

FINADYNE INJECTION 50 MG/ML

250 ml

Batch # CNXC 6658B

TESTS AND ASSAYS

ANALYTICAL DATA

SPECIFICATIONS

A DESCRIPTION

Conform

Clear, colourless to light yellow solution, free from foreign matters.

Degree of coloration
 Clarity

Conform
 Conform

≤ B5
 Clear.

B IDENTIFICATION

Flunixin meglumine

(TLC)

Conform

Presence

(HPLC)

Conform

Presence

Phenol (HPLC)

Conform

Presence

Propylene glycol (GC)

Conform

Presence

Sodium edetate

Conform

Presence

Sodium formaldehyde

Sulfoxylate (HPLC)

Conform

Presence

C TESTS

Fill

Conform

Not less than label claim

pH

8.3

7.8 to 9.0

Relative Density

1.044

1.041 to 1.047

Sterility

Conform

No microbial growth

Endotoxins LAL

< 1

< 125 UE/ml

D ASSAYS

Flunixin meglumine

81.6

79.0 to 87.0

mg/ml

Phenol

4.9

4.5 to 5.5

mg/ml

Propylene Glycol

207.2

197.0 to 217.0

mg/ml

Sodium formaldehyde Sulfoxylate

2.00

1.90 to 2.75

mg/ml

Sodium edetate

0.098

0.090 to 0.110

mg/ml

Manufacturing date : April 19th 2016

Expiry date : March 2019

This lot of FINADYNE INJECTION 50 MG/ML has been manufactured and released in accordance with GMP requirements and according to the Marketing Authorization.

Release date : June 3rd 2016


Nolwenn FORBIN
 Qualified Person

025817 - Romania