



C221024004

## CERTIFICATE OF ANALYSIS

PRODUCT <b>IDEBENONE</b> PRODUCT INTERNAL CODE: 5216	MANUFACTURE DATE: October 2022
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: October 2022  RETEST DATE: October 2027
BATCH: <b>PR222365</b>	

TESTS	SPECIFICATIONS	RESULTS
Description	Yellow - orange crystalline powder without conglomerations	Conforms
<b>Identification</b>		
IR	Positive	Positive
Melting point	Positive	Positive
Melting point	[52 - 54] °C	53.8 °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	<= 0.1 %	0.05 %
Heavy metals	<= 20 ppm	< 20 ppm
Water	<= 0.20 %	0.03 %
<b>Related substances</b>		
Impurity A	<= 0.50 %	0.14 %
Impurity B	<= 0.10 %	0.03 %
Impurity C	<= 0.10 %	< 0.03 %
Any unspecified impurities (max value)	<= 0.10 %	< 0.03 %
Total impurities	<= 1.0 %	0.17 %
<b>Residual solvents</b>		
Methanol	<= 500 ppm	< 30 ppm
Ethyl ether	<= 100 ppm	< 15 ppm
Cyclohexane	<= 100 ppm	< 15 ppm
Toluene	<= 100 ppm	< 15 ppm
n-Heptane	<= 50 ppm	< 15 ppm
Benzene	<= 0.6 ppm	< 0.6 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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TESTS	SPECIFICATIONS	RESULTS
Assay	[98.0 - 102.0] % calculated on the anhydrous basis	100.4 %
<b>Particle size</b>		
d95	<= 65 micron	42 micron
d50	<= 30 micron	15 micron
d10	<= 10 micron	4 micron
<b>Metals</b>		
Lead	<= 10 ppm	< 1 ppm
Palladium	<= 5 ppm	< 1 ppm
<b>Microbiology</b>		
TAMC	<= 10 <sup>3</sup> CFU/g	< 10 CFU/g
TYMC	<= 10 <sup>2</sup> CFU/g	< 10 CFU/g
Escherichia Coli	Absent/g	Absent

BATCH RELEASED BY  
dr. Marco Radice ON  
2022-10-19 15:14:50

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