

HALOPERIDOL (EUR. PH.)

PRODUCT CODE: 002938	CAS Nº: 52-86-8	ANALYSIS Nº: 182/21
MANUFACTURER BATCH: HAL3002112	CERTIFICATE ID: 32.275	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2021	
METAPH BATCH: 0090721	RETEST DATE: 30/04/2026	

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 %	0.09 %
Impurity G	=< 0.15 %	Not Detected
Impurity H	=< 0.15 %	0.06 %
Unspecified impurities	=< 0.10 %	0.09 % (RT = 15.99 min)
Total impurities	=< 1.0 %	0.24 %
Loss on drying	=< 0.5 %	0.03 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 101.0 %	100.6 %
Residual solvents [In-house]		(*) (**)
Ethyl acetate	=< 800 ppm	172 ppm
Methanol	=< 100 ppm	2 ppm
Methylene Chloride	=< 100 ppm	< LoD
Toluene	=< 400 ppm	< LoD
Benzene	=< 2 ppm	< LoD

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Haloperidol is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

Analysis date: 16/09/2021
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001140
 RPG LIFE SCIENCES
 25, MIDC Land, Thane- Belapur Road
 400703 NAVI MUMBAI
 (India)





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STORAGE

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

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