



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		
МЕТАРН ВАТСН:	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 quidelines 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.

Analysis date: 16/09/2021

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

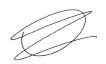
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