OFFICIAL QUALITY CONTROL TESTS OF TABLETS

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OFFICIAL QUALITY CONTROL TESTS OF TABLETS AS PER I.P

- ***WEIGHT UNIFORMITY***
- ***FRIABILITY***
- ***CONTENT UNIFORMITY***
- ***DISINTEGRATION TEST***
- ***DISSOLUTION TEST***
- ***HARDNESS (Un Official)***

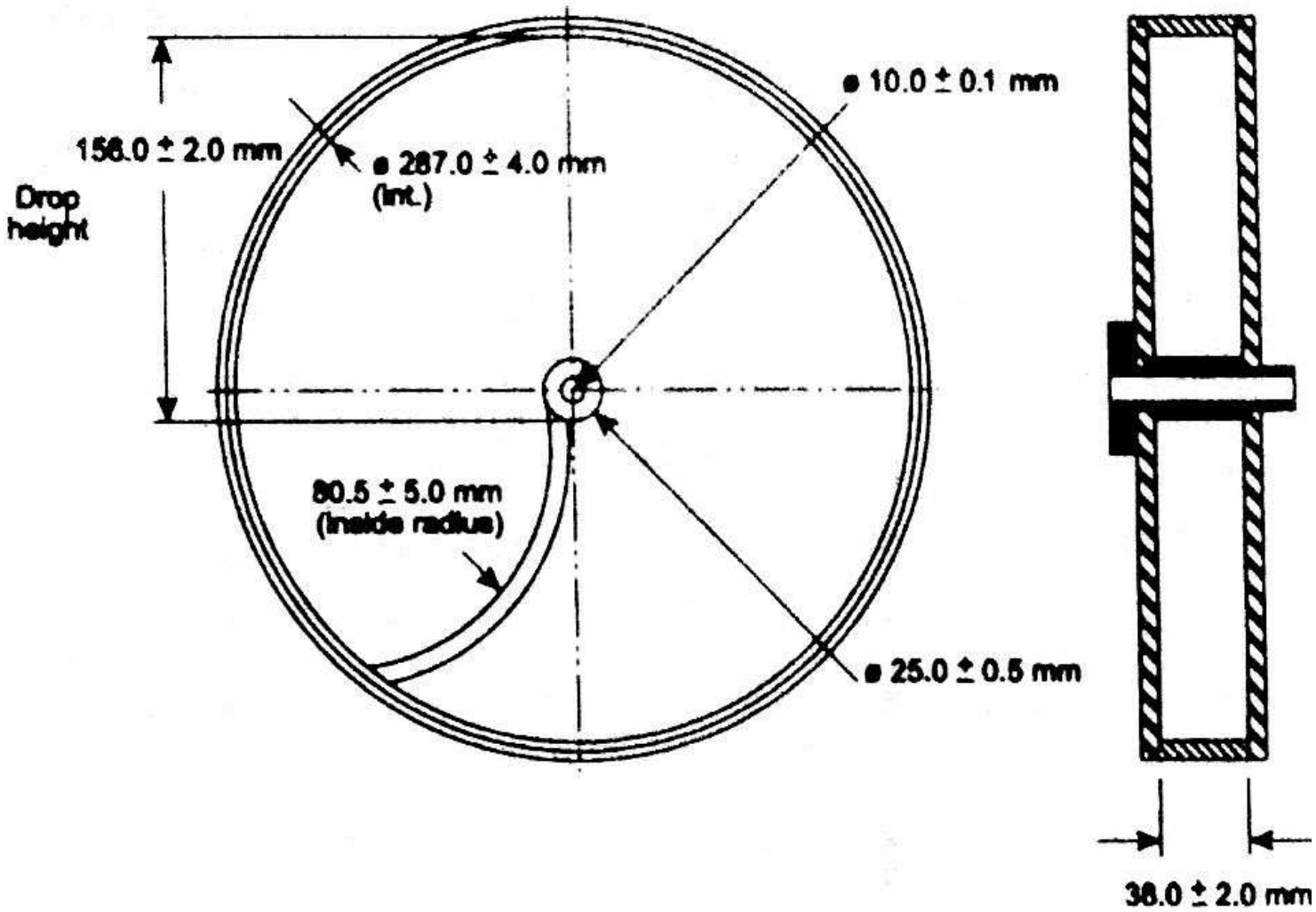
WEIGHT UNIFORMITY

Table

Dosage form	Average weight	Percentage deviation
Uncoated and film-coated tablets	80 mg or less	10
	More than 80 mg but less than 250 mg	7.5
	250 mg or more	5

