



COFFEIN COMPAGNIE

ITALY

Albenga, 10/01/2023

NATURAL CAFFEINE ANHYDROUS EP

Standard powder form

Batch no: **P383**

of **24/12/2022**

Expiry: **24/12/2027**

Manufacturing facility: Coffein Compagnie Italy S.r.l. a Socio Unico - Regione Abissinia
Località Lago Azzurro - 17031 Albenga (SV) - Italia

Customer: PRINOVA EUROPE LIMITED

CERTIFICATE OF ANALYSIS

Test	Method	Limit	Result
1. Organoleptic	EP	White powder, odourless, bitter taste	Conform
2. Identification	EP 2.2.24 + 2.2.14	Conform to standard	Conform
3. Appearance of solution S	EP 2.2.1 + 2.2.2, II	Clear and colourless	Conform
4. Acidity	EP	Max 0.2 ml NaOH 0.01 M	Conform
5. Melting point	EP 2.2.14	234.0 °C .. 239.0 °C	236.9 °C
6. Related substances	EP 2.2.29	Max 0.10 % each, max 0.10 % total	Conform
7. Sulfates	EP 2.4.13	Max 500 ppm	Conform
8. Heavy metals	EP 2.4.20	Conform to EP 5.20	Conform
9. Loss on drying	EP 2.2.32	Max 0.500 %	0.040 %
10. Sulfated ash	EP 2.4.14	Max 0.100 %	0.015 %
11. Assay	EP 2.2.20	98.50 % .. 101.00 %	99.95 %
12. Granulometry	EP 2.9.38	Max 5 % on 355 micron test sieve	Conform
13. Residual solvents	USP <467>	Max 1 ppm dichloromethane	Conform
14. Readily carbonizable substances	USP <271>	No more color than Matching Fluid D	Conform

Heavy metal specifications have been set considering ICH Q3D (Guideline for Elemental Impurities) option 3. Cd max 1 ppm, Pb max 1 ppm, As max 1 ppm, Hg max 0.1 ppm, Co max 1 ppm, V max 1 ppm, Ni max 1 ppm

We hereby certify that all manufacturing process was performed in full compliance of relevant procedures and the product conforms to European Pharmacopoeia 10.0

Flavio Melstrio

Coffein Compagnie Italy
Albenga