



Specification

8.17058.0000 Maleic acid EMPROVE® ESSENTIAL Ph Eur,NF

Specification		
Assay (calc.on anhydrous substance)	99.0 - 101.0	%
Assay (HPLC, calc. on anhydrous substance)	98.0 - 102.0	%
Identity (wet chemistry)	passes test	
Identity (HPLC)	passes test	
Identity (pH)	passes test	
Identity (TLC)	passes test	
Identity (IR)	passes test	
Appearance of solution	passes test	
Fe (Iron)	≤ 5	ppm
V (Vanadium)*	≤ 1	ppm
Fumaric acid (TLC)	≤ 1.5	%
Fumaric acid (HPLC)	≤ 1.0	%
Malic acid (HPLC)	≤ 0.5	%
Residual solvents (ICH Q3C)	excluded by the production process	
Sulfated ash	≤ 0.1	%
Water (K. F.)	≤ 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, NF

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Responsible laboratory manager quality control

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