93283-CAPSULES 00 YELLOW

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.
Name: Capsules 00 yellow
Bulk code: 93283
Internal code: 55200
Valid from batch: 0120284

1.2 Synonyms.
No data available.

2. DESCRIPTION

Appearance: Two pieces of hard gelatin. The gelatin used meets all the requirements of the European Pharmacopoeia and USP.
The hard gelatin capsule sections are separated freely before filling and the edges of the separated cap and body are cut cleanly and evenly with no visible roughness.

Size: 00
Head/body color: yellow/yellow
Color Index No .: 19-11 / 19-11
Head external diameter (mm): 8.55±0.03
Body external diameter (mm): 8.22±0.03
Odor: Odorless
Taste: Tasteless
Origin: Croatia
Preparation method: The capsules are made with pharmaceutical grade gelatin.

Approximate capsule filling content in mg

Density / Size	0.6g/ml	0.8g/ml	1.0g/ml	1.2g/ml
00	570	760	950	1,140

3. COMPOSITION/INFORMATION ON COMPONENTS.

Capsule composition:

93283-CAPSULES 00 YELLOW

COMPONENT	HEAD PERCENTAGE	BODY PERCENTAGE
Water	14-15%	14-15%
Sunset Yellow E-110 (Colorant)	0.0044%	0.0044%
Quinolone Yellow E-104 (Colorant)	0.9197%	0.9197%
Titanium Dioxide E171 (opacifier)	1.33%	1.33%
Jelly	Csp 100%	Csp 100%

Limitations: The composition data indicated are target values based on laboratory scale development. Actual values may vary depending on color.

The product is manufactured in an ISO certified plant.

Regulatory information under food law on the color used:
Products to be consumed in the European Union use colors that comply with (EU) 231/2012 which establishes specifications for food additives.
Where applicable, as in products to be consumed in the US, the colors are certified by the FDA in accordance with 21CFR parts 73 and 74 for foods and drugs.
The amount of color additive used in the above product is in accordance with the ADI according to WHO/FAO as applicable.
Globally accepted colorants, such as iron oxides, when used conform to the acceptance criteria of regulated markets such as the EU and USA.
The elemental iron content does not exceed 5 mg per day according to 21CFR part - 73.120 for foods and part 73.1200 for drugs.

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, consult the analysis bulletin.
hard gelatin capsules they disintegrate in less than 15 minutes .

5. PROPERTIES/USES.

The capsules are SUITABLE for human consumption.
Hard gelatin capsules are distributed worldwide and are designed for use in pharmaceutical and food products.
The capsules hard gelatin they are soluble in hot water 98.6 °F ± 1.8 ° F (37 ° c ± 1 ° C).
Moisture content of gelatin capsules hard remains between 13% and 16% .

6. DOSAGE.

No data available.

7. OBSERVATIONS.

SPECIFICATION:

The capsules comply with all the requirements established in the EP and USP .

STORAGE:

The capsules are manufactured with a moisture content carefully controlled and you have to consider this to get the best performance filling; if the conditions are not are respected will appear problems of maintenance . The capsules they will be too dry and brittle and will contract due to the loss of moisture , or they will become sticky and soft due to the greater humidity.

The capsules they keep their characteristics , as long as they are stored at temperatures between fifteen ° c and 25 ° C , and to a humidity relative of 35 % to 65 % and the following precautions are taken into account :

- The capsules not must be exposed directly to the sunlight or stored near fountains of heat or humidity . They must be stored in a dry place and fresh and they should be allowed balance the conditions in the filling area before using .
- The capsules They must be kept in their original packaging . The containers will be tightly closed during his transportation and storage to guarantee its quality through time . In the case of one is extracted amount of capsules For any exam or For filling , it is essential to close perfectly the packaging .
- It's recommended that during filling of capsules , only the number of capsules necessary , to avoid expose them heat of the filling machines they generate. The areas filling must be between twenty ° c and 25 °C already a humidity relative between 45 % and 55 % to maintain moisture content of the capsules in it desired range of 13 % to 16 %.

