

DT		USP33	Pharm. Europ. 7 th Edition	ERWEKA
	Units	Physical Tests, No. 711/724	Chapter 2.9.3	
Device				
Water bath temperature	°C	37 ±0,5	37 ±0,5 32 ±0,5	37 ±0,5 32 ±0,5
Speed tolerance	%	±4	±4	±4
Max. centering deviation vessel/shaft	mm	2	2	<2
Vessel 1000ml				
Height	mm	160-210	160-210	162,5 ± 1
Inside diameter	mm	98-106	98-106	104,0 ± 1
Material		Glas or inert material	Glas or other inert transparent material	Glas or plastic
Vessel 2000ml				
Height	mm	280-300		280-300
Inside diameter	mm	98-106		98-106
Material		Glas or inert material		Glas
Vessel 4000ml				
Height	mm	280-300		285,5 ±1
Inside diameter	mm	145-155		150 +1
Material		Glas or inert material		Glas
Mini-Vessel				
Height with flange	mm			122 ± 1
Height without flange	mm			118,5 ± 1,5
Inside diameter	mm			78 ±1
Material				Glas
Mini-Paddle				
Material				1.4571
Upper length	mm			55,5
Lower length	mm			31,2
Height	mm			13,9
Thickness	mm			2,7 ±0,1
Large radius	mm	not described	not described	30,8
Small radius	mm			0,5
Distance Paddle / bottom of vessel	mm			16,7
Wobble	mm			0,5 max.
Diameter shaft	mm			7,2
Fixation point A	mm			0,5
Fixation point B	mm			0,5

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Shaft

Material:		Stainless steel type 316 or other inert material	Stainless steel type 316 or equivalent	1.4571
Outside diameter	mm	9,4 - 10,1	9,4 - 10,1	10h6

Basket: Apparatus 1

Material holder		Stainless steel type 316 or other inert material	Stainless steel type 316 or equivalent	14.571
Retention spring			w. 3 tangs on 120center	w. 3 tangs on 120center
Material retention spring		Stainless steel type 316 or other inert material	Stainless steel type 316 or equivalent	14.310
Screen material		Stainless steel type 316 or other inert material	Stainless steel type 316 or equivalent	14.401
Material rings		Stainless steel type 316 or other inert material	Stainless steel type 316 or equivalent	14.571
Outside diameter ring	mm	25,0±3	25,0±3,0	25
Outside diameter screen	mm	22,2±1	22,2±1,0	22,1
Diameter inner ring	mm	20,2±1	20,2±1,0	20,2±0,1
Basket height	mm	37,0±3,0	37,0±3,0	36,8
Holder height	mm	5,1±0,5	5,1±0,5	5,3
Height tissue	mm	27,0±1	27,0±1,0	27
Diameter free opening	mm		20,2±1,0	20,2±1,0
Mesh (40mesh)	mm	0,36-0,44	0,36-0,44	0,375
Wire diameter (40mesh)	mm	0,25-0,31	0,25-0,31	0,25
Thicknes gold coating	µm	2,5	2,5	2,5
Distance basket / bottom of vessel	mm	25±2	25±2	25
Wobble	mm	±1,0	±1,0	<=1

Paddle: Apparatus 2

Material		Stainless steel type 303 or suitably inert material	Stainless steel type 316 or equivalent	14.581
Upper length	mm	74,0-75,0	74,5±0,5	74,5±0,3
Lower length	mm	42 ±1	42 ±1,0	42 ±1
Height h	mm	19,0±0,5	19,0±0,5	19±0,3
Thickness d	mm	4,0±1	4,0±1,0	4,0±0,3
Large radius	mm	41,5 ±1	41,5 ±1,0	41,5
Small radius	mm	1,2 ±0,2	1,2 ±0,2	1,2
Distance paddle / bottom of vessel	mm	25±2	25±2	25
Runout accuracy	mm		0,5	

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Paddle over disc, Appartus 5

Material rings		Stainless steel	Stainless steel	14.571
Outside diameter	mm	41,2	41,2	41,2
Inside diameter	mm		32,2	33,8
Ring thickness	mm	3,3	3,3	3,3
Sieve material			Stainless steel	Stainless steel
Mesh	mm		0,125	0,15
Wire diameter	mm			0,1

Transdermalcylinder, short: Apparatus 6

Material		Stainless steel	Stainless steel type 316 or equivalent	1.4571
Diameter holes	mm	11,11±0,2	11,11±0,127	11,1±0,1
Hole diameter circle	mm	25,4±0,2	25,40±0,254	25,4±0,1
Angle of the holes	°	63,4±0,5	63,4 ±0,5	63,4
Outside diameter	mm	44,5±0,2	44,44±0,254	44,5±0,1
Inside diameter	mm	42,7-43,0	42,92±0,254	43,0±0,1
Length	mm	50,79±0,13	50,79±0,127	50,8±0,1
Deep inside diameter	mm	39,67±0,13	39,67±0,127	39,7±0,1
Radius at the end of the inside diameter	mm	3	< 3,00	max3

