



August 31, 2015

GOPHARMA SRL

VIA CARLO ALBERTO DALLA CHIESA N° 3

I-20068 PESCHIERA BORROMEO

CERTIFICATE OF ANALYSIS

SPIRONOLACTONE MICRONISED

1806152180

Batch number : 1506273780

Purchase: 1000136817 / August 05, 2015

Delivery: 1080165760

Manufacturing date : March 21, 2015

Expiry date : March 20, 2020

Retest date : N/A

Analytical method : CCF.2258.006.I.1.11

Storage conditions : Storage: controlled room temperature (up to 25°C).

Inspection lot number : 6626410

Compliance : This batch is accepted and complies with the specifications.

Tests	Analytical results	Specifications
Characters	Complies	Practically white powder
Identification IR	Positive	Positive
Identification UV	Positive	Positive
Identification LC	Positive	Positive
Specific optical rotation at 20°C (c = 1 % w/v, in chloroform) (*)	-35.5	-37.0 to -33.0 °
Specific optical rotation at 25°C (c = 1 % w/v, in chloroform) (*)	-36.0	-37.0 to -33.0 °
Specific optical rotation at 25°C (c = 1 % w/v, in ethyl alcohol 96 %v/v) (*)	-43.0	-45.0 to -41.0 °
Melting point	206	198 to 209 °C
LC - Canrenone	< 0.1	<= 0.2 % w/w
LC - Any other impurity	0.03	<= 0.10 % w/w
LC - Total impurities content	< 0.1	<= 0.5 % w/w
Free-mercapto compounds (**)	0.0	<= 0.1 mL
GC - Methanol	< 30	<= 500 ppm
GC - Isopropyl alcohol	< 80	<= 1000 ppm
GC - Dichloromethane	< 50	<= 500 ppm
GC - Pyridine	< 40	<= 200 ppm
Loss on drying	0.0	<= 0.5 % w/w
Sulphated ash	< 0.1	<= 0.1 % w/w
Assay by LC (*)	100.2	97.0 to 103.0 % w/w
Assay by spectrophotometry (*)	100.0	97.0 to 102.0 % w/w



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Particles <= 5 µm (determination in volume)	73	>= 50 %
Particles <= 15 µm (determination in volume)	99	>= 95 %
Particles <= 30 µm (determination in volume)	100	100 %
Identification LC (Ph Eur)	Positive	Positive
Specific optical rotation at 20°C (c=1 % w/v, in ethyl alcohol 96%v/v) (*) (Ph Eur)	-43.0	-46.0 to -41.0 °
LC - Impurity I (Ph Eur)	< 0.1	<= 0.5 % w/w
LC - Impurity E (7 beta spironolactone) (Ph Eur)	< 0.1	<= 0.3 % w/w
LC - Impurity F (Canrenone) (Ph Eur)	< 0.1	<= 0.3 % w/w
LC - Impurity A (Delta 20-spironolactone) (Ph Eur)	< 0.1	<= 0.2 % w/w
LC - Impurity C (Ketolactone) (Ph Eur)	< 0.1	<= 0.2 % w/w
LC - Impurity D (Dethio spironolactone) (Ph Eur)	< 0.05	<= 0.15 % w/w
LC - Any other impurity (Ph Eur)	< 0.05	<= 0.10 % w/w
LC - Total impurities content (Ph Eur)	< 0.1	<= 0.7 % w/w
Assay by LC (*) (Ph Eur)	99.6	97.5 to 102.0 % w/w



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Tests	Analytical results	Specifications
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(*) calculated with reference to the dried substance

(**) ≤ 0.1 ml of a 0.01 N iodine solution

The test for chromium has not been carried out, as this element is not used in the synthesis process

Other O.V.I. described in the USP are not used in the synthesis process

Compliant with Ph.Eur. ,USP and JP requirements

The certificate of analysis has been produced by a validated Laboratory Information Management System and signed electronically the July 30, 2015 at 10:53:37 by Isabelle ANDRE

Quality Assurance

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