The documentation corresponding to the regulatory part of the product that is available for it is what we reflect below

BSE/TSE:

The gelatin used is a pharmaceutical grade gelatin mixture based on product quality requirements and regulations. All gelatin used complies with the pharmacopoeia and applicable food standards. Bovine gelatin, when used is derived from the bones and skins of healthy animals that have been certified as fit for human consumption by a veterinary officer at the slaughterhouse. The fabrics used in the manufacture of gelatin are free of specified risk materials.
Additionally, bovine gelatin complies with the following regulations applicable in the country of BSE use such as:

- Regulation (EC) No. 999/2001 and its amendments.
- Regulation (EC) No. 853/2004.

• USFDA, September 1997, Guidance for Industry on Sourcing and Processing Gelatin to Reduce the Potential Risk Posed by BSE in FDA-Regulated Products.
• USFDA 21 CFR parts 189, 589, 700 related to livestock materials prohibited in human foods, drugs and cosmetics, and animal feed.
• USFDA 9 CFR Part 94.23 regarding the importation of bovine gelatin.
• Commission Directive 2003/63/EC and Ph. Eur – 1483, accredited by the certificate of suitability.
• Note on the Guide to minimize the risk of agents of transmission of animal spongiform encephalopathy via products for human and veterinary use (EMA/410/01 Rev. 03).
• Furthermore, no ingredients of animal origin are used in the manufacturing of the above product.

Therefore, hard gelatin capsule shells do not pose any risk of BSE.

GMO:

Hard gelatin capsule shells are not subject to or derived from any genetic modification techniques as defined in Article 2(2) of European Directive 2001/187EC.
The ingredients used in the manufacture of the above product are not subject to or derived from any genetic modification techniques as defined above.
The ingredients used in the manufacturing of the above product can be traced back to its origin.
The product does not contain GMO (Genetically Modified Organisms).
According to the above, hard gelatin capsule shells comply with EC 298/2008 (previously 189/2003) and EC 1830/2003 on genetically modified food and feed.

NANOMATERIALS:

The product is not considered a nanomaterial according to the definition described in the EC directive 1169/2011.
Furthermore, the ingredients used in the above product are not manufactured as nanomaterials nor is nanotechnology used.

RESIDUAL SOLVENTS:

Hard gelatin capsule shells do not contain any Class I and II solvents according to CPMP/ICH/283/95 and the current edition of USP General Chapter <467> on Residual Solvents.
The following class III solvents (glacial acetic acid, isopropyl alcohol , ethyl alcohol and n-butyl alcohol) are likely to be present in our product in amounts less than 5000 ppm. No other solvents are used in the manufacturing process.

ELEMENTAL IMPURITIES:

The product complies with:

- ICHQ3D Guide to Impurities elementals , final version of April 26 , 2022.

- EMA/CHMP/ICH/353369/2013 ICH Q3D Guide to Impurities elemental from March 22 , 2019.
- USP <232> Impurity Limits elementals .

Regulatory compliance is based on three _ _ components of the ICH Q3D: the evaluation of the potentials impurities elementals , comparison of levels potentials with exposure daily permitted (PDE) for each element of toxicological concern and controls development _ designed for limit the inclusion of impurities elementals in products medicinal by below (PDE) .

CONTAMINANTS:

Melamine : The capsules do not contain melanin.
Gluten: The capsules are gluten free.
Aflatoxins : The capsules do not contain aflatoxins .
Pesticides: The capsules contain no residual pesticides and are safe for human consumption.
Dioxins: The capsules do not contain dioxins.
PAH and PCB: The capsules do not contain PAH or PCBs.

ALLERGENS:

Allergen-free according to VO (EU) No. 1169/2011 and US FDA Industry Guide (Labeling on food allergens and consumer protection).
The possible presence of SO_2 comes from the used gelatin and is found in quantities less than 50 ppm.

PRESERVATIVES:

The product does not contain preservatives.

MANUFACTURER CERTIFICATIONS:

cGMP , ISO 9001:2015, 14001:2015, Kosher, Halal ,