Transdermalcylinder, long: Apparatus 5

Material		Stainless steel	Stainless steel type 316 or equivalent	1.4571
Diameter holes	mm	11,11±0,2	11,11±0,127	11,1±0,1
Hole diameter circle	mm	25,4±0,2	25,40±0,254	25,4±0,1
Angle of the holes	°	63,4±0,5	63,4 ±0,5	63,4 ±0,5
Outside diameter	mm	44,5±0,2	44,44±0,254	44,5±0,1
Inside diameter	mm	42,69-42,7	40,9±0,254	41,0±0,1
Length	mm	107,91±0,13	107,91±0,127	107,8±0,1
Deep inside diameter	mm	96,79±0,13	96,79±0,127	96,7±0,1
Radius at the end of the inside diameter	mm	3	< 3,00	max3

Japan-Sinker

Material		Acid-resistant	Stainless steel	14.571
Inside diameter	mm	12±0,2	12,0±0,2	12,0±0,2
Length	mm	25-26	25-26	25-26
Wire diameter	mm	not described	not described	1
Wire spacing	mm	3,5-4,0	3,5-4,0	3,5-4,0
Spacing wire spiral	mm	3,0-3,5	3,0-3,5	3,0-3,5

DFZ Apparatus 4	Units	USP33, Physical Tests, No. 711 apparatus	Pharm. Europ. 7th Edition Kap. 2.9.3	ERWEKA
Water bath temperature	°C	37 ±0,5	37 ±0,5	37 ±0,5
Tube connections inside diameter	mm	1,6	1,6	1,6
Tube connections material		polytef	polytef	Teflon
Flanged end connections material		chemical inert	chemical inert	chemical inert
Material of cell		transparent and inert	transparent and inert	PMMA
Pump				
Flowrate per minute	ml	4, 8, and 16ml	4, 8, and 16	HPK: 2,0 to 32,0
Flowrate accuracy	ml	± 5%	± 5%	±5%
Pulsation	pulse/minute	120±10	120±10	120±10
Large Cell				
Cylinder lenght	mm	35,5 ± 0,5	35,5 ± 0,5	35,5 ± 0,5
Cylinder diameter	mm	22,6 ± 0,2	22,6 ± 0,2	22,6 ± 0,2
Cylinder neck lenght	mm	5	5	5
Cylinder neck diameter	mm	20 ± 0,2	20 ± 0,2	20 ± 0,2
Cylinder lenght btw score & conus	mm	15	15	15
Conus angle	°	40 ± 1	40 ± 1	40 ± 1
Bore hole lenght min.	mm	3	3	3
Bore hole diameter	mm	0,8 ± 0,05	0,8 ± 0,05	0,8 ± 0,05
Conus end diameter	mm	3	3	3
Sieve	mm	40mesh d=0,2 w=0,45	d=0,2 w=0,45	d=0,2 w=0,45
Tablet holder for large cell				
Wire size	mm	0,5	0,5	0,5
Holden Heights	mm	6,5	6,5	6,5
Total length	mm	24,0 + 0,5	24,0 + 0,5	24,0 + 0,5
Hold length	mm	9,5	9,5	9,5
Total width	mm	7,5	7,5	7,5
Hold width	mm	2,5± 0,25	2,5± 0,25	2,5± 0,25
Radius	mm	3	3	3
Small Cell				
Cylinder lenght	mm	50 ± 0,5	50 ± 0,5	45
Cylinder diameter	mm	12 ± 0,2	12 ± 0,2	12 ±0,2
Cylinder neck lenght	mm	5,5 ± 0,5	5,5 ± 0,5	8,6
Cylinder neck diameter	mm	20 ± 0,2	20 ± 0,2	???
Upper conus angle	°	50 ± 1	50 ± 1	50
Cylinder lenght btw score & lower conus	mm	15	15	15
Lower conus angle	°	40 ± 1	40 ± 1	40
Bore hole lenght min.	mm	3	3	ca. 8,5
Bore hole diameter	mm	0,8 ± 0,05	0,8 ± 0,05	0,8 ± 0,05
Conus end diameter	mm	3	3	3
Sieve	mm	40mesh d=0,2 w=0,45	d=0,2 w=0,45	d=0,2 w=0,45
Tablet holder for small cell				
Wire size	mm	0,5	0,5	0,5
Holder height	mm	6,5	6,5	6,5
Total length	mm	13,5 + 0,5	13,5 + 0,5	13,5 + 0,5
Holder length	mm	9,5	9,5	9,5
Total width	mm	6	6	6
Holder width	mm	2,5± 0,25	2,5 ± 0,25	2,5± 0,25

