

**CLONIDINA HCL (EUR. PH.)**

PRODUCT CODE: 410	CAS Nº: 4205-91-8	ANALYSIS Nº: 159/24
MANUFACTURER BATCH: CLD20240321	CERTIFICATE ID: 42.497	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 21/03/2024	
METAPH BATCH: 0050624	EXPIRY DATE: 20/03/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Soluble in water and in anhydrous ethanol	Complies (*)
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
pH	4.0 - 5.0	4.7
Related substances		
Unspecified impurities	=< 0.10 %	0.08 %
Total impurities	=< 0.2 %	0.08 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	98.5 - 101.0 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 20/06/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349