Key role of Hospital Pharmacy in a Non-Profit Study involving Ruxolitinib 5 mg cps: Implementation and Quality Assurance of an Investigational Manufacturing Product

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Background
For a no-profit study evaluating efficacy of Ruxolitinib 5 mg in patients with Hodgkin’s lymphoma Investigators had to use their Research Fund able to meet only the cost of Jakavi 20 mg tablets, cheaper than the other dosages.

Aim and Objectives
The Hospital Pharmacy aims were to improve the pharmaceutical formulation producing capsules of Ruxolitinib 5 mg starting from Jakavi 20 mg tablets

Materials and Methods
• For each batch (200 cps) 50 tablets of Jakavi 20 mg and 6 mg of starch were used
• 80 samples were allocated to conduct Uniformity of mass single-dose preparations and stability studies
• Stability studies: three samples of 20 capsules for each one, in amber glass bottles at storage condition (25°C – 2°C) per 12 months were prepared and every months by HPLC Assay were determined Ruxolitinib concentration

Results
Ruxolitinib used

102 packs instead of 408 packs

Uniformity of mass studies: no more than 2 of the individual capsules masses deviated from the average mass by more than 10% and none deviates more than twice that percentage.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Theoretical Concentration (mg/ml)</th>
<th>Trueness(%)</th>
<th>Repeatability (%CVw)</th>
<th>Intermediate Precision (%CVp)</th>
<th>Tolerance Interval (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruxolitinib Phosphate</td>
<td>0,045</td>
<td>96,3</td>
<td>1,3</td>
<td>1,3</td>
<td>94,5-98,2</td>
</tr>
<tr>
<td></td>
<td>0,12</td>
<td>100,3</td>
<td>1,1</td>
<td>2,9</td>
<td>94,4-106,3</td>
</tr>
<tr>
<td></td>
<td>0,14</td>
<td>106,3</td>
<td>1,1</td>
<td>1,2</td>
<td>104,4-108,2</td>
</tr>
</tbody>
</table>

Conclusions
The role of pharmacist has proved to be essential for the no profit trial implementation. Pharmacists allowed the compounding required from study design, ensuring safety and quality with a significant cost saving. Stability test demonstrated also that the compounding can be stored for up six months in standard conditions.