

## PRODUCT SPECIFICATION

Product : **Enrofloxacin Base** 

Appearance : Slightly yellow or pale orange yellow crystalline powder,

odorless, slightly bitter; becoming orange-red on

exposure to light.

Solubility : Freely soluble in chloroform, sparingly soluble in

Dimethyl-Formamide, slightly soluble in Methanol, and in Sodium Hydroxide TS, very slightly soluble

in water.

Melting rage : 221 – 226°C

Identification : 1) HPLC: the retention time of the major peak of the

sample solution corresponds to the reference 2) IR: conforms to the reference spectrum

Clarify of solution : Clear (1 g/20 ml IN 0.15 mol/L NaOH solution)

Colour of solution : Not more intensely coloured than Y4 or GY4

(1 g/20 ml IN 0.5 mol/L NaOH solution)

Fluoroquinolonic Acid : ≤ 0.2 %

Related substances : 1) Ciprofloxacin ≤ 0.5 %

2) Any other single impurity ≤ 0,3 %

3) total impurities ≤ 0.7 %

Loss on drying :  $\leq 0.5 \%$ 

Residue on ignition :  $\leq 0.2 \%$ 

Heavy metals : ≤ 20 ppm

Assay : ≥ 99.0 % (dried substance)



MSDS : available upon request