Please note that the changes made to the article are for personal understanding mainly due to the low level of English

Compatibility studies of rivaroxaban with inactive substances using DSC and FT-IR spectrophotometers

Comment: The origin title needs to be improved further.

Abstract:

Objective: To conduct compatibility studies of rivaroxaban (RN) with selected commonly used pharmaceuticals excipients.

Purpose: To test the possibility of formulating rivaroxaban with pharmaceutical excipients.

Methodology: Compatibility studies have been conducted with rivaroxaban crospovidone, sodium starch glycolate, magnesium stearate, talc, microcrystalline cellulose, aerosil, HPMC K100 M, croscarmellose sodium using differential scanning calorimeter and FTIR spectrophotometer.

Results: DSC thermograms of rivaroxaban and physical mixture of individual pharmaceutical excipient showed a drug transition range between 224ºC and 232ºC. The FTIR plots showed that the wave numbers of rivaroxaban corresponded to all selected pharmaceuticals combinations of excipients.

Conclusion: DSC and FTIR studies have shown that RN was not interactive with selected pharmaceutical excipients and can be carried over for further research.

Comment: The abstract should be written in one paragraph with three sections: introduction to rivaroxaban, methodology and main results.

Keywords: Rivaroxaban, FTIR, DSC.

Comment: None

1. Introduction

Rivaroxaban (RN) is a newly developed potent oral anticoagulant patented in 2007 and approved for medical use in 2011. In 2019 during the COVID-19 pandemic it was the most commonly prescribed drug. It is a direct factor Xa inhibitor used to treat blood clots caused by various conditions such as COVID-19, accidents, bleeding, etc.,

Chemically it is (S)-5-chloro-N-((2-oxo-3-(4-(3-oxomorpholino)phenyl)oxazolidin-5yl)methyl)thiophene-2-carboamide (Fig. 1).

The study of physico-chemical interactions is the most important consideration for developing pharmaceutical dosage form. Drug interaction with a pharmaceutical excipient affects physical, chemical, therapeutic properties and stability of the dosage form. Hence the effective stable dosage form depends on the choice pharmaceutical excipient. In view of the large significance of the formulations of rivaroxaban and to develop an effective and stable dosage form,

In this article, an attempt has been made to characterize the physicochemical incompatibility of rivaroxaban with widely used selective pharmaceutical excipients, namely crospovidone (CPN), sodium starch glycolate (SS), magnesium stearate (MS), aerosil, talc, hydroxypropyl methylcellulose K100M (HPMC K100 M) microcrystalline ellulose(MCC), croscarmellose sodium (CS).

In this study differential scanning calorimetry and Fourier transforming infrared spectroscopy was used assess physico-chemical incompatibility.

Differential Scanning Calorimetry is a thermal analytical method providing sample phase transition temperature based on the difference in heat required for maintains the same reference temperature and sample bowls (4). In DSC x-axis temperature in ºC, and on the Y axis, the heat flux in W/g exists. In infrared Fourier transform Spectroscopy (FTIR), plotted with wavenumber along the x-axis and transmittance along along the Y axis from 4000 cm-1 to 500 cm-1.

Comment: The introduction should consist of three main paragraphs. The first paragraph is an introduction to the main heading or what you are doing. The second paragraph is why you are doing this. The third paragraph is how you do your work.

2. Method

2.1 Materials:

Rivaroxaban was received as a gift sample from Alfamed Formulations, Hyderabad. crospovidone, sodium starch glycolate, magnesium stearate, aerosil, talc, hydroxypropyl methylcellulose K100M, microcrystalline cellulose and croscarmellose sodium purchased from Merck was used in the present study.

2.2 Instrument:

DSC thermograms were obtained using DSC, Model Q20 of TA tools with TAQ20 software. FTIR spectra were recorded on BRUKER alpha model infrared spectrophotometer with OPUS software (8). Thermal analysis was carried out for PH, PH and physical mixture RN chosen pharmaceutical excipients (CPN, SSG, MS,

Comment: The methodology should consist of one paragraph.

3. Results and Discussion:

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4. Conclusions:

Since the transition temperatures of the drug, rivaroxaban and selected pharmaceuticals the excipients of the present study were within the range limits (DSC thermograms), as well as the appearance of FTIR spectra was similar in the case wave numbers in relation to the drug, it can state that it was not possible physicochemical interactions of rivaroxaban and selected pharmaceutical excipients (crospovidone, sodium starch glycolate, magnesium stearate, aerosil, talc, hydroxypropyl methylcellulose K100M, microcrystalline cellulose and croscarmellose sodium). The results are that these combinations are compatible and can be used for further research to develop pharmaceutical drugs with rivaroxaban.

Comment: Conclusions must be at a high level of English.