



Technological Development of Hard Capsules of Sertraline Hydrochloride

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SUMMARY. Fast release capsules, containing sertraline hydrochloride, pregelatinized maize starch and microcrystalline cellulose were formulated. For this purpose, different technological assays were elaborated being the formulation 2 selected as the better technological variant. Dry powders were filled into hard gelatin capsules. From this formulation were derived capsules with satisfactory technological properties. The quantification of sertraline through HPLC UV detection method was validated for accuracy, precision, linearity and selectivity. The method was linear over the concentration range 0.5 to 0.75 mg/mL and was shown to be highly reproducible. It could be used, without any interference of capsule excipients, for determination of sertraline from solid dosage form. Hard capsules showed an adequate stability during 24 months demonstrating the feasibility from the process of production of this formulation. Parameters, *f1* and *f2*, were used to confirm similarity of dissolution, in deaerated distilled water, of test formulation and capsules of Proserlin as reference product.

KEY WORDS: hard gelatin capsule, sertraline, stability, validation of analytical methods

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