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Research Article

PREPARATION AND EVALUATION OF PIROXICAM TABLETS BY DIRECT COMPRESSION METHOD EMPLOYING PREPARED LACTOSE-STARCH AND LACTOSE-SUCROSE DIRECTLY COMPRESSIBLE VEHICLES

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Abstract

Piroxicam, is a potent non steroidal anti-inflammatory drug (NSAID) with a long-life that permits once daily dose. Piroxicam is approved in the United States for the treatment of Rheumatoid arthritis and Osteoarthritis.

Piroxicam tablets are formulated by Direct compression method which has several advantages over Grannulation methods. The objective of the present study is to prepare and evaluate Lactose-Starch and Lactose-Sucrose directly compressible vehicles by Grannulation technique and were subjected to micromeritic evaluation for size and flow properties, and Piroxicam tablets were prepared by Direct compression technique employing prepared DCV's, the tablets were evaluated in comparision to commercial Piroxicam tablets.

Finally, Dissolution of Piroxicam from tablets prepared employing DCV's were found to be superior to that of commercial, as indicated by the parameter, DE30 i.e.., 76.44,67.947and 35.88 % for Lactose-Sucrose, Lactose-Starch and Commercial tablets respectively.

Keywords:

Dissolution, Piroxicam, Lactose-starch, Lactose-sucrose, DCV.

Introduction

Preparation of tablets by direct compression method has several advantages such as less time consuming and economic as fewer steps are involved in the processing; relatively fast dissolution of drug from the tablets made by direct compression when compared to Grannulation methods. Direct compression methods requires excipients particularly diluents which exhibit good flow and compressility. Exipients or vehicles which possess good flow and compressibility are known as directly Compressible Vehicles. Thers is several DCV's available in the market.

Examples include Starch 1500 (pregelatinized starch), Microcrystalline cellulose (avicel PH102), Spray dried lactose (lubritos SD), Encompress (dicalcium phosphate).

The objective of the present study is to prepare and evaluate Lactose-Starch and Lactose-Sucrose directly compressible vehicles by Grannulation technique and were subjected to micromeritic evaluation for size and flow properties, and Piroxicam tablets were prepared by Direct compression technique employing prepared DCV's, the tablets were evaluated in comparision to commercial Piroxicam tablets.

Materials and Methods

Materials*:*

Piroxicam is obtained as gift sample from Dr.Reddy's Lab, Hyderabad. Crosspovidone was purchased from Sd Fine chemicals Limited, Mumbai. All other chemicals used in the study were analytical grade.

Methods*:*

Method of Preparation of DCV's:

Wet Grannulation method was used for preparing the DCV's. Aratio of 80: 20 in the case of Lactose-Starch and 90: 10 in the case of Lactose-Sucrose were used in the preparations. Lactose and Starch or Lactose and Sucrose were blended thoroughly in a dry mortar. The blend of powders were then granulated with 8% w/v mucilage of acacia(q.s.). The duff mass formed was pressed through mesh no: 12. The wet granules formed were dried at 75^0c for 2 hrs. The dried granules were again passed through mesh no: 12 to break agglomerates. The fines formed were removed by sieving through mesh no: 80. The product that passes through mesh no:12 and retained on mesh no : 80 were collected as directly compressible vehicles.

Evaluation of DCV's prepared:

The DCV's prepared were evaluated for size and size distribution using standard sieves and for flow characteristics by measuring Angle of repose and compressibility index. The results are given in table:

Preparation of tablets by direct compression method:

Piroxicam tablets were prepared by direct compression method employing prepared DCV's as per the formula given in table: Piroxicam, cross povidone, lactose are thoroughly blended in a dry mortar. The blend was then transferred into a polythene bag. DCV, talc, magnesium stearate were added to the blend of drug in polythene bag and shake thoroughly. The blend of powder was compressed into tablets on a CADMACH 16 station tablet compression machine.

Evaluation of tablets: All the prepared tablets were evaluated for disintegration time, dissolution time, hardness and friability. Hardness was measured using Pfizer hardness tester. Friability was determined using Roche friabilator.

Disintegration time: The *in vitro* disintegration time was determined using disintegration test apparatus. One tablet was placed in each of six tubes of apparatus and one disc was added to each tube. The basket assembly was positioned in water. The time taken for complete disintegration of the tablet was measured.

Dissolution test: *In vitro* dissolution studies for tablets were carried out using USP paddle method in 900ml of 0.1 N HCL, using ELECTROLAB 8 station dissolution rate test apparatus maintained at 37±0.5℃ at 50 rpm. Five millilitres of aliquots were withdrawn at 5, 10, 15, 20, 30, 40 and 60minutes from the basket and replaced by 5ml of fresh dissolution media. The collected samples were analyzed after suitable dilution at 333nm using UV- Visible spectrophotometer against the blank.

