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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:

a. Sample
b. Average reference weight
c. Percentage and acceptance requeriments
d. 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.

Quality control carried out: **RSP-method**

Quality control applied to the revised elaborations: **USP-method.** The theoretical weight of a capsule was calculated:

- Average weight 5 empty capsules (0.0493g)
- Batch content weight: [13.8g=dexamethasone(4g)+excipient(9.8g)]
- Acceptance interval (0.169-0.206g)

RESULTS

A	SAMPLE	AVERAGE REFERENCE WEIGHT	PERCENTAGE AND ACCEPTANCE REQUERIMENTS	ELABORATING PROCESS
RSP-method	**20** capsules	**Sample** weight	Deviation of **±10% or ±7.5%** depending on the average weight. *No >2 capsules can deviate from the limits and none more than double.*	Volumetric filling (Spanish National Formulary). Excipients weight is not required.
USP-method	**5% or 10** capsules (whichever is less)	**Theoretical** weight	Deviation **±10%** respect to the theoretical weight. *No capsule must deviate.*	Requires knowing the theoretical capsule weight (excipients weight is requerid).

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.

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