METAPHARMACEUTICAL

TECHNICAL DATA SHEET

002734-TDS-ENG-2026

CAPSULAS 000 BLANCAS		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: ---	EC Nº: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 002734

ATTRIBUTES	SHOULD BE
Gelatine Identification	Positive
TiO2 Identification	Complies
Physico-chemical parameters	
Average weight	153 - 173
Desintegration time	<= 15 min
Sulfated ash	<= 7 %
Loss on drying	13.0 - 16.0 %
Lubricant content	<= 0.5
Dioxido de sulfuro	<= 50
Heavy metals	
Arsenic	<= 1 ppm
Cadmium	<= 0.5 ppm
Cobalt	<= 5 ppm
Chromium	<= 2 ppm
Mercury	<= 0.1 ppm
Nickel	<= 20 ppm
Lead	<= 1 ppm
Vanadium	<= 10 ppm
Microbiological control	
TAMC	<= 1000 CFU/g
TYMC	<= 100 CFU/g
E. Coli	Absence/1g
S. Aureus	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/10g

COMPLIES WITH

Manufacturer Specifications

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Body composition:
Titanium dioxide: 2.0000%
Gelatin: qsp 100%

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Cap composition:
Titanium dioxide: 2.0000%
Gelatin: qsp 100%

Store at: 15 - 25 oC and 35% - 65% relative humidity

Opacifer: Titanium dioxide: E171; C.I. Nº 77891; conform to (EU) 231/2012, 21 CFR, EP, JP, USP/NF

Structure: Gelatin: conform to EP, JP, USP/NF

In accordance with ICH Q3C residual solvent guideline, Class 3 Solvents may be used according to good manufacturing practices such that their cumulative value does not exceed 5000ppm or 0.5%, under option 1 as defined in ICH Q3C, USP<467>, and EP General Text 5.4.

Manufacturing process:
No Ethylene Oxide Treatment
No Addition of Preservatives
No Irradiation Treatment

Heavy Metals:
With reference to ICH Q3D and other applicable standards controlling levels of elemental impurities in drug products and food supplements, the empty capsules are meeting below levels of applicable elements. Monitoring testing is in place under validated methods. A documented risk assessment based on the ICH Q3D principles is available.

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