METAPHARMACEUTICAL IND SL
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HALOPERIDOL (EUR. PH.)

PRODUCT CODE: 002938	CAS Nº: 52-86-8	ANALYSIS Nº: 208/24	
MANUFACTURER BATCH:	HAL3002417	CERTIFICATE ID:	43.184
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/07/2024
METAPH BATCH:	0030824	RETEST DATE:	30/06/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water, slightly soluble in ethanol (96 %), in methanol and in methylene chloride	Complies (*)
Identification B	Complies	Complies
Identification E	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7	Complies
Related substances		
Impurity D	=< 0.5 %	Not Detected
Impurity B	=< 0.3 %	< 0.05 %
Impurity G	=< 0.15 %	Not Detected
Impurity H	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 1.0 %	< 0.05 %
Loss on drying	=< 0.5 %	0.1 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	99.0 - 101.0 %	100.3 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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

(*) 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

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

Analysis date: 09/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001140