Journal Name:	Journal of Pharmaceutical Research International	
Manuscript Number:	Ms_JPRI_81539	
Title of the Manuscript:	Stability Assessment Approaches for Amoxicillin Nano-suspension as Promising Tool for Drug Delivery System	
Type of the Article	Original research article	

## **General guideline for Peer Review process:**

This journal's peer review policy states that <u>NO</u> manuscript should be rejected only on the basis of '<u>lack of Novelty'</u>, 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:

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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
Communication DEVICION		his/her feedback here)
<u>Compulsory</u> REVISION comments	Review of the article entitled Stability Assessment Approaches for Amoxicillin Nano-suspension as Promising Tool for Drug Delivery System, Ms JPRI 81539	
	This article is within the scope of the journal and suitable for publication after some revision.	
	The English language should be improved. On page 1, Lines 1 and 2, the first sentence of the abstract should be improved as follows Amoxicillin Nano-suspension is one of the approaches for improving dissolution rate of amoxicillin that is widely used as antibiotic. In the second sentence delete dot after nano. Stabilizing these nano dosage forms is always a challenge. Line 3, Nano precipitation can be divided Line 14, use comma to connect the sentences, instead of dot, after isothermal degradation periods, while no isothermal method ignores the effect of the storage conditions Line 15, begin the sentence with Isothermal and no isothermal treatments would allow On page 2, in the first sentence of the Introduction delete which, and state Penicilloic acid subsequently decomposes to penilloic acid by decarboxylation. Line 7, delete dot after base-catalyzed self-aminolysis. State nucleophile attack Line 8, state in the same row <i>p</i> -lactam carbonyl moiety Correct spelling neighboring Paragraph 2, line 1, delete dot after The degradation of amoxicillin trihydrate over pH 3-10.5 at 35 °C. Line 3, The third sentence should begin in the second row.	
	Line 5, correct spelling is Polymerization Move subtitle Stability Testing of New Drug Substances to the next page Line 9, use the abbreviation pH, instead of PH, as well as in the rest of the manuscript	
	On page 3, paragraph 2, line 1, Nano-particulate systems can be used, instead of nano-particulated systems On page 4, paragraph 1, line 2, state no isothermal, as well as in the rest of the manuscript Paragraph 3, line 5, put dot after no isothermal conditions.	
	Paragraph 4, when enumerating, use a comma between items that begin with a lowercase letter The first capital letter can be used for Nano-suspension Paragraph 5, state bio-pharmaceutical properties Move to the next page subheading MATERIALS AND METHOD CHEMICALS	

On page 5, paragraph 1, Nano precipitation in line 1, micro-nano-size, line 2 and nano suspension, lines 3 and 4, can be divided

Paragraph 2, lines 1 and 2, add one space for polyvinyl pyrrolidone K30, surface active agent

and for Tween 80, Benzalkonium chloride

Paragraph 3, state the abbreviation after Differential Scanning Calorimetry (DSC) Specify the abbreviation after the first mention of a term, in the rest of the text either the abbreviation or the entire term can be used

In Methods, put dot at the end of the first sentence of listing, after UV –Visible spectrometer.

The second sentence should be These results are summarized in tables.

Move in a separate row the fourth item of listing

4. DSC scans of pure drug sample and polymer were recorded.

Move to the next page subtitle Isothermal Stage

On page 6, paragraph 1, line 6, use singular for was recorded

Paragraph 2, no isothermal should be separated

Line 2, begin the sentence with the first capital letter

The kinetic parameters were calculated for the isothermal and no isothermal methods.

Paragraph 3, line 2, state Samples would be taken

State pH 5 within listing

Use one space between the number and the unite of measure in the entire manuscript

Correct spelling is octadecylsilane

Delete some repeated terms and state

Flow rate: 1 ml/min Injection volume: 20 µl

On page 7, the first paragraph should be modified

143.6 mg of amoxicillin trihydrate internal reference standard was used, which is equivalent to 125 mg of amoxicillin added in anhydrous state to 100 ml volumetric flask and completed to 100 ml with mobile phase. The obtained mixture was stirred in a magnetic stirrer for

15 min, filtered and the first 10 ml filtrate was discarded.

In paragraph 2, when listing, use a dot between items that begin with a capital letter

Begin item 4 with the first capital letter and end it with a dot.

