



Specification

1.37038.0000 Phenol red (phenolsulfonphthaleine) EMPROVE® ESSENTIAL Ph Eur

Specification		
Assay (bromatometric, calculated on dried substance)	98.0 - 102.0	%
Purity (HPLC)	≥ 98.0	% (a/a)
Identity (A (Ph Eur))	1900 - 2100	
Identity (B (Ph Eur))	passes test	
Identity (C (Ph Eur))	passes test	
Insoluble substances	≤ 0.5	%
Related substances (TLC)	passes test	
Sum of all impurities (HPLC)	≤ 2.0	% (a/a)
Acetone (HS-GC)	≤ 5000	ppm
2-Propanol (HS-GC)	≤ 5000	ppm
Toluene (HS-GC)	≤ 890	ppm
Other residual solvents (Ph Eur)	excluded by production process	
Sulfated ash	≤ 0.2	%
Loss on Drying (105 °C)	≤ 1.0	%

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 (*).

conforms Ph Eur

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

Dr. Christoph Wink
Responsible laboratory manager quality control

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