



## REVISION OF METHOD OF ANALYSIS:

### 5.3 DISINTEGRATION TEST FOR TABLETS AND CAPSULES

(February 2014)

*DRAFT FOR COMMENT*

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**REVISION OF METHOD OF ANALYSIS:**

**5.3 DISINTEGRATION TEST FOR TABLETS AND CAPSULES**

	Date
Draft monograph received from a WHO Expert	February 2014
Draft monograph mailed out for comments	February – April 2014
Discussion at informal consultation on specifications for <i>The International Pharmacopoeia</i>	3–4 April 2014
Collation of comments	April 2014
Presentation to forty-ninth WHO Expert Committee on Specifications for Pharmaceutical Preparations for discussion	October 2014
Further follow-up action as required	

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#### 4 **Revision of method of Analysis: 5.3 Disintegration test for tablets and capsules**

5 *[Note from the Secretariat.*

6 *It is proposed to include a disintegration test for large tablets in the test for disintegration of tablets*  
7 *and capsules. The proposed method is reproduced with permission from The European*  
8 *Pharmacopoeia.*

9 *Changes from the current text are indicated in the text by insert or ~~delete~~.]*

10

### 11 **5.3 DISINTEGRATION TEST FOR TABLETS AND CAPSULES**

12 This test is provided to determine whether tablets or capsules disintegrate within the prescribed time  
13 when placed in a liquid medium under the experimental conditions presented below.

14 For the purposes of this test disintegration does not imply complete dissolution of the unit or even  
15 of its active constituent. Complete disintegration is defined as that state in which any residue of the  
16 unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test  
17 apparatus or adhering to the lower surface of the discs, if used, is a soft mass having no palpably  
18 firm core.

19 Use apparatus A for tablets and capsules that are not greater than 18 mm. For larger tablets and  
20 capsules use apparatus B.

21 Test A. Tablets and capsules of normal size

22 *This text is based on the internationally-harmonized texts developed by the Pharmacopoeial*  
23 *Discussion Group (PDG). Some editorial modifications have been made in order to be in line with*  
24 *the style used in The International Pharmacopoeia.*

25 Apparatus. The apparatus (**Figure 1**) consists of a basket-rack assembly, a 1000 ml, low-form  
26 beaker, 138–160 mm in height and having an inside diameter of 97–115 mm for the immersion  
27 fluid, a thermostatic arrangement for heating the fluid between 35 °C and 39 °C, and a device for  
28 raising and lowering the basket in the immersion fluid at a constant frequency rate between 29 and  
29 32 cycles per minute, through a distance of not less than 53 mm and not more than 57 mm. The  
30 volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh  
31 remains at least 15 mm below the surface of the fluid and descends to not less than 25 mm from the  
32 bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly  
33 become submerged. The time required for the upward stroke is equal to the time required for the  
34 downward stroke and the change in stroke direction is a smooth transition, rather than an abrupt  
35 reversal of motion. The basket-rack assembly moves vertically along its axis. There is no  
36 appreciable horizontal motion or movement of the axis from the vertical.

37 Basket-rack assembly. The basket-rack assembly consists of six open-ended transparent tubes, each  
38 75.0–80.0 mm long and having an internal diameter of 20.70–23.00 mm and a wall 1.0–2.8 mm  
39 thick; the tubes are held in a vertical position by two plates, each 88–92 mm in diameter and 5.00–  
40 8.50 mm in thickness, with six holes, each 22–26 mm in diameter, equidistant from the centre of the  
41 plate and equally spaced from one another. Attached to the lower surface of the lower plate is a

42 woven stainless steel wire mesh, which has a plain square weave with 1.8–2.2 mm apertures and  
43 with a wire diameter of 0.570–0.660 mm. The parts of the apparatus are assembled and rigidly held  
44 by means of three bolts passing through the two plates. A suitable means is provided to suspend the  
45 basket-rack assembly from the raising and lowering device using a point on its axis.

46 The design of the basket-rack assembly may be varied somewhat provided the specifications for the  
47 glass tubes and the screen mesh size are maintained. The basket-rack assembly conforms to the  
48 dimensions shown in Figure 1.

