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Diploma in Pharmacy 1st Year
Pharmaceutics
Experiment

To demonstrate the content uniformity test of the capsules as per the Monographs.

Aim:

To demonstrate the content uniformity test of the capsules as per the Monographs.

Reference :

‘ Dr. Gupta G.D , Dr. Sharma Shailish , Dr. Sharma Neelam’ “Practical Manual of Pharmaceutics” Published by Nirali Prakashan, Page no 152 – 155

Apparatus and Materials Required :

Capsules and weighing scale.

Theory :

The test for the assay of contents is described in individual monographs and calculates the API quantity in each capsule. In accordance with the IP, the monograph provides that not less than 20 capsules are required to perform this assay. In case of unavailability of 20 tablets, not less than 5 tablets can be utilised to perform this assay.

Table 4 presents wide range of tolerant values allowed for sampling errors.

Table 4: IP Limits for Content of Active Ingredients

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Weight of API in each Capsule (gm)	Subtract from Lower Limit for Samples of			Add to the Upper Limit for Samples of		
0.12 or less	15	10	5	15	10	5
More than 0.12 but less than 0.3	0.2	0.7	1.5	0.3	0.8	1.8
0.3 or more	0.2	0.5	1.2	0.3	06	1.5

In accordance with the BP, 10 capsules are randomly selected for their content evaluation using a method described in monograph or other appropriate analytical methods of equivalent accuracy and precision. The Acceptance Value (AV) for this test is calculated by using the following formula:

AV=M-X+KS

Where, M= Reference value.

X = Mean of individual content (x1, x2.... xn) expressed as percentage of the label claim.

K=Acceptability constant.

S=Sample standard deviation.

Procedure :

1) 10 capsules are taken and subjected to assay
2) 9 of 10 capsules will obey with this test if not more than one of the capsule is outside the limits of 85-115% of the average value and none is outside the limits of 75-125%
3) On the contrary, capsules fail to comply with the test if the contents of more than 3 capsules deviate from the range of 85 115% of the average content or if one or more capsule contents are outside the limits of 75 125% of the average content
4) The process is performed again taking another 20 capsules, if the contents of 2 or 3 capsules lie outside the range of 85-115% of the average content.
5) The capsules comply with this test if in a sample of 30 capsules, the contents of not more than 3 capsules lie outside the range of 85 115% and not a single capsule lie outside the range of 75-125% of the average content.

Table 5 presents the limits for content uniformity (CU) and mass variation (MV) tests of capsules us specified in IP. BP, USP, and PhEur. In accordance to IP, this test is not valid for multivitamins or trace elements containing capsules .

Table 5: IP, RP, USP and PhEur Limits for Content Uniformity (CU) and Mass Variation (MV) Test

Capsules	Variation (MV) Tests Dose and Ratio of Active Substance	
	≥ 25 mg and ≥ 25 %	< 25 mg or < 25 %
Hard	MV	CU
Soft	CU	CU

Result :

The coutent uniformity test of the capsules as per the monographs was studied.

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