



Specification

1.00886.0000 Ethyl 4-hydroxybenzoate sodium salt EMPROVE® ESSENTIAL Ph.Eur.,BP,
NF

Specification		
Assay (HPLC, calc. on anhydrous substance, Ph.Eur.)	95.0 - 102.0	%
Assay (HPLC, calc. on anhydrous substance, NF)	95.0 - 102.0	%
Identity (IR-spectrum)	passes test	
Identity (wet chemistry)	passes test	
Appearance of solution (100 g/l, CO ₂ -free water)	clear and not more intense in color than reference solution BY ₆	
pH-value (1 g/l in CO ₂ -free Water)	9.5 - 10.5	
Chloride (Cl)	≤ 350	ppm
Sulfate (SO ₄)	≤ 300	ppm
Related substances (HPLC, Ph. Eur.)	passes test	
4-Hydroxy benzoic acid (Ph. Eur.)	≤ 3.0	%
Sum of all impurities (without 4-Hydroxybenzoic acid (Ph.Eur.))	≤ 1.0	%
Largest unspecified impurity (Ph.Eur.)	≤ 0.5	%
Related substances (HPLC, NF)	passes test	
4-Hydroxy benzoic acid (NF)	≤ 3.0	%
Sum of all impurities (without 4-Hydroxybenzoic acid (NF))	≤ 1.0	%
Largest unspecified impurity (NF)	≤ 0.5	%
Methanol (HS-GC)	≤ 3000	ppm
Acetone (HS-GC)	≤ 5000	ppm
Ethanol (HS-GC)	≤ 5000	ppm
Other residual solvents (ICH Q3C)	excluded by manufacturing process	
Water (according to Karl Fischer)	≤ 5.0	%

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 Ph Eur, BP,NF

Dr. Sebastian Lips

Responsible laboratory manager quality control

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