METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002938-TDS-ENG-2024

HALOPERIDOL (EUR. PH.)		
DESCRIPTION DCI: haloperidol	DESCRIPTION DOE: HALOPERIDOL	
CAS Nº: 52-86-8	EC Nº: 200-155-6	AEMPS CODE: 1693A
MOL. WEIGHT: 375,87	MOL. FORMULA: C21H23ClFNO2	ARTICLE CODE: 002938

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Practically insoluble in water, slightly soluble in ethanol (96 %), in methanol and in methylene chloride
Identification B	Complies
Identification E	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Related substances	
Impurity D	=< 0.5 %
Impurity B	=< 0.3 %
Impurity G	=< 0.15 %
Impurity H	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.0 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Haloperidol 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.

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.