ZT		USP33	Pharm. Europ. 7 th Edition	ERWEKA
	Units	Physical Tests, No. 701	Kap. 2.9.1	
Device				
Stroke frequency		29-32	29-32	29-32
Stroke	mm	53-57	55 ±2	55
Distance sieve - vessel bottom	mm	25	25	25
Distance basket - fluid surface	mm	15	15	15
Temperature	°C	35-39 C	35-39	35-39
Material waterbath		not described	not described	PA
Vessel:				
Volume vessel	ml	1000 ml	1000	1000
Vessel height	mm	138-160	149 ±11	140
Inside diameter vessel	mm	97-115	106 ±9	100
Holding basket				
Outside diameter	mm	88-92	90 ±2	90
Thickness upper plate	mm	5,0-8,5	6,75 ±1,75	6,75 ±1,75
Thickness lower plate	mm	5,0-8,5	6,75 ±1,75	6,75 ±1,75
Plate material		not described	Transparent plastic	PA
Hole for glass tubes	mm	22-26	24 ±2	
Material of the distance bolts		not described	not described	14.571
Glass tube:				
Inside diameter	mm	20,7-23,0	21,85 ±1,15	20,7-22,5
Wall thickness:	mm	1,0-2,8	1,9 ±0,9	1,2±0,2
Length:	mm	77,5±2,5	77,5±2,5	78-0,5
Disc				
Material:		transparent plastic	transparent plastic	PA
Relative density:		1,18-1,20	1,18-1,20	PA
Weight	g	not described	not described	3,0 ±0,2
Diameter:	mm	20,7±0,15	20,7 ± 0,15	20,7±0,15
Thickness:	mm	9,5±0,15	9,5 ± 0,15	9,5±0,1
No. / hole diameter	mm	5 / 2 ±0,1	5 / 2 ±0,1	05-Feb
Hole circle diameter	mm	12 ±0,4	12 ±0,4	12
Notch:				
Upper width	mm	9,4±0,2	9,4±0,2	9,5±0,15
Upper depth	mm	2,6±0,1	2,6±0,1	2,55
Lower width	mm	1,6 ±0,1	1,6 ±0,1	1,6
Lower depth	mm	1,5-1,8	1,5-1,8	1,6
Sieve				
Material		Stainless steel	Stainless steel	14.401
Wire diameter	mm	0,57-0,66	0,615 ±0,045	0,635
Mesh	mm	1,8-2,2	2,0 ±0,2	2

ZT		USP33	Pharm. Europ. 7 th Edition	ERWEKA
	Units	Physical Tests, No. 701	Kap. 2.9.1	
Holding basket (for large tablets.)				
Outside diameter	mm		97	97
Thickness upper plate	mm		9	9
Thickness lower plate	mm		9	9
Plate material			transparent plastic	PA
Material of the distance bolts			Metall	VA
Glass tube (for large tablets)				
Inside diameter	mm		33,0 ± 0,5	33,0 ± 0,3
Wall thickness:	mm		2,5 ± 0,5	2,5 ± 0,2
Length:	mm		77,5 ± 2,5	78,0 - 0,5
Disc (for large tablets)				
Material:			transparent plastic	PA
Relative density:			1,18-1,20	1,18-1,20
Diameter:	mm		31,4 ± 0,13	31,5 - 0,1
Thickness:	mm		15,3 ± 0,15	15,3 ± 0,15
No. / hole diameter	mm		7 / 3,15 ± 0,1	7 / 3,15 ± 0,1
Hole circle diameter	mm		11,55 ± 0,1	11,55 ± 0,1
Sieve (for large tablets.)				
Material			Stainless steel	14.401
Wire diameter	mm		0,63 ± 0,03	0,635
Mesh	mm		2 ± 0,2	2

TA		USP33	Pharm. Europ. 7 th Edition	Erweka
	Units	Physical Tests, No.1216	Kap. 2.9.7	

Device

Speed	min ⁻¹	25	25	TA: 25 ± 1
Speed tolerance	min ⁻¹	± 1	± 1	TAR: 20-100

Friability drum

Material		transparent synthetic Polymer	Polymer	PMMA
Outside diameter	mm	302,5±4	302,5±4	298,5
Inside diameter	mm	287,0±4	287,0±4,0	288
Depth	mm	38,0±2	38,0±2,0	38
Drop height	mm	156,0±2	156,0±2	156,5
Inside diameter of axis	mm	10,0±0,1	10,0±0,1	10
Outside diameter of axis	mm	25,0±0,5	25,0±0,5	25,0±0,2
Radius of curve projection	mm	80,5±5	80,5±5,0	80,5±5,0

