Result	Specification
HPLC identification of Vitamin B12	Positive	Positive
HPLC identification of Vitamin D	Positive	Positive
HPLC identification of Vitamin E	Positive	Positive
HPLC content of Vitamin A	904 mcg/tablet	640 ÷ 1200 mcg/tablet
HPLC content of Vitamin B1	1,36 mg/tablet	0,88 ÷ 1,65 mg/tablet
HPLC content of Vitamin B2	1,76 mg/tablet	1,12 ÷ 2,10 mg/tablet
HPLC content of Vitamin PP (Vitamin B3)	18,0 mg/tablet	12,8 ÷ 24,0 mg/tablet
HPLC content of Pantothenic acid (Vitamin B5)	7,04 mg/tablet	4,80 ÷ 9,00 mg/tablet
HPLC content of Vitamin B6	1,69 mg/tablet	1,12 ÷ 2,10 mg/tablet
HPLC content of Vitamin H (Vitamin B8)	61 mcg/tablet	40 ÷ 75 mcg/tablet
HPLC content of Folic acid (Vitamin B9)	259 mcg/tablet	160 ÷ 300 mcg/tablet
HPLC content of Vitamin B12	3,08 mcg/tablet	2,00 ÷ 3,75 mcg/tablet



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S.I.I.T. Servizio Internazionale Imballaggi Termosaldanti srl
Stabilimento autorizzato alla produzione di specialità medicinali e dietetici per conto terzi
Cap. Soc. € 2.000.000 int. Vers. - R.E.A. Milano N. 535706 - Reg.Imprese/Partita I.V.A./Cod. Fisc. 00820090157
PEC:direzioneamministrativa.siiit@pec.it



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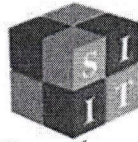
Test	Result	Specification
Appearance	Complies	Three-layer tablets red, grey-green, yellow
Dissolution test fast layer <i>in 5 minutes (marker = Vitamin B3/PP)</i>	109 %	> 75 %
Dissolution test normal layer <i>in 45 minutes (marker = Zinc)</i>	97 %	> 75 %
Dissolution test retard layer 8° hour <i>(marker = Vitamin C)</i>	94 %	> 90 %
HPLC identification of Vitamin A	Positive	Positive
HPLC identification of Vitamin B1	Positive	Positive
HPLC identification of Vitamin B2	Positive	Positive
HPLC identification of Vitamin PP <i>(Vitamin B3)</i>	Positive	Positive
HPLC identification of Pantothenic acid <i>(Vitamin B5)</i>	Positive	Positive
HPLC identification of Vitamin B6	Positive	Positive
HPLC identification of Vitamin H <i>(Vitamin B8)</i>	Positive	Positive
HPLC identification of Folic acid <i>(Vitamin B9)</i>	Positive	Positive



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CERTIFICATE OF COMPLIANCE

Customer: **DELTA MEDICAL PROMOTIONS AG**

Product: **ZEST MULTIVITAMIN, tablets#60**

Batch N°: **NW512**

Expiry date: **10/2025**

We declare the batch compliance with:

-Chemical specifications (where applicable)

Guidelines on analytical tolerances applicable for the official (Italian Ministry of Health, 16/06/2016); Ref. Decree of Dep. of Health n°7, 30/10/2002.

-Microbiological specifications

Ref. Regulation CE n°2073/2005 and amendments and/or Ph. Eur. current edition.

SIIT guarantees the above compliance according to its own analytical plan.

-Specifications for primary packaging and labelling

Ref. Regulation CE n°2023/2006; Regulation CE n°1935/2004; Decree of Dep. of Health 21/03/1973 and amendments.

-Specifications related to in process controls

Internal Standard operating procedures.

We declare that the production and packaging steps comply with the SIIT self-control plan HACCP, according to the regulation CE 852/2004

THE BATCH HAS BEEN APPROVED

QC Manager Flavio Gazzuso

Date 28/11/2022

SIIT can support this declaration with all in process documentation. The request must be directed to the QC Manager, within 15 days after the product shipment.

The producer recommends for the maintenance of properties and quality of the product the following storage conditions:

- < 25°C
- 15-25°C
- 8--25°C
- 2-8°C

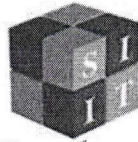
We recommend also, not to expose the product to hot localized fonts, to sun and to water contact.

