COMPARISON OF DISSOLUTION METHODS

Introduction

Dissolution tests are used to determine an amout of released drug, usually from a solid dosage form (e. g. tablets, capsules and suppositories) in a specified liquid and at a specified time. These tests are important for the development and quality control of medicinal product. They are also irreplaceable in bioequivalence studies.

Apparatus 2 (Paddle apparatus) and Apparatus 4 (Flow-through cell) will be used in this task. Both will be operated in a closed system. In the case of apparatus 2, samples will be collected by the collector into test tubes and the absorbance will be then manually measured. In the case od apparatus 4, a flow-though cuvette will be used. At the end of the experimental work, the values of a relative amount of released drug (m_{rel}) will be calculated and the dissolution profiles of tablets will be evaluated.

The aim of the work

The aim of the work is to evaluate the dissolution profiles of tablets containing 30 mg of paracetamol and a retarding component using a paddle apparatus and a flow-through cell apparatus.

Equipment

Substances: prepared tablets containing paracetamol and a retardant excipient, purified water

Laboratory tools: graduated cylinder, test tubes, 10mm cuvettes, flow-through cuvette, dissolution medium container, beakers, wash bottle

Laboratory apparatus: dissolution apparatus Sotax AT-7 Smart with 1 l dissolution vessels and paddles, collector, peristalic pump, dissolution apparatus Sotax CE-1, flow-through cell, ruby ball and small glass balls, piston pump, water bath with stirrer, spektrophotometr Specord 205

Procedure – Paddle apparatus:

1. Check the temperature setting (37 °C) and the rotational speed of the paddles (50 ot. /min.).
2. Connect the sampling tube and attach it to the peristaltic pump.
3. Fill the collector test tube tray with empty and clean test tubes. Press the RESET button on the collector and then START.
4. Prepare one tablet with the drug, place the tablet in the dissolution vessel and start the test (RUN) – the device will start collecting samples at set time intervals.
5. After collecting the last sample, rinse the sampling tube with purified water. Carefully remove, empty and wash the dissolution vessel and turn off the dissolution apparatus.
6. Remove the test tube tray with test tubes from the collector and measure its absorbance at 244 nm on a spectrophotometer against a blank sample (distilled water), 1:1 dilution. Enter the values in the appropriate table prepared on the computer.
7. Calculate the relative amount of released drug and construct its dissolution profile.

Procedure – Flow-through cell dissolution:

1. Check the temperature setting of water bath (37,5 °C) and the dissolution medium (37 °C, 2 liters).
2. Check the rotational speed of the stirrer placed in the container with the dissolution medium (250 rpm).
3. Check the flow rate through the piston pump (30 ml/min).
4. Put a ruby ball, a glass balls scoop and finally a tablet into the flow-throug cell.
5. Carefully attach the filter head to the flow-through cell and place it in the holder.
6. Check the connection of the tubes (container of medium → pump → flow-through cuvette → dissolution cell → container of medium).
7. Start the pump and observe the contents of the flow cell.
8. The dissolution medium contained in the cuvette is used as the blank sample before the test is started. When the dissolution medium level reaches the tablet, start the measurement on a spectrophotometer (= the blank).
9. The spectrophotometer measures the absorbance of the dissolution medium at 244 nm (first measurement of the sample is after 2 minutes)
10. Enter the measured values in the table on the computer for subsequent calculations and construction of dissolution profiles.
11. Rinse the pump and tubes with purified water, then turn off the pump and water bath.
12. Carefully open the holder, disassemble the dissolution cell and rinse all parts thoroughly with purified water and dry.
13. Calculate the relative amount of released drug and construct its dissolution profile.

Topics for discussion

Pharmacopoeia requirements for evaluation of dissolution profiles. Influence of chosen method on dissolution profiles. Influence of dissolutiondevice settiong on dissolution profiles.

Conclusion

Construct the dissolution profiles based on the calculated results. Compare dissolution profiles of both dissolution methods.