METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

410-TDS-ENG-2023

CLONIDINA HCL (EUR. PH.)		
DESCRIPTION DCI: CLONIDINE HCl	DESCRIPTION DOE: CLONIDINA HCl	
CAS Nº: 4205-91-8	EC Nº: 224-121-5	AEMPS CODE: 636CH
MOL. WEIGHT: 266.56	MOL. FORMULA: C9H9Cl2N3·HCl	ARTICLE CODE: 410

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water and in anhydrous ethanol
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
pH	4.0 - 5.0
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a well-ventilated place. Keep container tightly closed.

REMARKS

Clonidine HCl 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.