Paragraph 3, when listing, use a comma between items that begin with a lowercase letter and end it with a dot.

In the item 3, re injected can be separated

Paragraph 4, line 1, use singular for Weight content per 5 ml was determined Line 2, correct spelling is labeled

The third sentence should be corrected, for example as follows

It was multiplied by 5 to obtain the content per 5 ml and then the percentage of the content to the labeled quantity.

In the fourth sentence state The same was repeated for all the samples

On page 8, lines 1 and 2, in the first sentence of the second paragraph, use commas

for listing

Line 2, delete repeated Particle size

Line 3, state size, instead of sizer

Lines 6 and 7, correct sentence should be

The high surface energy of these particles triggers agglomeration of the drug crystals.

State The UV spectrophotometric method was selected for the estimation of amoxicillin

The melting point was found to be 197 - 204 °C

Move to the next page item 3. FTIR

On page 9, in the first and the second paragraph, grammar should be improved, the past tense should be used adequately, as well as the unit of measure cm<sup>-1</sup>

Paragraph 1, Line 1, FTIR was used

Line 2, The FTIR spectra were taken

Correct the third sentence

The FTIR spectra of all the samples are shown in Figure 1.

The fourth sentence should be

Row amoxicillin and precipitated nanoparticles exhibited the same FTIR spectra, the amoxicillin showed peak at 3468 cm<sup>-1</sup> for N-H and the range is from 3300-3500 cm<sup>-1</sup>, and the nano-suspension showed the peck at 3543 cm<sup>-1</sup>, which demonstrates that the chemical structure of the drug is not changed before and after the precipitation process.

In the second paragraph grammar should be improved also, the first and the second sentence should be corrected for example, as follows.

Nano-suspensions were prepared using Nano precipitation solvent evaporation technique (aqueous phase and organic phase), the aqueous phase contained different amounts of polymer and surface active agent at 25 °C, at the ratios of 1:1, 1:2, 1:3, 1:4, 1:5 (Chart 1). The organic phase containing active ingredient was dissolved in an ethanol solvent at 25 °C.

The organic phase was poured into aqueous phase, subsequently stirred on mechanical stirrer and then the volatile solvent was allowed to evaporate. Line 7, use singular for Organic solvent was left to evaporate Move the item 4. DSC to the next page

On page 10, paragraph 1, state was examined by DSC Paragraph 6, line 3, correct spelling is reformulation

On page 11, paragraph 2, lines 5 and 6, improve the last sentence of this paragraph HPLC (USP method) was used to assay the amoxicillin content initially, after one month, and after 6 months.

On page 12, paragraph 1, line 1, state

High temperature accelerates deterioration of a pharmaceutical product, instead of accelerate

Paragraph 2, line 1, use comma after appearance, and correct spelling odor and color

Paragraph 2, lines 2 and 3, state in the same row 76 ml

Lines 5 and 6, use the past tense in the last two sentences of this paragraph

#### PART 2:

		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)  There are no ethical issues in this manuscript	
Are there competing interest issues in this manuscript?	There are no competing interest issues in this manuscript	
If plagiarism is suspected, please provide related proofs or web links.	There is no plagiarism suspected in this manuscript	

#### PART 3: Declaration of Competing Interest of the reviewer:

Here reviewer should declare his/her competing interest. If nothing to declare he/she can write "I declare that I have no competing interest as a reviewer"

I declare that I have no competing interest as a reviewer

# PART 4: Objective Evaluation:

Guideline	MARKS of this manuscript	
Give OVERALL MARKS you want to give to this manuscript		
( Highest: 10 Lowest: 0 )		
Guideline:		
Accept As It Is: (>9-10)		
Minor Revision: (>8-9)	Major Revision: (>7-8)	
Major Revision: (>7-8)		
Serious Major revision: (>5-7)		
Rejected (with repairable deficiencies and may be reconsidered): (>3-5)		
Strongly rejected (with irreparable deficiencies.): (>0-3)		

PART 5: Reviewer Details:
This information is mandatory to prepare the Reviewer Certificate properly.
Certificate prepration will not be possible if incomplete information is received.

Name of the Reviewer	Tamara Jovanovic	
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5-8 Keywords regarding expertise of Reviewer	Materials, chemistry, medicinal and pharmaceutical chemistry, chemical technologies, nanotechnologies, biomedical	
	engineering, spectroscopy	