

## Certificat d'analyse

Produit

### Idébenone

N° Lot	<b>PR200901</b>	Date de fabrication	05/2020
CAS-Nr.	58186-27-9	Date de retest	<b>01/05/2025</b>

Paramètres	Spécifications internes fabricant	Résultats
Aspect*	Poudre cristalline jaune orangé sans agrégats.	Conforme
<b>Identité</b> Spectre IR* Point de fusion*	Conforme au standard Selon spécifications	Conforme Conforme
<b>Pureté</b> Aspect de la solution (10% dans acétate d'éthyle)* Cendres sulfuriques* Métaux lourds* Eau* Substances apparentées (CL)* - Impureté A* - Impureté B* - Impureté C* - Toute impureté non spécifiée (valeur maximale)* - Total des impuretés*	Pas plus opalescente que la solution de référence II de la Ph. Eur. ≤ 0.10% ≤ 20 ppm ≤ 0.20% ≤ 0.50% ≤ 0.05% ≤ 0.05% ≤ 0.05% ≤ 1.0%	Conforme 0.01% < 20 ppm 0.04% 0.30% Non détecté Non détecté Non détecté 0.30%
Solvants résiduels - Méthanol - Ether éthylique - Cyclohexane - n-Heptane - Toluène	≤ 500 ppm ≤ 100 ppm ≤ 100 ppm ≤ 50 ppm ≤ 100 ppm	< 30 ppm < 15 ppm < 15 ppm < 15 ppm < 15 ppm
Métaux - Plomb - Palladium	≤ 10 ppm ≤ 5 ppm	< 1 ppm < 1 ppm
<b>Dosage (CL)*</b>	98.0 à 102.0% (substance anhydre)	99.3%
<b>TSE/BSE</b>	Conforme	Conforme
<b>Fabricant d'origine</b>	Industriale Chimica s.r.l. Saronno (VA), Italie	GMP avec DMF

#### **Stockage dans un récipient étanche fermé à l'abri de la lumière, entre +15°C et +25°C.**

Le produit a été contrôlé selon les procédures pharmaceutiques en vigueur,  
il est conforme aux spécifications internes du fabricant d'origine.

Analyses :

28/05/2020

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Italie  
Tél. : +39 02 964 26411

Contrôle et libération le 08/01/2021

Emilie Grawey-Kling  
Pharmacien INRESA

\*11/12/2020

Dr. Felix Heppeler  
Responsable Contrôle Qualité  
Untersuchungsinstitut Heppeler GmbH (sous-traitant INRESA)  
Marie Curie Strasse 7  
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## CERTIFICATE OF ANALYSIS

C201015002

PRODUCT: IDEBENONE  
PRODUCT INTERNAL CODE: 5216

MANUFACTURED AND RELEASED IN:  
Industriale Chimica S.R.L - Via E.H. Grieg, 13 - 21047 Saronno  
(VA) - Italy  
Tel. +39 02 964 26411 - Fax +39 02 962 1997  
[www.chemogroup.com](http://www.chemogroup.com)

BATCH: PR200901

MANUFACTURE DATE:  
May 2020

RELEASE DATE:  
May 2020  
RETEST DATE:  
May 2025

TESTS	SPECIFICATIONS	RESULTS
Description	Yellow - orange crystalline powder without conglomerations	Conforms
<b>Identification</b>		
IR	Positive	Positive
Melting point	Positive	Positive °C
Appearance of solution	10% ethyl acetate solution is not more opalescent than Ph.Eur.Reference Solution II	< Ph.Eur.Ref.Sol.II
Sulphated ash/residue on ignition	<= 0.10 %	0.01 %
Heavy metals	<= 20 ppm	< 20 ppm
Water	<= 0.20 %	0.09 %
<b>Related substances</b>		
Impurity A	<= 0.50 %	0.32 %
Impurity B	<= 0.05 %	< 0.03 %
Impurity C	<= 0.05 %	< 0.03 %
Any unspecified impurities (max value)	<= 0.05 %	< 0.03 %
Total impurities	<= 1.0 %	0.32 %
<b>Residual solvents</b>		
Methanol	<= 500 ppm	< 30 ppm
Ethyl ether	<= 100 ppm	< 15 ppm
Cyclohexane	<= 100 ppm	< 15 ppm
n-Heptane	<= 50 ppm	< 15 ppm
Toluene	<= 100 ppm	< 15 ppm
Assay	[98.0 - 102.0] % calculated on the anhydrous basis	99.8 %
<b>Metals</b>		
Lead	<= 10 ppm	< 1 ppm

HANDLING PROCEDURES - Storage  
Preserve in well-closed, light-resistant containers. Store at USP controlled room temperature.  
The manufacturing, packaging and testing of this batch was performed according to QMPS requirements (ref. ICH Q7 - EU GMP Guide Vol. 4 part II)

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MANUFACTURE DATE:  
May 2020

RELEASE DATE:  
May 2020  
RETEST DATE:  
May 2025

TESTS	SPECIFICATIONS	RESULTS
Palladium	<= 5 ppm	< 1 ppm
<b>Particle size</b>		
d100	<= 130 micron	73 micron
d95	<= 65 micron	36.98 micron
d75	<= 60 micron	19.88 micron
d60	<= 45 micron	14.47 micron
d50	<= 30 micron	11.8 micron
d10	<= 10 micron	2.6 micron

BATCH RELEASED BY  
dr. Cristina Fochi ON  
2020-05-28 10:24:02

HANDLING PROCEDURES - Storage  
Preserve in well-closed, light-resistant containers. Store at USP controlled room temperature.  
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