

PNO352/13
 11/26

CERTIFICATE OF ANALYSIS

PRODUCT: CYDEC/FIN INJ SH* 50 GB

CODE: 459415

BATCH No.: 18002A

MANUF. DATE: 03/2013

EXPIRY DATE: 14/MAR/16

QUANTITY: 850 U

COMPOSITION (ACTIVE INGREDIENT): Moxidectin, 10 mg/ml

| | RESULTS | CHARACTERISTIC VALUES |
|--------------------------|--------------------|--|
| APPEARANCE | Meets requirements | Yellow to pale yellow solution, free from suspended matter |
| IDENTIFICATION | Meets requirements | Moxidectin: Characteristic retention time when compared to a standard (HPLC) Benzyl Alcohol: Characteristic retention time when compared to a standard (GC) Butylated Hydroxytoluene: Characteristic retention time when compared to a standard (GC) |
| MOXIDECTIN | 1.05 % w/v | 1.0 - 1.10% w/v |
| pH | 8.5 | 6.2 - 8.6 |
| DENSITY | 1.045 g/ml | 1.036 - 1.047 g/ml |
| DISODIUM EDTATE | 0.027 % w/v | 0.024 - 0.030% w/v |
| BUTYLATED HYDROXYTOLUENE | 0.259 % w/v | 0.225 - 0.275% w/v |
| BENZYL ALCOHOL | 4.1 % w/v | 3.6 - 4.4% w/v |
| STERILITY | Sterile | Sterile |
| ENDOTOXINS | Meets requirements | Not more than 25 EU/mg of Moxidectin |
| VOLUME | Meets requirements | Not less than 50.5 ml |

OBSERVATIONS:

This batch has been manufactured in accordance with GMP regulations.

Quality Control Manager:

Date: 30 May 13

J.Homs