



Specification

5.00115.5000 Choline hydrogen tartrate suitable for use as excipient EMPROVE® exp
DAB 10,FCC

Specification

Assay (perchloric acid titration, calculated on dried substance)	98.0 - 101.0	%
Identity	passes test	
Appearance of solution (5 %; water)	passes test	
Acidity or alkalinity	passes test	
Melting temperature	147 - 152	°C
Spec. rotation $[\alpha]_{25/D}$ (40.0 g/ 100 ml; water)	17.5 - 18.5	°
Heavy metals (as Pb)	≤ 0.001	%
As (Arsenic)	≤ 0.0003	%
Pb (Lead)	≤ 0.0002	%
Ammonium, volatile amines	passes test	
Ammonium, primary amines	passes test	
1,4 Dioxane	passes test	ppm
Methanol (HS-GC)	≤ 3000	ppm
Residual solvents (Ph Eur /ICH) class 3	≤ 0.5	%
Other residual solvents (Ph Eur/ICH)	excluded by production process	
Residue on ignition	≤ 0.1	%
Loss on drying (105 °C)	≤ 0.3	%
Water	≤ 0.5	%

Residues of metal catalysts or metal reagents acc. to EMEA/C HMP/SWP/4446/2000 are not likely to be present.

Corresponds to DAB 10, FCC

Dr.Katharina Ziegler

Responsible laboratory manager quality control

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