FRIABILITY

FRIABILITY



Tablet friability apparatus

CONTENT UNIFORMITY

Table

Weight of active ingredients in each tablet	Subtract from 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	1.6	0.3	0.8	1.8
More than 0.12 g but less than 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

DISINTEGRATION APPARATUS

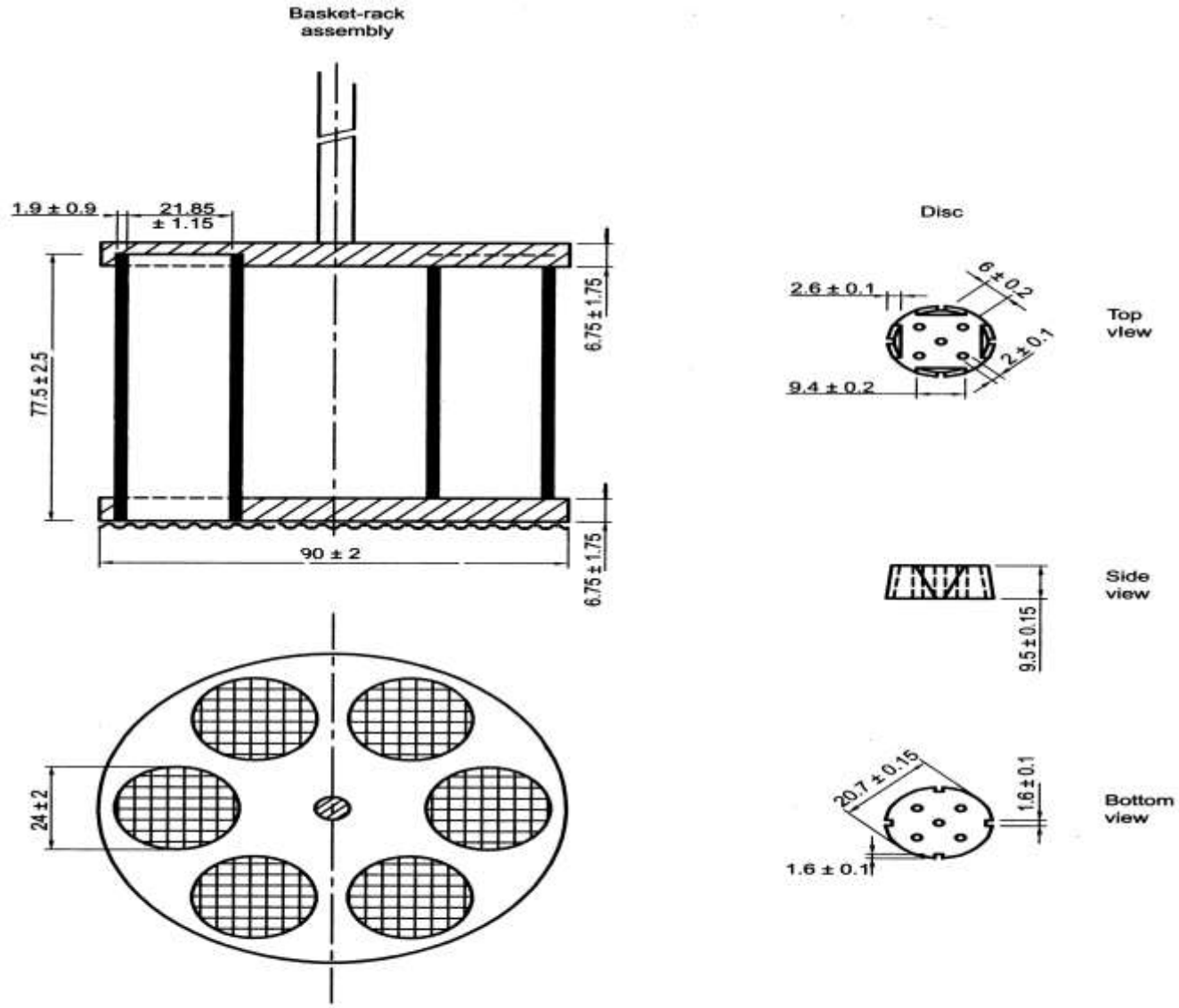


Figure 2.9.1.-1. – *Disintegration apparatus A*

Dimensions in millimetres

A. UNCOATED TABLETS

- No of Tablets : 06
- Disintegration Medium : Distilled Water
- Disintegration Time : 15 minutes
- Temperature : 37^{0}c