Results and Discussion

Lactose-Starch and Lactose-Sucrose directly compressible vehicles were prepared by wet granulation method. The DCV's prepared were granular, discrete and free-flowing. The size and size distributions are shown in table:

The size frequency distributions of the 2 DCV's prepared are approximately normal distributions. In the micromeritic evaluation the DCV's prepared exhibited good flow characteristics. The Angle of repose was found to be 16.6 and 24.4 respectively with lactose-starch and lactose-sucrose DCV's. The compressibility index values were found to be 13.27 and 16.66 in case of lactose-starch and lactose-sucrose DCV's.

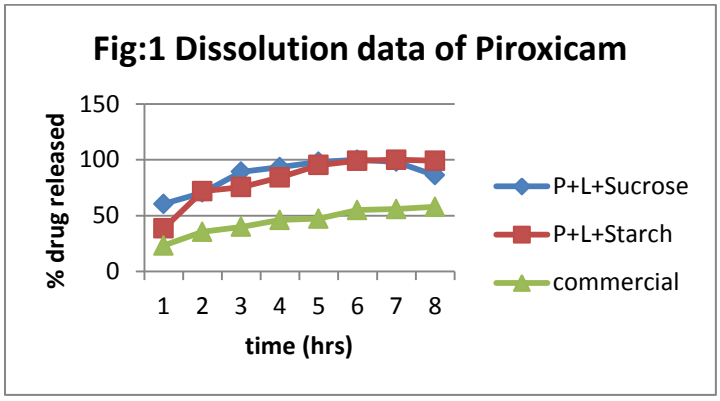
Piroxicam tablets were prepared by direct compression method employing Lactose-Starch and Lactose-Sucrose DCV's and the tablets were evaluated in comparision to a commercial Piroxicam tablet formulation. Piroxicam tablets formulated disintegrated rapidly within 50 sec. The hardness and friability of the formulated tablets were in the range of 4-5 kg/cm^2 and 0.3-0.4 % respectively. The formulated tablets also gave rapid dissolution of Piroxicam when compared to commercial tablets. The dissolution rate was found to be 0.1316, 0.096 and 0.0124 min^{-1} respectively with the tablets prepared employing Lactose-Starch, Lactose-Sucrose and commercial tablets. Dissolution efficiency was also higher in the case of formulated tablets when compared to commercial product.

Conclusion

Lactose-Starch and Lactose-Sucrose directly compressible vehicles prepared by Grannulation method were found to be granular and free-flowing. The size distribution of DCV's approximated to normal distribution. As such the two DCV's prepared were found to be suitable for use in direct compression method for preparation of tablets.

Piroxicam tablets with rapid disintegration and dissolution characteristics could be formulated using Lactose-Starch and Lactose-Sucrose DCV's prepared in the laboratory. The dissolution rate and dissolution efficiency of the formulated tablets were much higher than those of commercial products.

Figure 1: Dissolution data of Piroxicam.



P+L+Sucrose (piroxicam+lactose+sucrose)
P+L+Starch (piroxicam+lactose+starch)

Table-1: Physical parameters of Piroxicam tablets.

Formulation	Hardness(kg/cm2)	Fraibility(%)	Disintegration time (min-sec)
Lactose+Sucrose	5	0.3	0-48
Lactose+Starch	4	0.41	0-50
Commercial	4	0.75	0-24

Table-2: Dissolution parameters of Piroxicam tablets.

Formulation	PD10 (%)	T50 (min)	K(1/min)	DE30(%)
Lactose+Sucrose	70.66	3	0.132	76.44
Lactose+Starch	71.881	5.5	0.096	67.947
Commercial	35.509	34	0.0124	35.88

Table-3: Formula of Piroxicam tablets prepared by Direct Compression method.

INGREDIENTS	QUANTITY(1 TAB)
Piroxicam	20 mg
Cross povidone (5%)	11.5 mg
Magnesium stearate (2%)	4.6 mg
talc (2%)	4.6 mg
DCV (70%)	161 mg
Lactose	28.3 mg

Table-4: Micromeritic Properties of prepared Grannules.

PROPERTY	Lactose-Starch	Lactose-Sucrose
Particle size	830.499 µm	782.026 µm
Bulk density	0.434 g/cc	0.385 g/cc
Tapped density	0.479 g/cc	0.462 g/cc

Angle of repose	16.633	24.2
Compressability	13.272	16.6
Hausners ratio	1.104	1.2

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