



SDI Review Form 1.6

Journal Name:	Archives of Current Research International
Manuscript Number:	Ms_ACRI_52101
Title of the Manuscript:	An approach to drug stability studies and shelf life determination
Type of the Article	Review 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. To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)



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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)																				
<p>Compulsory REVISION comments</p>	<p>Line 318: "To establish stability indicating nature of drug molecules". The stability indicating capacity is of the method, not of the molecule. Line 335-336: "for small pharmaceutical molecules". It is not clear what you mean by "small molecules". Line 339, Table 4. Add "Relative humidity" in column "Experimental conditions" when applicable. Correct the time point for thermal and humidity test. Generally the time points are 7,14,28 days. The minimum time are generally 1 week.</p> <table border="1" data-bbox="890 693 1899 898"> <tr> <td>Thermal</td> <td>Heat chamber</td> <td>60 ° C</td> <td>1,3,5</td> </tr> <tr> <td></td> <td>Heat chamber/ Relative humidity</td> <td>60 ° C/75% RH</td> <td>1,3,5</td> </tr> <tr> <td></td> <td>Heat chamber</td> <td>80 ° C</td> <td>1,3,5</td> </tr> <tr> <td></td> <td>Heat chamber/ Relative humidity</td> <td>80 ° C/75% RH</td> <td>1,3,5</td> </tr> <tr> <td></td> <td>Heat control</td> <td>Room temp.</td> <td>1,3,5</td> </tr> </table> <p>Line 479-485. Summarize the advantages of TLC and HPLC over HPLC in one sentence. TLC and HPTLCover HPLC Line 486-488. The current method most used to determine stability is HPLC-DAD. Line 488-491. Correct the sentence "HPLC-PDA or DAD has a wide range of detection." UV and DAD are UV detectors, therefore the LOD is the same. Line 492-493. Add that mass analysis allows the identification of degradation products. Line 597-600. "The main advantage of the method is that the whole spectrum of interfering substance is cancelled. Accordingly, the choice of the wavelength selected for calibration is not critical. The best results in terms of signal to noise ratio, sensitivity and selectivity followed using 5 mg/mL [42]". Delete the sentence. Line 615-617. The applications mentioned are mainly carried out by HPTLC and not by TLC Line 623-628. "LC-MS/MS studies were carried out in +APCI ionization mode in the mass range of 50-2000 amu. High purity helium was used as carrier gas, and nitrogen was used as a nebulizer. Mass parameters were optimized to the following values: R_f loading: 80%; capillary voltage: 80 volts; syringe volume: 250µl; spray chamber temperature: 50°C; nebulizer pressure: 35psi; drying gas temperature: 300°C; drying gas pressure: 10psi; vaporizer gas temperature: 350°C; vaporizer gas pressure: 20psi; spray shield voltage: ± 600.0 volts [46]". Delete the sentence or explain to which it corresponds.</p>	Thermal	Heat chamber	60 ° C	1,3,5		Heat chamber/ Relative humidity	60 ° C/75% RH	1,3,5		Heat chamber	80 ° C	1,3,5		Heat chamber/ Relative humidity	80 ° C/75% RH	1,3,5		Heat control	Room temp.	1,3,5	
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<p>Minor REVISION comments</p>	<p>Line 69-70: "The main aim of accelerated stability study to predict the stability profile of a drug product that prediction of the shelf life of the product before launching into the market". Write the sentence again as it is not well understood. Line 114-115: Change the sentence "may not be good, so. A more refined" by "may not be good. So a more refined". Point 1.4.2: explain what is chemical stability. Line 216-217: "The active ingredient in hydrolytic groups such as hydroxyls, surfactants can be used to protect and limit their degradation". Write the sentence again as it is not well understood. Line 267: Figure 2 must be named in the text. Line 283: Figure 3 must be named in the text. Line 339. Table 4 must be named in the text. Line 480. Explain "large no". No is number? Line 483, Table 6. Do not put abbreviators inside the column (AMLO-VAL-HCTZ) Line 485-495. Make some comments about UPLC, as it is mentioned in table 6</p>																					



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	Line 496. I believe that point 7.1 should not go inside ANALYTICAL TOOLS.	
Optional/General 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?	<i>(If yes, Kindly please write down the ethical issues here in details)</i>	

Reviewer Details:

Name:	Marta de Diego Glaría
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