DISSOLUTION TEST FOR SOLID ORAL DOSAGE FORMS
Proposal for revision for *The International Pharmacopoeia*

Comments on the draft should be sent to **Dr Herbert Schmidt**, Medicines Quality Assurance Programme, Technologies Standards and Norms, Department of Essential Medicines and Health Products, World Health Organization, 1211 Geneva 27, Switzerland; email: schmidth@who.int by **31 March 2018.**

Specific Comments

Page/Section	Original text	Proposed change	Justification/Comment
Line 88	Its sides are flanged at the top.	This sentence should be removed from the text.	There are vessels that are not flanged at the top, but instead have a connecting ring used to attach them to the bath. Since the flange does not come into contact with the dissolution medium, the presence or absence of a flange has no impact on the test.
Line 85-86	A speed-regulating device is used that allows 85 the shaft rotation speed to be selected and maintained at a specified rate within ± 4%.	Recommend that the "+/- 4%" be listed with an applicable range, such as "…within ± 4% over the range of 25-200 rpm."	Some newer baths can go as low as 1 RPM. There is development work done with semi-solids and hydrogels where speeds as low as 10 RPM have been used.
Line 144-145	If the dissolution medium is a buffered solution allow the medium to equilibrate to a temperature of 37 ± 0.5 °C and adjust the solution so that its pH is within 0.05 units of the specified pH.	The pH should not be adjusted at 37 degree. C.	•The pH scale itself changes with temperature (the autoprotolysis constant of water is temperature-dependent), •The pKas of the buffer salts change with temperature, •The response of a pH meter is affected by temperature and needs to be accounted for – not all pH meters have

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			temperature compensation •Typically, dissolution media at volumes of 50 and even 100 L are prepared, and there is no equipment to heat this volume of medium to 37C prior to pH adjustment. I assume this is not unique to my company. •The temperature of an aliquot taken for pH measurement would also need to be kept stable – simply heating the bulk medium to 37C and taking off an aliquot for pH measurement is not reliable as the aliquot will cool during measurement without some sort of thermostating. (To minimize contamination risk, pH probes are not placed directly into bulk dissolution media.)
Line 227-229	"The 5%, 15% and255 values in the table are percentages of the labelled content so that these values and Q 228 are in the same terms."	It should read "25%".	It seems that "255" is a typo.
Line 246:	"Test Conditions"	Add the following: These are method parameters that in some cases can affect results. Other "equivalent" filters, cannulas, and tips may be used if a product is insensitive to these variables.	Monographs should specify the material and pore size of the filter used, the dimensions of the cannula and/or filter tip used.
		The reference to the USP PVT reference tablets should not be removed.Suggest changing the wording to "…and the analysis	Readers of the chapter need to know that suitable reference tablets are available and provide certificates with

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		of suitable reference tablets (e.g. USP Prednisone Reference Standard Tablets, provided with certificates) to verify the performance of the test assembly."	ranges based on international collaborative testing