



June 20, 2012

CERTIFICATE OF ANALYSIS

SPIRONOLACTONE MICRONISED

1806152180

Batch number : 1204782535

Purchase: 1000119569 / June 11, 2012

Delivery: 1080145799

Manufacturing date : April 23, 2012
 Expiry date : April 23, 2017
 Analytical method : CCF.2258.006.1.1.11
 Storage conditions : Storage: controlled room temperature (up to 25°C).
 Inspection lot number : 6495101
 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 g w/v, in chloroform) (*)	-35.0	-37.0 to -33.0 °
Specific optical rotation at 25°C (c = 1 g w/v, in chloroform) (*)	-36.5	-37.0 to -33.0 °
Specific optical rotation at 25°C (c = 1 g w/v, in ethyl alcohol 96 %v/v) (*)	-43.0	-45.0 to -41.0 °
Melting point	208	198 to 209 °C
LC - Canrenone	< 0.1	<= 0.2 g w/w
LC - Any other impurity	0.03	<= 0.10 g w/w
LC - Total impurities content	< 0.1	<= 0.5 g w/w
Free-mercapto compounds (**)	0.0	<= 0.1 ml
GC - Methanol	< 30	<= 500 ppm
GC - Isopropyl alcohol	115	<= 1000 ppm
GC - Dichloromethane	< 50	<= 500 ppm
GC - Pyridine	< 40	<= 200 ppm
Loss on drying	0.1	<= 0.5 g w/w
Sulphated ash	< 0.1	<= 0.1 g w/w
Assay by LC (*)	99.8	97.0 to 103.0 g w/w
Assay by spectrophotometry (*)	98.8	97.0 to 102.0 g w/w
Particles <= 5 µm (determination in	74	>= 50 g

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Tests	Analytical results	Specifications
volume)		
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)	-42.8	-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)	100.1	97.5 to 102.0 % w/w

(*) 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 June 01, 2012 at 11:18:50 by Catherine REBEYROL

Quality assurance

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CAP.SOC. EU RO 2.000.000 I.V.
R.I. PC 032-1483
R.D. PC 44507
MECC.EXPORT PC002237

Spett.le

METAPHARMACEUTICAL IND S.L.
D.ssa Miriam Miguel Sala
C/Josep Plà, n° 163, 2° 5ª
08020 Barcelona

Fiorenzuola, 14 lug. '14

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta confermiamo la corrispondenza dei seguenti lotti:

003978 SPIRONOLATTONE Ph.Eur.
Lotto 12291002

cod. 003978
Lotto fornitore 1204782535

Restando a disposizione per eventuali chiarimenti porgiamo distinti saluti.

Fiorenzuola, 14 lug. '14

A.C.E.F. S.p.A.

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta

003978 SPIRONOLATTONE
Lotto 12291002

C.Q.

Restando a disposizione

Fiorenzuola, 14 lug. '14

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta

003978 SPIRONOLATTONE
Lotto 12291002

Restando a disposizione

Fiorenzuola, 14 lug. '14

Oggetto: Tracciabilità lotti

In riferimento alla Vs. richiesta

003978 SPIRONOLATTONE