

TECHNICAL DATA SHEET

0156-TDS-ENG-2019

AMILORIDE HCL (EP)			
DESCRIPTION DCI: AMILORIDE HYDROCHLORIDE		DESCRIPTION DOE: HIDROCLORURO DE AMILORIDA	
CAS Nº: 17440-83-4	EC Nº: 620-474-8		AEMPS CODE:
MOL. WEIGHT: 302.12	MOL. FORMULA: C6H13Cl2N7O3		ARTICLE CODE: 0156

ATTRIBUTES SHOULD BE

Appearance Pale yellow or greenish-yellow powder

Solubility Slightly soluble in water and in anhydrous ethanol, practically insoluble in heptane

Identification ACompliesIdentification CCompliesIdentification DComplies

Free acid = < 0.3 mL of 0.1 M NaOH

Related substances

 $\begin{array}{lll} \mbox{Impurity C} & = < 0.2 \ \% \\ \mbox{Unspecified impurities} & = < 0.10 \ \% \\ \mbox{Total impurities} & = < 0.4 \ \% \\ \mbox{Water} & 11.0 - 13.0 \ \% \\ \mbox{Sulfated ash} & = < 0.1 \ \% \\ \mbox{Assay} & 98.0 - 101.0 \ \% \end{array}$

Residual solvents

Methanol =< 1000 ppm
Acetonitrile =< 200 ppm
Dimethylformamide =< 500 ppm

COMPLIES WITH

European Pharmacopoeia 9.7

STORAGE

Keep container tightly closed. Protect from light.

REMARKS

Amiloride HCl Dihydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE are available upon request.