VALIDATION OF METHOD FOR RP-HPLC FOR THE DETERMINATION OF ETORICOXIB IN COATED TABLETS

Marisabel Bor*, Dhaimarys Villalba, María Ángeles Sánchez, Barbara Delgado, Glen Zea

Universidad Central de Venezuela, Facultad de Farmacia, Laboratorio de Análisis de Medicamentos

* marisabel.bor@gmail.com

Introduction:

Etoricoxib it is a non-steroidal anti-inflammatory drug (NSAID) of the selective inhibitor of the cyclooxygenase II (COX-II) enzyme. This drug is indicated in pathologies associated with the osteoarticular system that courses with symptoms like pain and inflammation; being selective for COX-II enzyme, it has greater efficiency in the treatment of pain, and it has less gastrolesive effects, among other unwanted effects associated with the chronic use of non-selective NSAIDs.[1]

In the present work, was validated an analytical method for the determination of the content of Etoricoxib coated tablets by HPLC. The validation of the proposed method was performed according to the parameters established by the ICH [2] and USP 42, specifically in its section <1225>, [3] corresponding to the validation of analytical methods. Precision was evaluated as repeatability and intermediate precision, performed by the same days, same instrument, on different analyst.

Results:

Chromatographic conditions

mobile phase	acetonitrile / water (35:65) at pH 7.0
Volume of injection	0.7 mL / min
Column	C18 (L1) 3.0 mm X 150 mm, 3.5 µm
wavelength	236 nm

Chromatogram and spectrum of standard and sample of etoricoxib

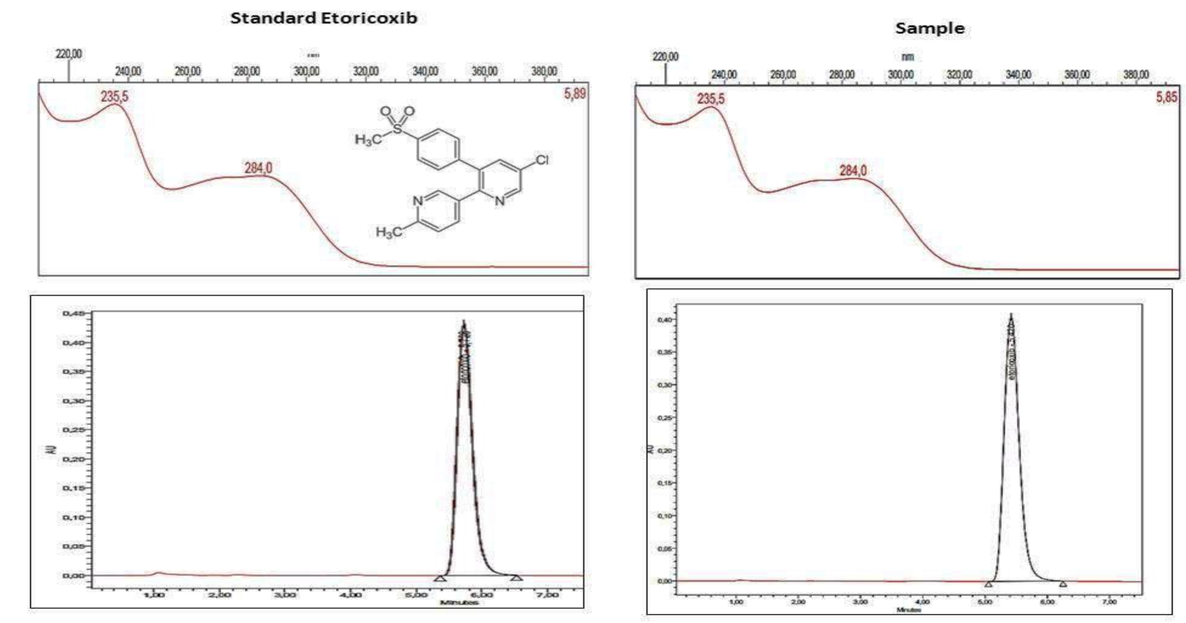

Table of results for the evaluation of accuracy precision of the method

Accuracy			Precision					
Level	Recovery (%)/RSDR	% recovered with respect to enrichment level	Repeatability		Intermediate precision C (mg/tab)			
			Replica	C (mg/tab)	Replica	Analyst 1	Analyst 2	Analyst 3
80	99.2 /1.9%	79.4	1	94.2	1	94.7	93.5	91.3
			2	93.6				
100	100.5 /1.2%	100.5	3	91.6	2	94.1	92.2	94.1
			4	92.1				
120	98.2/ 0.3%	117.8	5	94.2	3	91.7	94.6	95.5
			6	92.5				
Amount of etoricoxib declared= 90 mg/tab RSDR= Relative standard deviation			**Mean/RSDR**	93.0/1.2	**Mean/RSDR**	93.5/1.5	93.4/1.2	93.6/2.0
			% declared	103.3	**% declared**	103.9	103.8	104.0

Conclusions

The analytical method for the determination of Etoricoxib in tablets shows a linear behavior in the concentration range between 0.070 and 0.014 mg/mL and a coefficient of determination = 0.999. Accuracy measured as percentage of recovery was found between 98.2% and 100.5% for fortified concentration levels between 80, 100 and 120%, results that are within the limits of the acceptance criteria ranging from 98.0 to 102.0% for each level. The results of RSDR were less than 2%, which indicates that the precision evaluated through the repeatability of the method is within the limits established for chromatographic. The method proved to be precise, exact and specific, fulfilling the criteria established by the ICH for the validation of analytical methods.

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