



## Certificat d'analyse

Produit

**Idébénone**

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

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

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\*11/12/2020

Dr. Felix Heppeler

Responsable Contrôle Qualité

Untersuchungsinstitut Heppeler GmbH (sous-traitant INRESA)


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Contrôle et libération le 08/01/2021

Emilie Grawey-Kling  
Pharmacien INRESA



**CERTIFICATE OF ANALYSIS**


C201015002

<b>PRODUCT IDEBENONE</b> PRODUCT INTERNAL CODE: <b>5216</b>		MANUFACTURE DATE: May 2020
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		RELEASE DATE: May 2020  RETEST DATE: May 2025
BATCH: <b>PR200901</b>		

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 GMPs requirements (ref. ICH Q7 - EU GMP Guide Vol. 4 part II)

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BATCH: <b>PR200901</b>		

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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