B.COATED TABLETS

- No of Tablets : 06
- Disintegration Medium : Distilled Water/ replaced with 0.1NHCL
- Disintegration Time : 60 minutes
- Temperature : 37^{0}c

C. DISPERSIBLE TABLETS

UNIFORMITY OF DISPERSION

- No of Tablets : 02
- Temperature : 24^0C to 26^0C
- Disintegration Medium : **100ml** Distilled Water
- Dispersion Test : Pass through Sieve No ≠ **22**
  Disintegration Time : 3minutes

D. EFFERVESCENCE TABLETS

TEST FOR EFFERVESCENCE

- No of Tablets : **06**
- Disintegration Medium : **250ml** Distilled Water
- Disintegrated Time : **5minutes**
- Temperature : **20^0C to 30^0C**

E.ENTERIC – COATED TABLETS

- No of Tablets : 06
- Disintegration Medium : 0.1N HCl for 120min and replace it with 6.8*pH* phosphate buffer for 60min
- Temperature :37^0c

DISSOLUTION APPARATUS

DISSOLUTION TEST

Apparatus 1

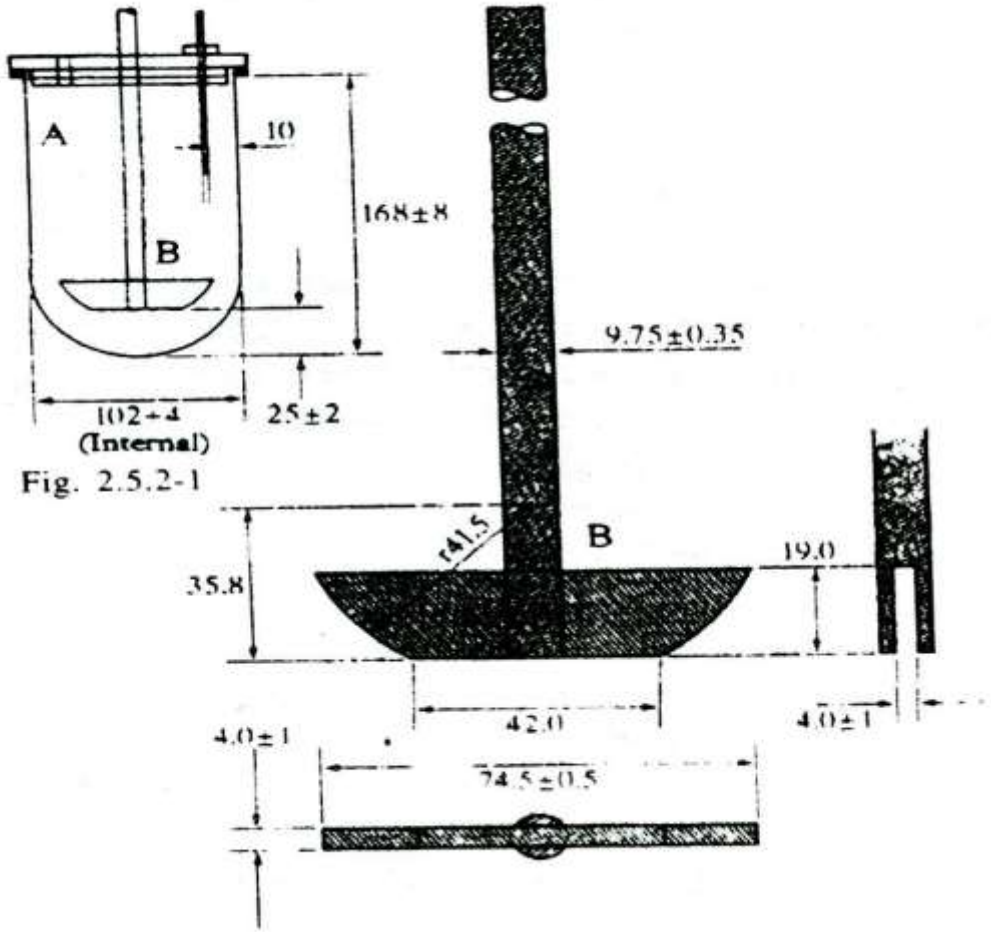


