STANOZOLOL RAPID HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) QUANTIFICATION METHOD FOR QUALITY CONTROL

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HEREDITARY ANGIOEDEMA (AHE) is a rare disease of autosomal dominant inheritance characterized by the presentation of recurrent edema. Among the agents used for the prophylaxis of AHE are androgens and among these is STANOZOLOL.

STANOZOLOL is not commercialized in Europe, but it can be elaborated as a compounding in pharmacies, being generally elaborated as 2mg capsules. Due to its low dosage, it is essential to establish a control of the uniformity of its content to ensure its correct elaboration.

Methods

HPLC conditions

Column: Agilent Poroshell 120®(C18 4.6 mm x 250mm, 5µm)
Temperature: 25ºC
Mobile Phase: methanol:water 85%:15% (Isocratic).
Flow: 1mL/minute
Injection volumen: 10 µL
Detector: array diode (λ=230nm).

GOALS

To develop and validate a method for the quantification of stanozolol by high performance liquid chromatography (HPLC) according to ICH guidelines.

All the reagents used had analytical certification and were obtained from Sigma-Aldrich (USA). The calibration line was generated by least squares regression.

Accuracy (99-101%)
Inter- and intra-day precision CV <2%.

Specificity and selectivity of the method:
2D and 3D spectral analysis

Results

All parameters met the established limits in linearity (R²>0.9999), accuracy (98.5-102.5%), intra-day and inter-day precision (CV<2%), specificity and selectivity, the limit of quantification and detection were 0.03 mg/mL and 0.01 mg/mL, respectively. An average recovery percentage of 100.46% was obtained.

Conclusions

An HPLC method has been validated to determine stanozolol in hard gelatin capsules according to ICH guidelines.

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