The producer is not responsible for damaged products which are caused by improper storage.

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Test	Result	Specification
Potentiometric content of Vitamin C	93 mg/tablet	64 ÷ 120 mg/tablet
HPLC content of Vitamin D	6,26 mcg/tablet	4,00 ÷ 7,50 mcg/tablet
HPLC content of Vitamin E	15,9 mg/tablet	9,6 ÷ 18,0 mg/tablet
Copper	1,09 mg/tablet	0,80 ÷ 1,45 mg/tablet
Iron	14,2 mg/tablet	11,2 ÷ 20,3 mg/tablet
Manganese	2,03 mg/tablet	1,60 ÷ 2,90 mg/tablet
Molybdenum	63,1 mcg/tablet	40,0 ÷ 72,5 mcg/tablet
Zinc	11,6 mg/tablet	8,0 ÷ 14,5 mg/tablet
Selenium	50,1 mcg/tablet	40,0 ÷ 72,5 mcg/tablet
Chromium	21,4 mcg/tablet	20,0 ÷ 36,3 mcg/tablet
Magnesium	54,01 mg/tablet	45,00 ÷ 84,56 mg/tablet
Cadmium <i>LoD = limit of detection</i> <i>LoQ = limit of quantitation</i>	< LoQ (= 0,000053 mg/kg) mg/Kg	<= 1,000 mg/Kg



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Test	Result	Specification
Mercury <i>LoD = limit of detection</i> <i>LoQ = limit of quantitation</i>	0,006 mg/Kg	<= 0,100 mg/Kg
Lead <i>LoD = limit of detection</i> <i>LoQ = limit of quantitation</i>	0,254 mg/Kg	<= 3,000 mg/Kg
Enterobacteriaceae	< 10 cfu/g	<= 100 cfu/g
Listeria monocytogenes	< 100 cfu/g	<= 100 cfu/g

APPROVED

QC Manager

Date **28/11/2022**



/Логотип компанії/

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Innovative Healthcare Products Contact Development & Manufacturing

СЕРТИФІКАТ АНАЛІЗУ

Сертифікат № 1_2211654

Код продукту: 06007100

Замовник **ДЕЛЬТА МЕДІКЕЛ ПРОМОУШІЗ АГ**

Продукт **ЗЕСТ МУЛЬТИВІТАМІН, таблетки №60**

Серія № **NW512**

Дата закінчення терміну придатності **10/2025**

ТЕСТ	РЕЗУЛЬТАТ	СПЕЦИФІКАЦІЯ
Залізо	14,2 мг/таблетка	11,2 ÷ 20,3 мг/таблетка
Марганець	2,03 мг/таблетка	1,60 ÷ 2,90 мг/таблетка
Молібден	63,1 мкг/таблетка	40,0 ÷ 72,5 мкг/таблетка
Цинк	11,6 мг/таблетка	8,0 ÷ 14,5 мг/таблетка
Селен	50,1 мкг/таблетка	40,0 ÷ 72,5 мкг/таблетка
Хром	21,4 мкг/таблетка	20,0 ÷ 36,3 мкг/таблетка
Магній	54,01 мг/таблетка	45,00 ÷ 81,56 мг/таблетка
Кадмій LoD = межа виявлення LoQ = межа кількісного визначення	< LoQ (= 0,000053 мг/кг) мг/кг	<= 1,000 мг/кг
Меркурій LoD = межа виявлення LoQ = межа кількісного визначення	0,006 мг/кг	<= 0,100 мг/кг
Свинець LoD = межа виявлення LoQ = межа кількісного визначення	0,254 мг/кг	<= 3,000 мг/кг
Ентеробактерії	< 10 КУО/г	<= 100 КУО/г
Лістерія моноцитогенна	< 100 КУО/г	<= 100 КУО/г

ЗАТВЕРДЖЕНО

Керівник служби контролю якості /підпис/

Дата **28.11.2022**

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SEDE LEGALE E STABILIMENTO: 20090 TREZZANO sul NAVIGLIO (MI) - Via Ariosto, 50/60 - Tel. 02 4843521 r.s. - Fax 02 48401793
Cap.Soc. C 50.590 Int.vers. - Reg delle Impr. di Milano N. 147406 - R.E.A. Milano N. 535706 - Partita I.V.A. Cod. Fisc. 00829090157

/Логотип компанії/

