chemistry / materials characterization

USP vs ISO

	USP Physicochemical Approach	Possible Risks with USP Approach	ISO Biological Evaluation Approach
FOCUS	Characterization of risk of contamination from packaging to medical product	Test approach for physico-chemical testing was designed for packaging, not devices	Characterization of safety of medical device / product
SAMPLE PREP	Single, water extraction	22% of comments cited the lack of challenging extractant*	Multiple extractions: polar, non-polar, mid-polar
METHODS	Residue weight, metals, buffering capacity, turbidity, color, pH effects	44% of comments cited lack of sufficient rigor in testing*	Compound and elemental quantitation and identification
ENDPOINT	Summary table	Lack of interpretation lets FDA make its own	Detailed analysis

* *Based on a random sampling of 49 requests for "Additional Information" from the FDA*

With the growing risk of regulatory pushback, you need to work with an experienced team who will partner with you on materials characterization testing for medical devices. While we recommend the ISO approach, there are circumstances where USP testing may make sense.

Talk to us for guidance in making educated decisions regarding your chemistry/materials characterization studies. No one knows more about regulatory requirements and materials characterization than WuXi AppTec.

Contact a WuXi AppTec Account Manager at
651-675-2000 or email: info@wuxiapptec.com

药明康德
WuXi AppTec

TS315-14-02.01.15