Fig. 2.5.2-1

DISSOLUTION TEST

Apparatus 2

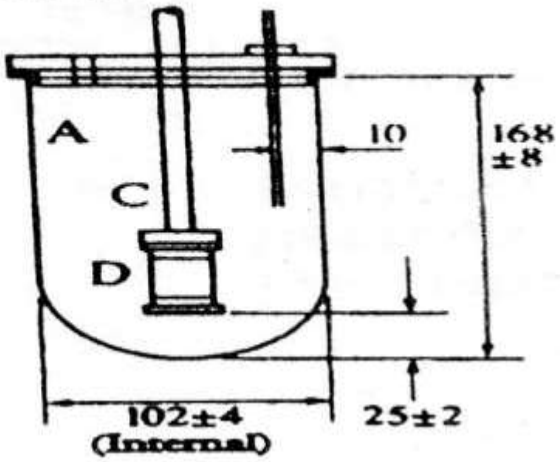
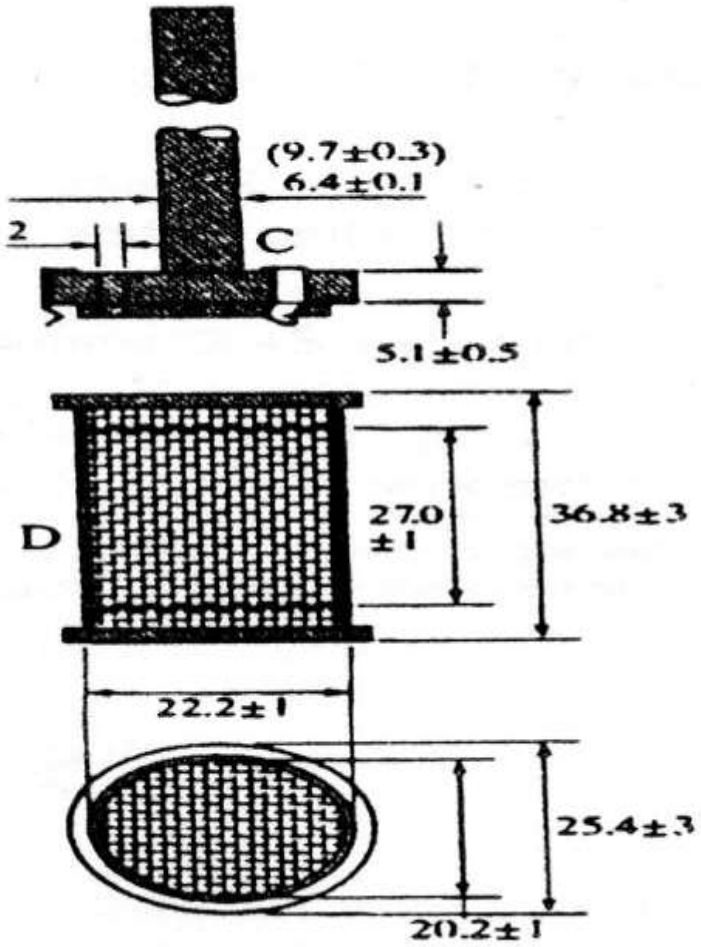


Fig. 2.5.2-3



DISSOLUTION TEST ACCEPTANCE CRITERIA

Table 1

Level	Number tested	Acceptance criteria
S_1	6	Each unit is not less than D* + 5 per cent**.
S_2	6	Average of 12 units (S_1 +S_2) is equal to or greater than D, and no unit is less than D – 15 per cent**.
S_3	12	Average of 24 units (S_1+S_2+S_3) is equal to or greater than D, not, More than 2 units are less than D – 15 per cent** and no unit is less than D – 25 per cent**.

*D is the amount of dissolved active ingredient specified in the individual monograph, expressed as a percentage of the labelled content.

**Percentages of the labelled content.

HARDNESS (UNOFFICIAL)

MONSANTO HARDNESS TESTER

HARDNESS (UNOFFICIAL)

Pfizer HARDNESS TESTER