

Pharmacopoeial Tests for Different dosage forms

Tablet

- **Uniformity of weight**

Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in Table 2 and none deviates by more than twice that percentage.

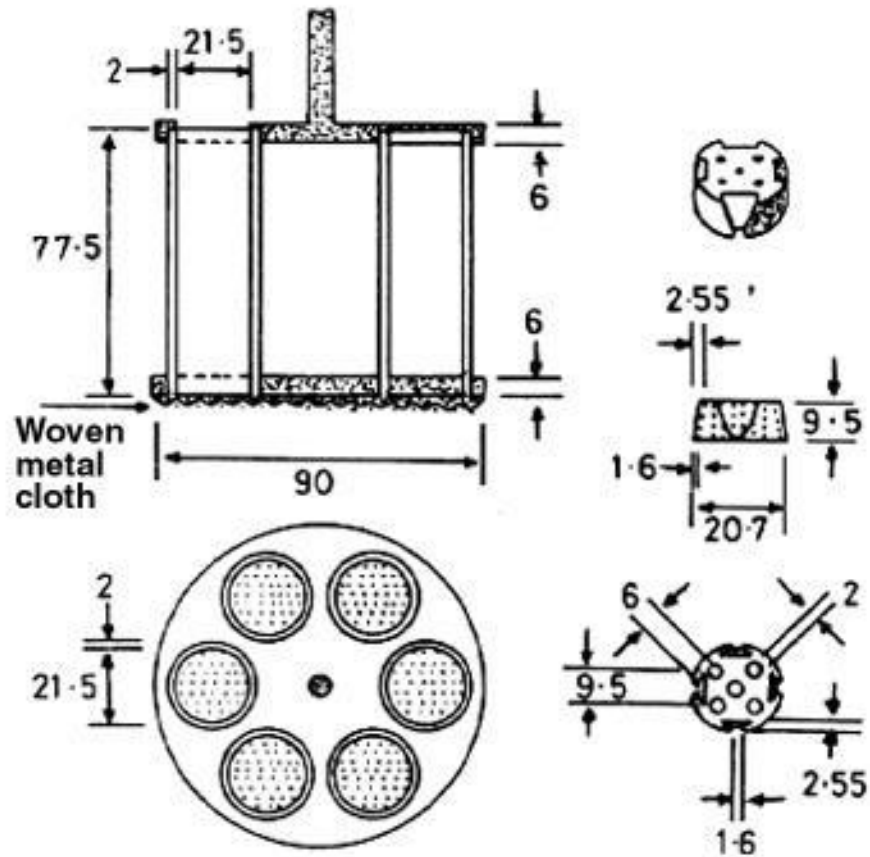
Average weight of tablet	Percentage deviation
80 mg or less	10
More than 80 mg but less than 250 mg	7.5
250 mg or more	5

- **Uniformity of content**

The tablets comply with the test if not more than one of the individual values thus obtained is outside the limits **85** to **115%** of the average value and none is outside the limits **75** to **125%** of the average value. If two or three of the individual values are outside the limits 85 to 115% of the average value and none is outside the limits 75 to 125%, repeat the determination using another 20 tablets. The tablets comply with the test if in the total sample of 30 tablets not more than three of the individual values are outside the limits 85 to 115% and none is outside the limits 75 to 125% of the average value.

- **Disintegration**

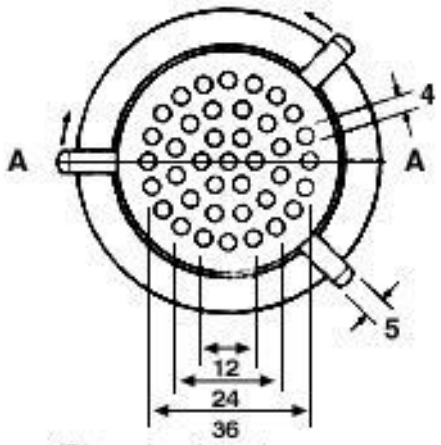
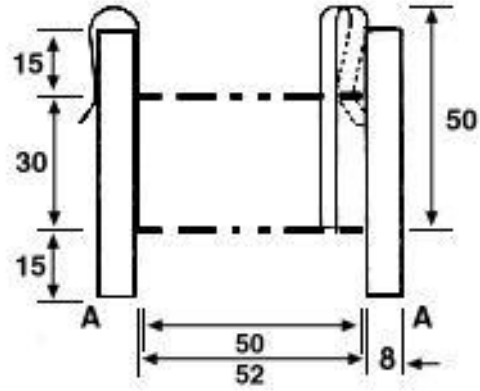
Type of capsule	Disintegration time	
Uncoated Tablets	15 minutes	
Coated Tablets	film-coated	30 minutes
	other coated tablets	60 minutes
Enteric-coated Tablets	<i><u>0.1M hydrochloric acid</u></i>	Should not disintegrate in 120 minutes
	<i><u>mixed phosphate buffer pH 6.8,</u></i>	60 minutes.
Dispersible and Soluble Tablets	within 3 minutes	
Effervescent Tablets	5 minutes	



