## **Calibration Criteria**

## CHEMICAL CALIBRATION / CALIBRATOR TABLETS

	USP	JP	BP	EP	PhRMA	FDA/DPA
Calibrator Tablets	6 Non Disintegrating, App. 1 6 Non Disintegrating, App.2 6 Disintegrating, App.1 6 Disintegrating, App 2	None	None	None		In House Calibrator

MECHANICAL CALIBRATION TOLERANCES, APPARATUS 1 (BASKET) AND APPARATUS 2 (PADDLE)

Calibration Parameter	USP	JP	BP	ASKET) AND APPARATUS 2 ( EP	PhRMA Proposed	DPA
Cambration Parameter	USF	Jr	br	Er	Piikivia Proposed	DFA
Vessel dimensions (Inspect at time of receipt only)	Internal diameter 98-106 mm External Height 160-210mm Hemispherical bottom, 1000ml	Internal diameter 98-106 mm Internal height 160-175 mm Round bottom, 1000ml	Internal diameter 98-106 mm Internal height 160-176 mm Hemispherical bottom, 1000ml	Internal diameter 98-106 mm Internal height 160-176 mm Hemispherical bottom, 1000ml	Same as USP	Same as USP
Basket dimensions (Inspect at time of receipt only)	Conforms to diagram in USP Mesh Size 0.40 +/- 0.04mm	Conforms to diagram in JP (Almost identical to USP) Mesh Size 0.425mm	Same as EU	Conforms to diagram in EU (Almost identical to USP) Mesh Size 0.381mm	Same as USP	Same as USP
Paddle dimensions (Inspect at time of receipt only)	Conforms to diagram in USP	Conforms to diagram in JP (Same as USP)	Same as EU	Conforms to diagram in EU (Almost identical to USP)	Same as USP	Same as USP
Visual inspection of belts, check ball bearings	None	None	None	None	Belts are tight, clean free of cracks, properly aligned, shafts turn freely	Belts are tight, clean free of cracks, properly aligned, shafts turn freely
Bath levelness	None	None	None	None	Level	Bubble within lines of a bubble level
Shaft verticality	None	None	None	None	Vertical as measured by a bubble level	Bubble within lines of a bubble level
Basket examination (Examine at time of use)	None	None	None	None	No gross defects as determined by visual inspection	No gross defects as determined by visual inspection
Paddle examination (inspect at time of receipt only)	None	None	None	None	No gross defects as determined by visual inspection	No gross defects as determined by visual inspection
Shaft wobble Shafts w/o baskets attached and paddle shafts	No significant Wobble	None	No significant Wobble	No significant Wobble	≤ 0.5 mm total runout	≤ 0.5 mm total runout
Basket wobble	± 1 mm	None	None	None	≤ 1.0 mm total runout	≤ 1.0 mm total runout
Vessel/Shaft Centering	NMT 2 mm at any point from vertical axis of vessel.	NMT 2 mm at any point from vertical axis of vessel.	NMT 2 mm at any point from vertical axis of vessel.	NMT 2 mm at any point from vertical axis of vessel.	2 mm from centerline	1 mm from centerline
Height check/ Basket Depth and Paddle Depth	25 ± 2 mm	25 ± 2 mm	25 ± 2 mm	25 ± 2 mm	25 ± 2 mm	25 ± 1 mm
Vibration	No significant Vibration	No significant Vibration	No significant Vibration	No significant Vibration	≤ 0.2 mil displacement	≤ 0.1 mil displacement
Rotational speed	± 4%	<u>+</u> 4%	<u>+</u> 4%	<u>+</u> 4%	<u>+</u> 2 rpm	<u>+</u> 1 rpm
Vessel temperature (Measure at time of use)	37 ± 0.5° C	37 ± 0.5° C	37 ± 0.5° C	37 ± 0.5° C	37 ± 0.5° C	37 ± 0.5° C