GTA			Pharm. Europ. 7 th Edition	ERWEKA
	Units		Kap. 2.9.41	

Device, method B

Radius swing arm	mm		152	152 ± 2
Escaping arc	°		42	37 ± 2
Oscillation frequency	1/min		0-400	0-400 ± 10
Time Setting	s		0-9999	0-9999

Containers

Material			Glas	Glas
Inside diameter	mm		49	----
Outside diameter	mm		----	49 ± 1,5
Height	mm		85	85 ± 1
Content	ml		105	105 ± 3

PM30		USP33	Pharm. Europ. 7 th Edition	ERWEKA
	Units		Kap.2.9.22	

Device, Apparatus A

Temperature	°C		36,5 ±0,5	36,5 ±0,5
Depth of immersion tube	cm		7	7

Glass tube

Inside diameter	mm		15,5	15,5 ±0,5
Outside diameter	mm		18	18
Length:	mm		ca 140	ca 140

Rod

Total weight including O-ring	g		30 ±0,4g	30 ±0,4g
Rod diameter	mm		5,0	5 ±0,2
Cone diameter	mm		12	12
Test tip diameter	mm		1	1
Test tip height	mm		2	2

Cover

Interior diameter	mm		5,2	5,2 ±0,1
Height	mm		ca. 35	35

ST30/32/35			Pharm. Europ. 7 th Edition	ERWEKA
	Units		Kap.2.9.2	

Device

Media temperature	°C		36,5 ±0,5	36,5 ±0,5
Vessel content	l		4	4
Minimal immersion depth turn cylinders	mm		90	90
Turn interval	min		10	10

Swing Cylinder

Material			Glas or transparent plastic	PMMA
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Use for swing cylinders

Material			Metal	Stainless steel
Number of Hooks			3	3
Inner hole circle	mm		12	12
Medium hole circle	mm		24	24
External hole circle	mm		36	36
Hole diameter	mm		4	4
Distance between plates	mm		30	30

SVM		USP 33	Pharm. Europ. 7 th Edition	ERWEKA
		Units	Physical Tests, No.616	Kap.2.9.34
Generally, Method 1				
Strokes	min ⁻¹	300	300 ±15	300
Height	mm	14 ±2	14 ±2	14 ± 2
Generally, method 2				
Strokes	min ⁻¹	250	250 ±15	250 ±15
Height	mm	3 ±10% = 3 ±0,3	3 ±0,2	3 ±0,2
Glass (250ml)				
Weight	g	220 ±44	220 ±44	220 ±40
Scaling	ml	2	2	2
Holder				
Weight	g	450 ±10	450 ±10	450 ±10
Glass (100ml)				
Weight	g	130 ±16	130 ±16	130 ±16
Scaling	ml	1	1	1
Holder				
Weight	g	240 ±12	240 ±12	240 ±12

Chewing Gum Tester			Pharm. Europ. 7 th Edition	ERWEKA
		Units	Kap. 2.9.25.-1,2,3 01/2005	
Chewing chamber				
Inside diameter	mm		24	24
Outside diameter	mm		40	40
Medium temperature	°C		37 ±0,5	37 ±0,5
Vertical Piston				
Length	mm		260	260
Diameter	mm		16	16
Stroke	mm		22	22
Horizontal pistons with O-rings				
Stroke	mm		25	25
Max. distance between Pistons	mm		50	50
Min. distance between Pistons	mm		0,1 - 1.0	0,1 - 1.0
Central chamber				
Inside diameter	mm		24	24
Outside diameter	mm		40	40
Funnel				
Lower inner diameter	mm		25	25
Upper inner diameter	mm		56	56
Interior Angle	°		10°	10°
Length	mm		92	92
Guides Section G-G				
First inside diameter	mm		24,95	24,95
Second inside diameter	mm		36	36

GTB			Pharm. Europ. 7 th Edition	ERWEKA
	Units		2.9.36 und 2.9.16	
Funnel				
Diameter of upper opening	mm		110	110
Diameter of lower opening	mm		30 +0,1	30 +0,1
Angle	°		40°±5'	40° ±0,1°
Nozzles				
Angle	°		40°±5'	40° ±0,1°
Upper diameter	mm		30,2 -0,1	30,2 -0,1
Lower diameter nozzle 1	mm		10±0,01	10±0,01
Lower diameter nozzle 2	mm		15±0,01	15±0,01
Lower diameter nozzle 3	mm		25±0,01	25±0,01
Cylinder height lower opening	mm		variable (30)	Is a result of upper and lower diameter, and the angle
Height lower cylinder	mm		1±0,2	1±0,2
Angle of Repose (EP 2.9.36)				
The funnel height maintained from the top of the powder pile as it is being formed in order to minimize the impact of falling powder on the tip of the cone			at approximately 2-4 cm	fixed height