



Specification

1.02584.1000 Caffeine EMPROVE® ESSENTIAL Ph Eur,BP,USP

	Specification	
Assay (perchloric acid titration, calculated on dried substance)	98.5 - 101.0	%
Assay (HPLC)	98.5 - 101.0	%
Identity	passes test	
Appearance of solution (1 %; water)	passes test	
Acidic substances	passes test	
Sulfate (SO ₄)	≤ 0.0500	%
Fe (Iron)	≤ 130	ppm
Heavy metals (as Pb)	≤ 0.001	%
Chloroform (HS-GC)	≤ 60	ppm
Related substances (HPLC, EP) (Highest single impurity)	≤ 0.10	%
Related substances (HPLC, EP) (Sum of all impurities)	≤ 0.10	%
Chromatographic purity (USP) (Highest single impurity)	≤ 0.1	%
Chromatographic purity (USP) (Sum of all impurities)	≤ 0.1	%
Theophylline (HPLC)	≤ 0.10	%
Other residual solvents (ICH Q3C)	excluded by the manufacturing process	
Sulfated ash	≤ 0.1	%
Loss on Drying (105 °C)	≤ 0.5	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Corresponds to Ph Eur, BP, USP

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Responsible laboratory manager quality control

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