



CAPSULAS N° 2 ROJO (fuente ACG)

PRODUCT CODE: 46433076	CAS N°: ---	ANALYSIS N°: C05/24
MANUFACTURER BATCH: 4100036832	CERTIFICATE ID: 43.672	
SUPPLIER BATCH: 240413-BO020455	MANUFACTURING DATE: 28/04/2024	
METAPH BATCH: 0041024	EXPIRY DATE: 31/01/2029	

ATTRIBUTES	SHOULD BE	IS
Colour	According to approved color tone	Complies
Identification		
Gelatin	Complies	Complies (**)
Titanium dioxide	Complies	Complies
Dimensional and physical tests		
Average weight	58.6 - 67.4 mg	63.5 mg
Odour	No strange smell	Complies
Chemical tests		
Gelatin	<= 15 min	1 min (***)
Purified water	UPSNF + Ph. Eur.	Complies
Loss on drying	Ph. Eur.	Complies
Sulfated ash	13.0 - 16.0 %	14.8 %
Lubricants	<= 7.0 %	Complies
Arsenic	<= 0.5 %	Complies
Cadmium	<= 1 ppm	Complies
Mercury	<= 0.5 ppm	Complies
Lead	<= 50 ppm	Complies
Microbiological control		
TAMC	<= 0.1 ppm	Complies
TYMC	<= 1 ppm	Complies
E. Coli	0 - 1000 CFU/g	20 CFU/g
Salmonella	0 - 100 CFU/g	< 10 CFU/g
P. Aeruginosa	Absence/1g	Absence/1g
Staphylococcus aureus	Absence/10g	Absence/10g
Capsule colour formulation		
Cap	Absence/1g	Absence/1g
Body	Ponceau 4R	0.5010 %
	Azorubine	0.1916 %
	Titanium Dioxide (Opacifier)	1.1000 %
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	Azorubine	
	Titanium Dioxide (Opacifier)	1.1000 %

COMPLIES WITH

Manufacturer Specifications

REMARKS

All data have been adapted from the authorized supplier's certificate of analysis.

The design weight of one size of capsules is 63.5 mg, the cap represents 40% and the body 60% of the capsule weight. The average weight of 100 capsules can vary between 58.6 - 67.4 mg.

Analysis date: 15/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies

Manufacturer: 40001159

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SUPPLIER BATCH:	240413-BO020455	MANUFACTURING DATE:	28/04/2024
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Raw material

GELATIN (**): Complies with the requirements of the current Editions of Eur. Ph. and USP/NF. It is of purely bovine origin, it complies with the current revision of the European guideline EMEA/410/01. Each supplier has a CEP for their product (R1-CEP-2000-027-Rev.02), R1-CEP-2000-029-Rev.05, R1-CEP-2000-045-Rev.03, R1-CEP- 2002-110-Rev.00 and R1-CEP-2001-211.Rev.01)

DYES: They comply with Directive 2009/35, Commission Regulation 231/2012 and, where applicable, with the requirements of the Eur. Ph. and USP/NF pharmacopoeias.

PRINTING INKS: They comply with pharmaceutical regulations.

Capsules

It does not contain preservatives and has not been treated with ethylene oxide. They comply with the CPMP/ICH/283/95 guideline of the European Agency for the Evaluation of Medicinal Products (EMA) and with the European Pharmacopoeia for residual solvents.

DISINTEGRATION (***): Less than 15 minutes per test according to Eur. Ph.. They have a breakdown time of less than 5 minutes according to US Federal Specification 285a on the acid solubility test.

With this we certify that the above information has been approved by technical management in accordance with the specifications, as described by the applicable regulatory requirements.

STORAGE

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

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