



SDI Review Form 1.6

Journal Name:	Journal of Advances in Medical and Pharmaceutical Sciences
Manuscript Number:	Ms_JAMPS_26825
Title of the Manuscript:	DEVELOPMENT AND VALIDATION OF STABILITY INDICATING UFLC METHOD FOR THE ESTIMATION OF ANTI-SPASMODIC DRUG - VALETHAMATE BROMIDE
Type of the Article	Original Research Article

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound.

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PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
Compulsory REVISION comments	1) In the study there is a lot of work for a determination and stability indication purposes. But, in literatures there are a lot of liquid chromatographic method for the determination of valethamate bromide in pharmaceutical preparations. Beside the speed of developed method, advantages of the developed method should be given by comparing with the previous methods published.(retention time, complex mobile phases line 44) Because, speed is not a great advantage for a method for the determination of only one active ingredient in a simple tablet formulation. Speed of a method is very important for the analysis of biological liquids or kinetic requirements or enzymatic reactions. UPLC is a wonderful method for this kind of works. For complex phases (as said by authors line 44) some examples should be given. 2) Article is original in terms of stability. 3) Authors said that "Valethamate Bromide formulation (Epidosin) was obtained from local Pharmacy" Line 59. But There is no analysis results of this preparations in the text by the proposed method . 4) Regression equation is shown as $Y=1836.3x+ 295.76$ in Table 2.	Few HPLC, HPTLC and colorimetric methods are available for the determination of valethamate bromide and no UFLC method are reported for the determination of valethamate bromide. In the reported HPLC method the column used is C8 and C18. In the reported method RT is more than 4.5 min, the linearity range is higher, used different wavelength, pH and different solvent ratio. The developed method is precise with short runtime, less organic solvent and less linearity concentration. The methods are incorporated in the introduction as suggested by the reviewer. In the UPLC method the column used is short and in most of the cases the resolution is very poor. 2. No stability indicating methods are reported 3. The method is developed is on the formulation obtained from the local pharmacy



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	a) The units of y and x should be given in the equation. b) Because the calibration equation is given in Table 2, there is no need for Figure 3 simple straight line containing calibration parameters. Figure 3 should be removed. 5) In chromatograms: Line 284: Figure 4: Chromatogram of sample solution What is sample? there is no chromatogram of pharmaceutical preparations. This is important for the selectivity or interference from other excipients. 6) In stressed conditions: chromatograms No. 10, 12 and 14 are omitted or the numbers of the chromatograms are confused. 7) In chromatograms: we see only the peak of Valethamate Bromide in decreasing intensity. Is there any degraded product?	4. $Y=1836.3x+ 295.76$ a. x is independent variable ie concentration and y dependent variable ie. Area b. Figure 3 is removed 5. Sample is tablet formulation (marketed product) Standard is the API 6. Chromatograms are included to know the difference when it is subjected to acid, alkali, oxidising agents and thermal etc. figure no. is given with captions it doesn't lead to confusion 7. Observed only change in the peak area and no additional peaks are seen By change in peak area we assumed that the drug is lost its strength
Minor REVISION comments		
Optional/General comments		