



CERTIFICATE OF ANALYSIS

PRODUCT IDEBENONE PRODUCT INTERNAL CODE: 5216	MANUFACTURE DATE: August 2024
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: September 2024 RETEST DATE: August 2029
BATCH: PR241941	

TESTS	SPECIFICATIONS	RESULTS
Description	Yellow - orange crystalline powder without conglomerations	Conforms
Identification		
IR	Positive	Positive
Melting point	Positive	Positive
Melting point	[52 - 54] °C	53.6 °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 %	0.03 %
Heavy metals	<= 20 ppm	< 20 ppm
Water	<= 0.20 %	0.07 %
Related substances		
Impurity A	<= 0.50 %	0.31 %
Impurity B	<= 0.10 %	0.04 %
Impurity C	<= 0.10 %	< 0.03 %
Any unspecified impurities (max value)	<= 0.10 %	< 0.03 %
Total impurities	<= 1.0 %	0.35 %
Residual solvents		
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	99.5 %
Particle size		
d95	<= 65 micron	43 micron
d50	<= 30 micron	15 micron
d10	<= 10 micron	5 micron
Metals		
Lead	<= 10 ppm	< 1 ppm
Palladium	<= 5 ppm	< 1 ppm
Microbiology		
TAMC	<= 10 ³ CFU/g	< 10 CFU/g
TYMC	<= 10 ² CFU/g	< 10 CFU/g
Escherichia Coli	Absent/g	Absent

BATCH RELEASED BY
dr. Manuela Interdonato ON
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