49 Discs. The use of discs is permitted only where specified or allowed. Each tube is provided with a  
50 cylindrical disc 9.35–9.65 mm thick and 20.55–20.85 mm in diameter. The disc is made of a  
51 suitable, transparent plastic material having a specific gravity of 1.18–1.20. Five parallel 1.9–2.1  
52 mm holes extend between the ends of the cylinder. One of the holes is centered on the cylindrical  
53 axis. The other holes are centered 5.8–6.2 mm from the axis on imaginary lines perpendicular to the  
54 axis and parallel to each other. Four identical trapezoidal-shaped planes are cut into the wall of the  
55 cylinder, nearly perpendicular to the ends of the cylinder. The trapezoidal shape is symmetrical; its  
56 parallel sides coincide with the ends of the cylinder and are parallel to an imaginary line connecting  
57 the centres of two adjacent holes 6 mm from the cylindrical axis. The parallel side of the trapezoid  
58 on the bottom of the cylinder has a length of 1.5–1.7 mm and its bottom edges lie at a depth of  
59 1.50–1.80 mm from the cylinder's circumference. The parallel side of the trapezoid on the top of the  
60 cylinder has a length of 9.2–9.6 mm and its centre lies at a depth of 2.5–2.7 mm from the cylinder's  
61 circumference. All surfaces of the disc are smooth. If the use of discs is specified, add a disc to each  
62 tube and operate the apparatus as directed under procedure. The discs conform to the dimensions  
63 found in Figure 1.

64 The use of automatic detection employing modified discs is permitted where the use of discs is  
65 specified or allowed. Such discs must comply with the requirements of density and dimension given  
66 in this chapter.

67 Procedure. Place one dosage unit in each of the six tubes of the basket and if specified add a disc.  
68 Operate the apparatus using water as the immersion fluid unless another liquid is specified and  
69 maintain its temperature at 35–39 °C. At the end of the specified time, lift the basket from the fluid  
70 and observe the dosage units: all of the dosage units have disintegrated completely. If one or two  
71 dosage units fail to disintegrate, repeat the test on 12 additional dosage units. The requirements of  
72 the test are met if not less than 16 of the 18 dosage units tested are disintegrated.

#### 74 Test B – Large tablets and large capsules

76 *This test is reproduced with permission from The European Pharmacopoeia.*

77 Apparatus. The main part of the apparatus (Figure 2) is a rigid basket-rack assembly supporting  
78 3 cylindrical transparent tubes  $77.5 \pm 2.5$  mm long,  $33.0 \text{ mm} \pm 0.5$  mm in internal diameter, and  
79 with a wall thickness of  $2.5 \pm 0.5$  mm. Each tube is provided with a cylindrical disc  $31.4 \pm 0.13$  mm  
80 in diameter and  $15.3 \pm 0.15$  mm thick, made of transparent plastic with a relative density of 1.18–  
81 1.20. Each disc is pierced by 7 holes, each  $3.15 \pm 0.1$  mm in diameter, 1 in the centre and the other  
82 6 spaced equally on a circle of radius 4.2 mm from the centre of the disc. The tubes are held  
83 vertically by 2 separate and superimposed rigid plastic plates 97 mm in diameter and 9 mm thick,  
84 with 3 holes. The holes are equidistant from the centre of the plate and equally spaced. Attached to

