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Preparation and Assessment of Globular Agglomerates of Antihypertensive Drug

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ABSTRACT

Low aqueous solubility is the major problem encountered with formulation development of new chemical entities as well as generic development. Although these techniques have commonly been used to increase dissolution rate of the drug, there are practical limitations with these techniques, the desired bioavailability enhancement may not always be achieved. In the current work, it will be concentrated on improvement of the solubility of antihypertensive drug by quasi emulsion solvent diffusion technique.

ORIGINAL RESEARCH ARTICLE

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INTRODUCTION

The evaluation of pharmaceutical raw materials and finished products for impurities and degradation products is an essential part of the process of drug development and production. Furthermore, toxicity data must be found on any drug-related impurities that represent a concentration of more than 0.1% of the active pharmaceutical ingredient (API). Conventional analysis of pharmaceutical QC and production fields has traditionally been performed by titration, Identification, Loss on drying, sulfate ash, dissolution, and disintegration test by using UV-visible, HPLC, GC, or IR detection. The most challenging task for research scientist is to formulate a successful drug product of a poorly soluble drug. This occurs mainly because of poor bioavailability. [1] Improving oral bioavailability of the drugs which are given as solid dosage forms remains a challenge for the formulation scientists due to solubility problems. Limited drug absorption resulting in poor bioavailability is paramount amongst the potential problems that can be encountered when delivering an active agent via the oral route. Poorly water-soluble drugs often show poor bioavailability because of low and erratic levels of absorption. The rate limiting process for absorption of poorly soluble drugs from the solid dosage form could be a slow dissolution rate. Various factors affecting the drug absorption from gastrointestinal tract are poor aqueous solubility or poor membrane permeability. A drug administered in solution form immediately available for absorption and efficiently absorbed than the same amount of drug administered in a solid dosage form such as tablet or capsule. Solubility is a most important parameter for the oral bioavailability of poorly soluble drugs poorly water soluble drugs often requires high doses in order to reach therapeutic plasma concentrations after oral administration. Low aqueous solubility is the major problem encountered with formulation development of new chemical entities as well as generic development. Although these techniques have commonly been used to increase dissolution rate of the drug, there are practical limitations with these techniques, the

desired bioavailability enhancement may not always be achieved. [2-3] In the current work, it will be concentrated on improvement of the solubility of antihypertensive drug by quasi emulsion solvent diffusion technique.

EXPERIMENTAL WORK

Identification and collection of all proposed drug material

The drug Nicardipine and other necessary excipients were composed from the pharma industries of mandideep area as gift sample. All the composed material was used for the proposed work.

Preparation of globular agglomerates by solvent diffusion techniques with solvents

Three dissimilar natural solvents as high-quality solvent including methyl acetate (MA), ethyl acetate (EA) and isopropyl acetate (IPA) were employed as a dispersed phase for making oil-in-water emulsions (O/W). Crystallization was carried out in a cylindrical vessel equipped with three baffles. Nicardipine was dissolved in 15 ml of good solvent. The solvent solutions were then poured dropwise during 3 min, under stirring (500 rpm), into 585 ml of water containing 0.1% w/v emulsifier. Tween 80, SLS, PVP or HPMC were used as emulsifiers. After 15 min agitation by a propeller type stirrer, the agglomerates were separated from the solution by filtration under vacuum and then were placed in a thin layer in an oven at 60°C for 3 h. The solubility of organic solvents in water was the basis of the selection of the solvents in making solvent-in-water emulsion.[4]

Table 1 Formula for Nicardipine globular agglomerates

Formulation Code	Nicardipine (mg)	SLS (%)	PVP (%)	Tween 80 (%)	Methyl acetate (ml)	Ethyl acetate (ml)	Isopropyl acetate (ml)
NCD F1	20	0.020	.....	.....	30	60	10
NCD F2	20	0.040	.....	.....	20	80	10
NCD F3	20	.....	0.010	.....	20	70	10

Evaluation of Nicardipine globular agglomerates [5-6]

Flow Properties

Pure Nicardipine and prepared spherical agglomerates were evaluated for bulk density and tapped density using density apparatus (TDA2, Campbell Electronics). The Carr's index and Hausners's ratio were then calculated by using ρb and ρt. The angle of repose was determined by fixed funnel method.

Production yield

The yield of prepared spherical agglomerates was determined based on the total weight of agglomerates obtained. The quantities of agglomerates obtained were weighed after drying and yield was calculated as per equation.

Where, a=Weight of agglomerates (mg), b= Weight of drug taken for preparation of agglomerates (mg).

RESULTS AND DISCUSSION

Evaluation of Nicardipine spherical agglomerates

Flow Properties

These results confirm that spherical agglomeration drastically improved the flow and compaction behaviour of Nicardipine. All the findings were recorded in table 2

Table 2 Flow Properties of Nicardipine and prepared agglomerates

Formulation Code	Angle of repose	Hausner's ratio	Carr's index
NCD F1	28.20^0	2.70	18.25 %
NCD F2	16.10^0	1.30	6.80
NCD F3	30.10^0	1.10	9.20

Production yield

During spherical crystallization, little drug was stuck to the stirring element, which led to decrease in yield of agglomerated product. Results are given in table 3.

Table 3 Production yield of Nicardipine and prepared agglomerates

Formulation Code	Production yield (%)
NCD F1	82.30±1.2
NCD F2	78.10±2.0
NCD F3	88.25±2.0

CONCLUSION

There is no uncertainty that nicardipine provides an appropriate alternative to other drugs available for the treatment of angina and hypertension. However, further well-designed comparative clinical trials are needed to clarify its relative place in the long term management of this disorder.

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