METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0614-TDS-ENG-2024

ESPIRONOLACTONA (EUR. PH.)		
DESCRIPTION DCI: spironolactone	DESCRIPTION DOE: ESPIRONOLACTONA	
CAS Nº: 52-01-7	EC Nº: 200-133-6	AEMPS CODE: 326A
MOL. WEIGHT: 416,57	MOL. FORMULA: C24H32O4S	ARTICLE CODE: 0614

ATTRIBUTES	SHOULD BE
Appearance	White or yellowish-white powder
Solubility	Practically insoluble in water, soluble in ethanol (96 %)
Identification A	Complies
Specific optical rotation	-41 / -46
Related substances	
Impurity I	=< 0.5 %
Impurity E	=< 0.3 %
Impurity F	=< 0.3 %
Impurity A	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.7 %
Free thiol compounds	Complies
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	97.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed and protected from light.

REMARKS

It shows polymorphism.

Spironolactone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses
SPIRONOLACTONE is a potassium-sparing diuretic with an antagonistic steroid structure of aldosterone, and therefore

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increases the excretion of sodium and water and decreases the excretion of potassium.
It is rapidly absorbed in the gastrointestinal tract. It binds 90% to plasma proteins. It is excreted mainly in the urine and also in the faeces, in the form of active metabolites (such as canrerona and other sulfur derivatives). Both SPIRONOLACTONE and its metabolites can cross the placental barrier, and in particular canrerona is excreted in breast milk.
It is used in the treatment of refractory edema associated with congestive heart failure, liver cirrhosis, ascites due to malignant processes, and nephrotic syndrome.
It is also used as an antihypertensive agent, and in the diagnosis and treatment of primary hyperaldosteronism.
It is often used together with other types of diuretics to minimize potassium losses.
It is also used as an antiandrogen in the treatment of hirsutism, especially in that caused by polycystic ovary syndrome, in some cases of resistant acne, and in androgenic alopecia.

Dosage
Oral route, at a dose of 25 - 400 mg / day according to pathology.
Topical route, 1 - 5% in creams and solutions.

Side effects
The most common are mastalgia, gynecomastia, amenorrhea, metrorrhagia, and dry skin.
Occasionally hyperkalemia, hyponatremia, headache, drowsiness, dry mouth, diarrhea, vomiting, dyspepsia, abdominal cramps, hirsutism, ataxia, confusion, and exanthematic eruptions.
Rarely or exceptionally, sexual impotence, increased blood urea nitrogen, and metabolic acidosis.

Contraindications
Patients with hyperkalemia, with severe renal insufficiency, or with tendency to acidosis. Patients in breastfeeding period.

Precautions
Potassium supplements should not be administered together with SPIRONOLACTONE.

Interactions
It can enhance the toxicity of amantadine, digoxin, potassium salts, NSAIDs, cyclosporine, and lithium.
It may increase the occurrence of hyperkalemia administered together with ACEIs, ARA-II, NSAIDs, cyclosporine, or trilostane.
It can reduce the effect of oral anticoagulants and carbenoxolone.
NSAIDs can decrease their effectiveness. Ammonium salts can increase their toxicity.
It can increase the effects of other antihypertensive drugs.

Incompatibilities
Ammonium chloride.

Other observations
It is thermolabile and photosensitive. In solution, it hydrolyzes giving sulfur compounds with an unpleasant odor.

Formulation examples

Lotion for androgenic alopecia
SPIRONOLACTONE - **1%**
Propylene glycol - **10%**
Hydroalcoholic solution 70% c.s.p. - **100 mL**

Modus operandi: Dissolve SPIRONOLACTONE in alcohol. Add the propylene glycol. Finally add the purified water little by little.

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Cream for hirsutism
SPIRONOLACTONE - **5%**
Base Beeler c.s.p. - **50 g**

Modus operandi: Moisten SPIRONOLACTONE in mortar with a little propylene glycol. Add the Beeler base little by little, homogenizing well with the pistil.