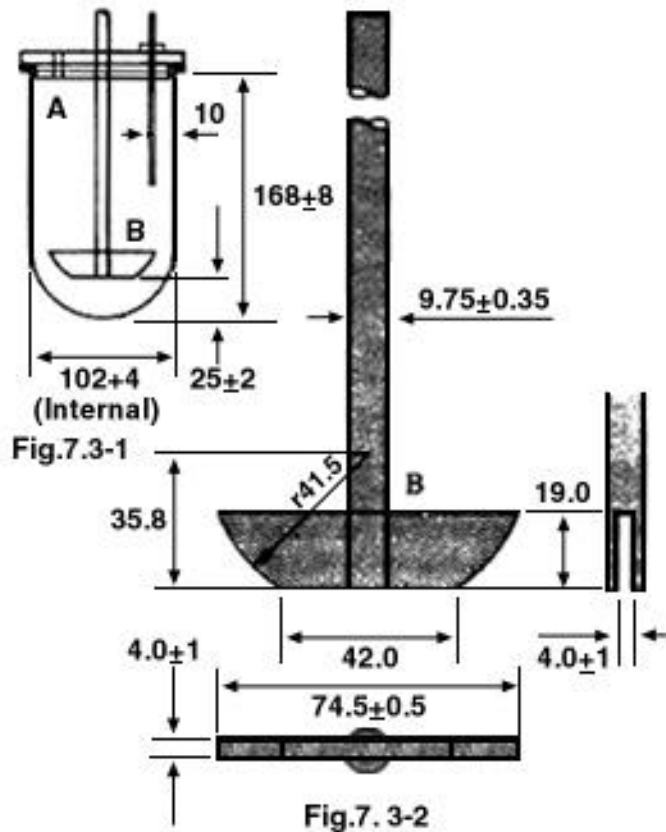
(Dimensions in mm)

APPARATUS FOR DISINTEGRATION OF TABLETS AND CAPSULES

Pharmacophore Solutions



(Dimensions in mm)
APPARATUS FOR DISINTEGRATION OF PESSARIES
AND SUPPOSITORIES



(Dimensions in mm)

APPARATUS FOR DISSOLUTION OF TABLETS AND CAPSULES

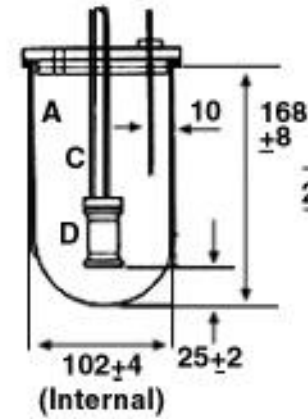


Fig.7.3-3

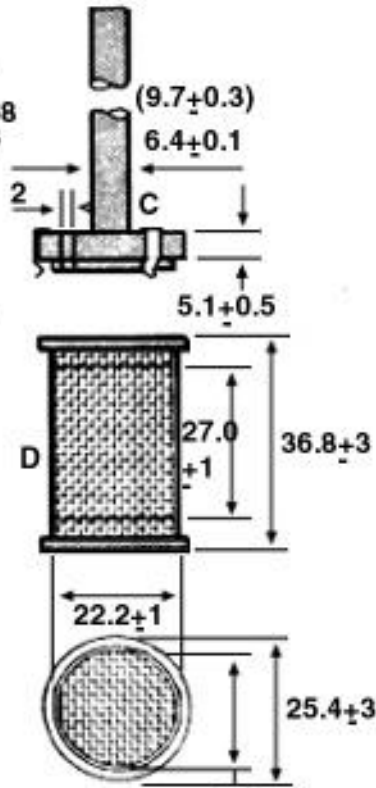


Fig.7.3-4

(Dimensions in mm)

APPARATUS FOR DISSOLUTION
OF TABLETS AND CAPSULES

Capsule

A. Content of active ingredients

Weight of active ingredients in each capsule	Subtract from the lower limit for samples of			Add to the upper limit for samples of		
	15	10	5	15	10	5
0.12 g or less	0.2	0.7	1.5	0.3	0.8	1.8
More than 0.12g And less than 0.3g	0.2	0.5	1.2	0.3	0.6	1.5
0.3g or more	0.1	0.2	0.8	0.2	0.4	1.0

B. Uniformity of weight

Average weight of capsule contain	Percentage deviation
Less than 300 mg	10
300mg or more	7.5

C. Uniformity of content:

The capsules comply with the test if not more than one of the individual values thus obtained is outside the limits 85 to 115% of the average value and none is outside the limits 75 to 125%. If two or three individual values are outside the limits 85 to 115% of the average value repeat the determination using another 20 capsules. The capsules comply with the test if in the total sample of 30 capsules not more than three individual values are outside the limits 85 to 115% and none is outside the limits 75 to 125% of the average value.

D. Disintegration:

Type of capsule	Disintegration time	
Hard Capsules	30 minutes	
Enteric Capsules	<i><u>0.1M hydrochloric acid</u></i>	Should not disintegrate in 2 hours
	<i><u>mixed phosphate buffer pH 6.8</u></i>	60 minutes
Soft Capsules	60 minutes	