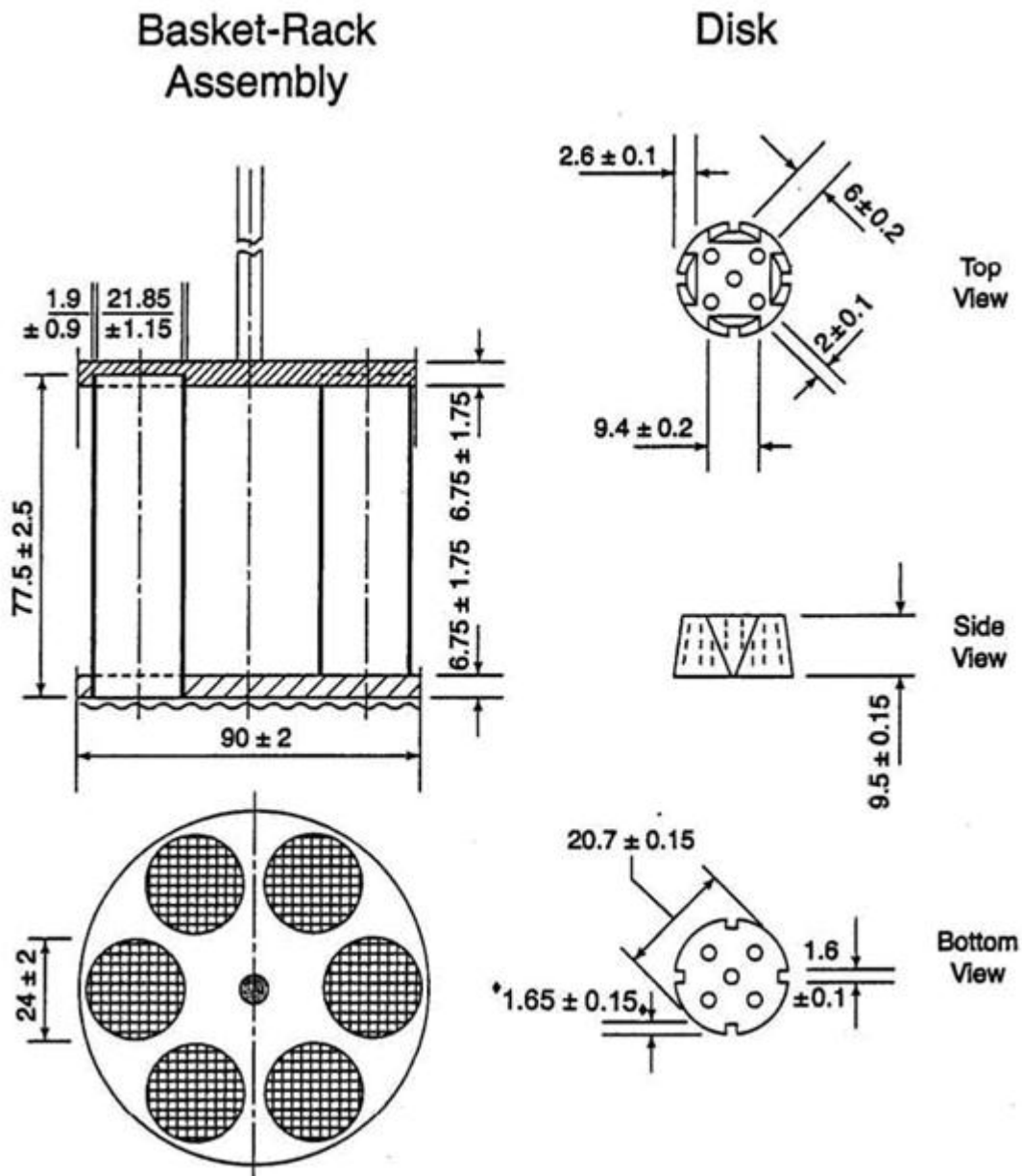
85 the under side of the lower plate is a piece of woven gauze made from stainless steel wire  
86 0.63 ± 0.03 mm in diameter and having mesh apertures of 2.0 ± 0.2 mm. The plates are held rigidly  
87 in position and 77.5 mm apart by vertical metal rods at the periphery. A metal rod is also fixed to  
88 the centre of the upper plate to enable the assembly to be attached to a mechanical device capable of  
89 raising and lowering it smoothly at a constant frequency of between 29 and 32 cycles per minute,  
90 through a distance of 55 ± 2 mm.

91 The assembly is suspended in the specified liquid medium in a suitable vessel, preferably a 1 litre  
92 beaker. The volume of the liquid is such that when the assembly is in the highest position the wire  
93 mesh is at least 15 mm below the surface of the liquid, and when the assembly is in the lowest  
94 position the wire mesh is at least 25 mm above the bottom of the beaker and the upper open ends of  
95 the tubes remain above the surface of the liquid. A suitable device maintains the temperature of the  
96 liquid at 35–39 °C.

97 The design of the basket-rack assembly may be varied provided the specifications for the tubes and  
98 wire mesh are maintained.

99 Method. Test 6 tablets or capsules either by using 2 basket-rack assemblies in parallel or by  
100 repeating the procedure. In each of the 3 tubes, place 1 tablet or capsule and, if prescribed, add a  
101 disc; suspend the assembly in the beaker containing the specified liquid. Operate the apparatus  
102 using water as the immersion fluid unless another liquid is specified for the prescribed period,  
103 withdraw the assembly and examine the state of the tablets or capsules. To pass the test, all 6 of the  
104 tablets or capsules must have disintegrated.

