Reviewer's report

Title: Are antibiotics substandard in Lebanon? Quantification of active pharmaceutical ingredients between brand and generics of selected antibiotics

Version: 0 Date: 29 Dec 2019

Reviewer: Chiara Di Lorenzo

Reviewer's report:

This is an interesting and well written paper underlying on the factors that can contribute to the antibiotic resistance. Only few issues need to be fixed/clarified by the authors.

Page 5 line 35: correct "madications" into medications

Page 5 line 56: Authors should indicate the meaning of API

Page 6, line 47: Authors should specify the conditions for defining generic and brand drugs "equivalent" as stated by the Ministry of Public Health.

Page 7, line 54-55. A space should be added between 0.025 (line 54) and M and 2 and L (line 55).

Page 8, Analysis. Please specify if the analysis was conducted using isocratic or gradient conditions.

Page 9 line 10. Authors stated that "the amount of drugs should not be less than 85% of the amount declared on the label". But this amount can exceed the 115% (+15%) of the amount declared on the label?

Page 11, line 34. The sentence "USP requirement clearly states that sample fails analysis if the assay is under &lt;90% or &gt;120% of the stated API content" seems to be in contrast with the sentence reported at line 10, page 9: "The amount of ciprofloxacin, amoxicillin and clavulanic acid in solution for each sample of the generic and brand antibiotic should not be less than 85% of the amount declared on the label (USP Monograph)". Please clarify.

Page 14, conclusion. Will the authors analyze other generic drugs belonging to other classes?

Table 2. Please indicate the abbreviation of ciprofloxacin (CIP) in the table header.

Table 3. Correct "amoxicilin per pill" into "amoxicillin per pill"

Table 4. Please indicate the abbreviation of clavulanic acid (CA) in the table header.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

Acceptable

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