METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002915-TDS-ENG-2025

CARBIDOPA (EUR. PH.)		
DESCRIPTION DCI: CARBIDOPA	DESCRIPTION DOE: CARBIDOPA	
CAS Nº: 38821-49-7	EC Nº: 249-271-9	AEMPS CODE: 564A
MOL. WEIGHT: 244,2	MOL. FORMULA: C10H14N2O4·H2O	ARTICLE CODE: 002915

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white powder
Solubility	Slightly soluble in water, very slighlty soluble in ethanol (96%), practically insoluble in methylene chloride. It dissolves in dilute solutions of mineral acids.
Identification A	Complies
Identification C	Complies
Appearance of solution	The solution is clear and not more intensely coloured than reference solution BY6 or B6
Specific optical rotation	-26,5 to -22,5
Hydrazine	Complies
Related substances	
Impurity A	=< 0,5%
Impurity J	=< 0,25%
Sum of impurities D and E	=< 0,2%
Impurities F, H, I	=< 0,15%
Unspecified impurities	=< 0,10%
Total impurities	=< 1,0%
Loss on drying	6,9% - 7,9%
Sulfated ash	=< 0,1%
Assay	98,5% - 101,0%

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Carbidopa is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.

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.