



TECHNICAL DATA SHEET

010535-TDS-ENG-2022

MEBICAR		
DESCRIPTION DCI: MEBICAR		DESCRIPTION DOE: MEBICAR
CAS N°: 10095-06-4	EC N°: 682-123-5	AEMPS CODE: ---
MOL. WEIGHT: 198.22	MOL. FORMULA: C ₈ H ₁₄ N ₄ O ₂	ARTICLE CODE: 010535

ATTRIBUTES	SHOULD BE
Appearance	White crystalline powder, odourless
Solubility	Freely soluble in water, chloroform, soluble in ethyl alcohol
Identification A	Complies
Identification B	Complies
Identification C	Complies
Melting point	225.0 - 229.0 °C
Clarity of solution	Clear comparing with ref. sus. I
Colour of solution	No more than ref. sol. B9
pH	5.9 - 7.5
Chlorides	=< 100 ppm
Sulfates	=< 500 ppm
Sulfated ash	=< 0.1 %
Loss on drying	=< 0.5 %
Heavy metals	=< 10 ppm
Related substances	
1,3-dimethylurea	=< 0.10 %
1,3-dimethylhydantoin	=< 0.10 %
Unspecified impurities	=< 0.10 %
Total of impurities	=< 0.50 %
Residual solvents	
Isopropyl alcohol	=< 5000 ppm
n-butanol	=< 500 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
E. Coli	Absence/1g
Assay	99.0 - 101.5 %

COMPLIES WITH

Manufacturer Specifications

STORAGE

Keep the container tightly closed. Store it in a dry and well-ventilated place, protected from the sunlight.

REMARKS

Mebicar is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.



TECHNICAL DATA SHEET

010535-TDS-ENG-2022

MEBICAR		
DESCRIPTION DCI: MEBICAR		DESCRIPTION DOE: MEBICAR
CAS N°: 10095-06-4	EC N°: 682-123-5	AEMPS CODE: ---
MOL. WEIGHT: 198.22	MOL. FORMULA: C ₈ H ₁₄ N ₄ O ₂	ARTICLE CODE: 010535

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.