Release Characteristics of Selected Drugs with a New Developed Polyvinyl Acetate Dispersion

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ABSTRACT SUMMARY:

Release characteristics of a newly available drug, Ibuprofen and a highly soluble drug, ascorbic acid were studied in conjunction with a newly developed polyvinyl acetate dispersion. The control granules and tablets comprised from coated granulated powder. Sustained release was achieved with ascorbic acid coated tablets but not with the ibuprofen acid coated tablets. A high release rate was obtained with ascorbic acid coated tablets and with ibuprofen coated tablets. The coated tablets were compressed into tablets with the hypothesis that the polymer would form a matrix structure. The release of both drugs was monitored by dissolution study of tablets and it was observed that a sponge-like polymer matrix remained as a residue.

EXPERIMENTAL:

A methodical investigation of drug – Ibuprofen and a soluble drug – ascorbic acid were used for this study. Fluid bed processors have been in use for granulation, coating and drug processing in the pharmaceutical industry. A coating formulation was granulated using a SPG1 Fluid bed processor to improve the size and powder flow properties. The granules were coated with the polyvinyl acetate dispersion using the spray method in the fluid bed processor. The coated granules were compressed in a tablet as far as a polymer matrix inside the tablet. Dissolution studies were carried out to ascertain the release characteristics from coated granules and compressed tablets.

I. Ibuprofen Tablets: Il. Ascorbic Acid Tablets:

Dissolution profiles of Ibuprofen and Ascorbic Acid before coating:

A. Composition of Polyvinyl acetate dispersion solution.

Table: Composition of Polyvinyl Acetate dispersion solution.

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinylacetate</td>
<td>27 %</td>
</tr>
<tr>
<td>Povidone</td>
<td>2.7 %</td>
</tr>
<tr>
<td>Polyvinylpyrrolidone</td>
<td>5 %</td>
</tr>
</tbody>
</table>

PREPARATION OF POLYVINYL ACETATE COATING DISPERSION

Polymer suspension
Kollidon SR 100 55.0 g
Polyvinylacetate 24.0 g
Methocel E 30 DP 3.2 g
Povidone 0.4 g

Spray nozzle purging air 1.5 bar
Inlet air temperature 40º C
Inlet air velocity 5 m/s
Spray nozzle diameter 0.5 mm
Atomizing air Preselection 1.5 bar
Stirring and mixture is homogenized. The two suspensions are mixed together. The coating film was obtained at 50% solids in the coating mixture.

Dissolution profiles of Ibuprofen and Ascorbic Acid coated granules:

For Ibuprofen granules coated with a total polymer content of 15 g per 100 mg of Ibuprofen, the dissolution was 100% from 1 - 2 hours in dissolution media. The dissolution media and the dissolution condition were as per the USP. Ibuprofen was assayed by UV measurements at 277 and 305 nm, whereas ascorbic acid was determined by CIP method of Titrations with 0.5 N (H2SO4) as the standard.

Dissolution profiles of Ibuprofen and Ascorbic Acid coated tablets:

For Ibuprofen granules coated with a total polymer content of 15 g per 100 mg of Ibuprofen, the dissolution time was 1.51 hr and 6.43 hr, respectively. In the case of ascorbic acid, sustained release from coated granules was not possible due to the coating of a highly soluble irregular shaped drug.

REFERENCES:

3) Journal of Pharmaceutical Sciences. 60: 1869 – 1874

RESULTS AND DISCUSSION:

The Granulated Ibuprofen is more uniform in particle size and shape, has better flow properties when compared to the control batches as well as the raw drug material. The granulated Ibuprofen has a more spherical shape than the control batches. The USP dissolution study of tablets and it was observed that a sponge-like polymer matrix remained as a residue.

CONCLUSION:

Declaration closes that sustained release is possible from lower polymer concentration for high solubility drugs. Sustained release was also achieved from Ibuprofen, indicating that the polyvinyl acetate dispersion in a suitable excipient for preparation of sustained release granules for low solubility drug candidates.

SEM photographs of Ibuprofen:

SEM photographs of Ascorbic Acid:

SEM of Tablet surfaces after dissolution studies:

Dissolution profiles of Ibuprofen and Ascorbic Acid coated tablets:

I. Ibuprofen Tablets: Il. Ascorbic Acid Tablets:

I. Ibuprofen Granules: II. Ascorbic Acid Granules:

The coated granules were compressed into tablets with the hypothesis that the polymer would form a matrix structure. The release of both drugs was monitored by dissolution study of tablets and it was observed that a sponge-like polymer matrix remained as a residue.