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107 Figure 1. Diagram for disintegration apparatus A (dimensions are expressed in millimeters).

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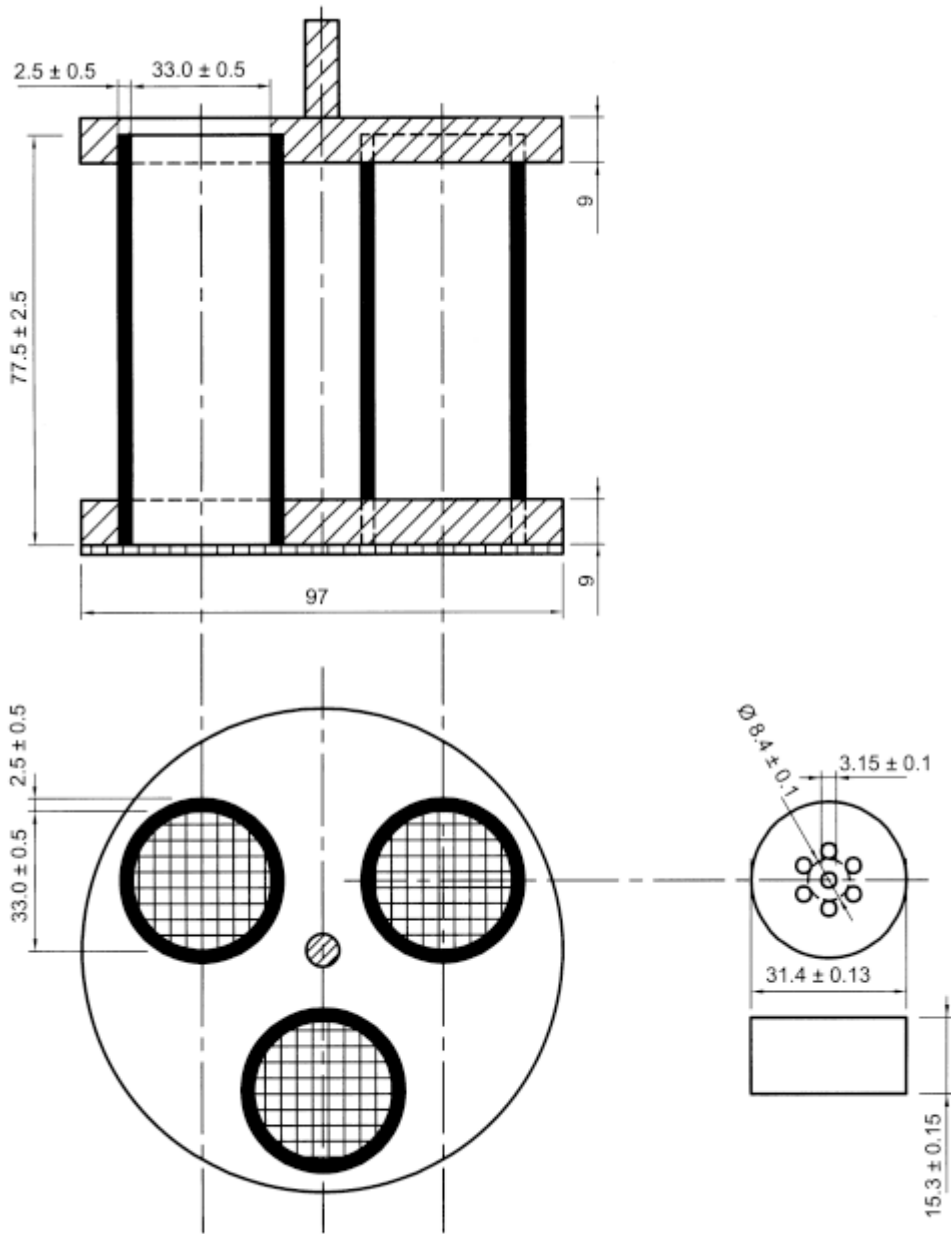


Figure 2.9.1.2. - Disintegration apparatus B  
Dimensions in millimetres

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110 Figure 2. Diagram for disintegration apparatus B (dimensions are expressed in millimeters).

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