Számlaszám : HUF-2021-00046520 **Kelt :** 2021.07.01 **Lejárat :** 2022.08.31

Cikk neve : Magne B6 Izom Plusz étrend kieg ftb 30x **Gyszám :** AR16FX

Certificate of Analysis / Batch Certificate

SANOFI

SANOFI-AVENTIS Sp. z o.o.
ul. Lubelska 52, Rzeszów, 35-233, Poland
Tel. +48 17 850 25 00

Authorisation Number: 167/0190/15
EudraGMDP Reference Number: 84226

Product Name:	**MAGNE B6 IZOM PLUSZ**		
Batch No:	**AR16FX**	Strength:	50 MG
GMID Code:	572492	Country:	Hungary
Dosage Form:	Coated tablets	Manufacturing Date:	16/03/2021
Packaging:	30x Tablets in blisters	Expiry Date:	AUG-2022

TESTS	SPECIFICATIONS	RESULTS
Appearance	oval coated tablets	complies
Colour	White	complies
Dimensions:		
- lenght	15.5 - 16.1 [mm]	15.9 mm
- width	9.8 - 10.4 [mm]	10.1 mm
Disintegration time	no longer than 45 [min]	22 min
Loss on drying	not more than 4 [%]	2.3 %
Average mass	881 - 973 [mg]	929 mg
Identification:		
- of vitamin B1 (Thiamine) by HPLC	complies	complies
- of vitamin B6 (Pyridoxine) by HPLC	complies	complies
- of vitamin D3 (Cholecalciferol) by UPLC	complies	complies
- of vitamin E (Alfatocopherol) by UPLC	complies	complies
- of magnesium ions by IC	complies	complies
- of potassium ions by IC	complies	complies
Assay by HPLC:		
- of vitamin B6 (Pyridoxine)	0.38 - 0.71 [mg/tbl]	0.42 mg/tbl
- of vitamin B1 (Thiamine)	0.30 - 0.56 [mg/tbl]	0.51 mg/tbl
Assay by UPLC:		
- of vitamin E (Alfatocopherol)	3.2 - 6.0 [mg/tbl]	5.3 mg/tbl
- of vitamin D3 (Cholecalciferol)	1.34 - 2.51 [ug/tbl]	2.01 ug/tbl
Assay by IC:		
- of Magnesium Citrate (expressed as Mg2+ ions)	42.5 - 57.5 [mg/tbl]	50.1 mg/tbl

Felszabadította : dr. Turbucz Béla 2021.04.26

Minőségbiztosítási sorszám : 2107712

PHARMAROAD KFT.
1106 Budapest, Kálvin u.2.
MINŐSÉGBIZTOSÍTÁS

Eredetivel megegyező elektronikus másolat

Számlaszám : HUF-2021-00046520 **Kelt :** 2021.07.01 **Lejárat :** 2022.08.31

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TESTS	SPECIFICATIONS	RESULTS
- of Potassium Citrate (expressed as K+ ions)	85.0 - 115.0 [mg/tbl]	99.5 mg/tbl
Heavy metals by ICP (first 3 batches, then 1 batch per year)		
- lead (Pb)	not more than 3 [ppm]	not applicable
- cadmium (Cd)	not more than 1 [ppm]	not applicable
- mercury (Hg)	not more than 0.1 [ppm]	not applicable
Microbiological purity:		
- total aerobic microbial count (TAMC) in 1g	not more than 1000 [CFU/g]	<10 CFU/g
- total combined yeasts/moulds count (TYMC) in 1g	not more than 100 [CFU/g]	<10 CFU/g
- Escherichia coli in 1g	absent	absent
- Staphylococcus aureus in 1g	absent	absent
- Salmonella in 25g	absent	absent

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation (S) of the destination country/countries

Quality Decision

Status of Decision:	Released
Date of Decision (UTC+1):	8-APR-2021 14:21:07.00
Quality Person:	Kochmanski Grzegorz

This Certificate of Analysis has been electronically signed from a validated LIMS

Felszabadította : dr. Turbucz Béla 2021.04.26

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