MASS UNIFORMITY OF HARD CAPSULES: ROYAL SPANISH PHARMACOPOEIA VS UNITED STATES PHARMACOPOEIA

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BACKGROUND AND IMPORTANCE
Quality control (QC) is an important part of the quality assurance of the elaborating process in a Hospital Pharmacy Department (HPD). The mass uniformity is the most commonly procedure used for QC of hard capsules.

AIM AND OBJECTIVES
Analyze comparatively the Royal Spanish Pharmacopoeia (RSP) hard capsule mass uniformity method versus the United States Pharmacopoeia (USP).

MATERIALS AND METHODS

A. The following parameters of each method were analyzed:
- Sample
- Average reference weight
- Percentage and acceptance requirements
- Elaborating process

B. Review February 2020 -> February-2021: elaborations of a batch of 100 hard capsules of dexamethasone 40 mg according the Hospital Pharmacy Department Standard Operating Procedure.

RESULTS

A. Sample

<table>
<thead>
<tr>
<th>Method</th>
<th>Capsules</th>
<th>Average reference weight</th>
<th>Percentage and acceptance requirements</th>
<th>Elaborating process</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSP-method</td>
<td>20 capsules</td>
<td>Sample weight</td>
<td>Deviation of ±10% or ±7.5% depending on the average weight. No &gt;2 capsules can deviate from the limits and none more than double.</td>
<td>Volumetric filling (Spanish National Formulary). Exipients weight is not required.</td>
</tr>
<tr>
<td>USP-method</td>
<td>5% or 10 capsules (whichever is less)</td>
<td>Theoretical weight</td>
<td>Deviation ±10% respect to the theoretical weight. No capsule must deviate.</td>
<td>Requires knowing the theoretical capsule weight (exipients weight is requerid).</td>
</tr>
</tbody>
</table>

B. Since February-2020 to February-2021, 8 batches of dexamethasone 40mg were elaborated. They were accepted with the RFE-method. After applying the USP-method, none were rejected.

CONCLUSION AND RELEVANCE
The USP-method is safer than the RSP-method because for the same acceptance interval (±10%) it does not admit any deviation. It also requires knowing the weight of all the excipients. Therefore, it is capable of detecting errors in the elaboration that the RFE-method would not detect (as long as the error is >10% and the capsules are homogeneous).

Currently, the USP-method has been incorporated in the Hospital Pharmacy Department as a reference of hard capsules quality control, since it provides greater safety in their preparation.