



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241631

Product:	IDEBENONE
Lot:	241631
Expiry date:	25/02/2027
Reference:	Especificaciones de fabricante
Synonyms:	
Formule:	C19H30O5
Poids moléculaire:	338,44 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,C)	Test (A, B, C)	
Organoleptic properties	Conform	Complies	
Melting point	54 °C	52 - 55 °C	
Absorption index	463	458 - 486	
Related substances (HPLC)	Conform	Conforme	
Loss on drying	0,00 %	<= 0,1 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay (HPLC)	99,6 % s.p.s.	>= 98,5 % s.p.s.	
Any impurity	0,16 %	<= 0,8 %	
Total impurities	0,18 %	<= 0,8 %	
Elemental impurities	Conform	Test	#
Residual solvent: Hexane	< 290 ppm	<= 290 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#

Organoleptic characteristics: Crystalline, yellow or yellow-orange powder. Insoluble in water, very soluble in methanol and chloroform, easily soluble in absolute ethanol and ethyl acetate.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 23/09/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00065 SUZHOU LIXIN PHARMACEUTICAL CO. LTD

Manufacturer batch: C07-20240403

Produit	Nom	Capacité	Lot
1160018	IDEBENONA	250 g	241631-N-1
1160020	IDEBENONA	1 kg	241631-P-2
1400332	IDEBENONA	100 g	241631-J-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.
Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

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