



SDI Review Form 1.6

Journal Name:	Asian Journal of Applied Chemistry Research
Manuscript Number:	Ms_AJACR_48651
Title of the Manuscript:	Validated Stability Indicating HPTLC, UHPLC and UV-Spectrophotometric Techniques for the Determination of Bepotastine Besilate
Type of the Article	Original Research Article

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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	<p>1- Title should be modified to be "Validated Stability Indicating HPTLC, UHPLC and UV-Spectrophotometric Techniques for the Determination of Bepotastine Besilate in presence of its oxidative degradate . to be distinctive your work</p> <p>2- Introduction is too short , please add more details Bepotastine besilate (Bepotastine-B) (its chemical structure is demonstrated in scheme 1) add it please Including RP-HPLC techniques [3-5] ; among these methods is method of LC-MS/MS one [reference 5] discusses it in details ; and also and stability indicating HPTLC determination of Bepotastine-B in presence of its acid degradate [6], discuss it in details because you choose it as reference method</p> <p>3- Experimental; add (twon , country) for each instrument and chemicals , like , USA ; RAMEDA CO, (..... , Egypt); , UK</p> <p>4- Preparation of degradation product; why you did not try 30 % H2O2 to reduce waiting time (2 days is too long time)?however, your method of preparation of oxidative degradate is very wonderful where no standard was available</p> <p>5- In 2.3.1 linearity , why you choose 266 nm in HPTLC and 260 nm in UPLC method , I think it should be the same detection wavelength</p> <p>6- In TLC method, it is very clear that normol TLC was not suitable for the drug because of very clear tailing ; why you did not try RP-TLC , however you can add it to future research plane to improve peak shape and reduce tailing .</p> <p>7- In results and discussion ; check the mass spectrum of oxidative degradate , you will found very clear peak at 163.18 m/z , give explanation please</p> <p>8- 1.3 application to pharmaceutical formulations (remove s in all manuscript please one tablet dosage form) , while UV-spectrophotometric methods are more simple , this is not true because it does not include direct measurement in zero order . you can say that UV spectrophotometer is cheap and easily available instrument</p>	<ul style="list-style-type: none"> It was modified to this title. Chemical structure of Bepotastine besilate was added. LC-MS/MS for determination of the drug in human plasma and urine where sample was prepared by solid phase extraction using mobile phase of acetonitrile: water: 200mmole/L ammonium formate (75:20:5) at flow rate 0.3 mL/min, 30° C and electrospray ionization mass spectrometry (MRM) detection. stability indicating HPTLC determination of Bepotastine-B in presence of its acid degradate using chloroform: methanol (5: 5) as mobile phase where Bepotastine-B and acid degradate was obtained at Rf 0.50 and 0.78, respectively at 225 nm. The acid degradate was undescribed in details. (twon , country) was added To allow its evaporation without heating. Different wavelengths (200 - 400 nm) was tested. Much better detector response was found to be at 266 nm. Densitogram of HPTLC was added mistake. It was a densitogram of first trials of separation and we added the correct one where there is no tailing present. The drug does not degradate upon treatment with H2O2 but it undergoes oxidation of both nitrogen atoms due to presence molecular ion peak (parent ion) at 581.45 m/z corresponding to its molecular weight. However when the vaporized drug passes into ionization champer of mass spectrum it is bombarded by a stream of electrons which break it to smaller fragments. The base peak 163.18 m/z may be due to fragmentation of the parent ion to give the most stable ion at 163.18 m/z which has molecular formula C9H9O2N. This fragmentation was illustrated in Scheme (2) where piperidine ring stabilize itself to more stable pyridine ring. Letter s is removed. while UV-spectrophotometric methods are more simple , this is removed . we said that UV spectrophotometer is cheap and easily available instrument



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Minor REVISION comments	9- Add future research plane after discussion; like application of the methods for determination of the drug in presence of acid degradates , alkaline degradates and photo degradation products	In Discussion (page 3), It has been stated that Stability of Bepotastine-B was studied under different stressed conditions. It was found that it was stable to acidic and alkaline hydrolysis upon refluxing with 5N HCL and 5N NaOH for 6 h while it is liable to oxidative degradation upon keeping with 10% H2O2 at room temperature for two days.
Optional/General comments	No comments	

PART 2:

	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)
Are there ethical issues in this manuscript?	(If yes, Kindly please write down the ethical issues here in details)	It was not applicable