



## *International Pharmaceutical Excipients Council of the Americas*

*Janeen Skutnik-Wilkinson  
Chair*

March 30, 2021

Kahzkashan Zaidi  
Principle Scientific Liaison  
United States Pharmacopeial Convention  
12601 Twinbrook Parkway  
Rockville, MD 20852  
e-mail: [kxz@USP.org](mailto:kxz@USP.org)

Cc: Catherine Sheehan  
John Giannone  
Galina Holloway

**Re: General Chapter <232> Elemental Impurities - Limits PF 47(1)**

Dear Dr. Zaidi,

Members of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) have reviewed the proposed revision to the General Chapter <232> Elemental Impurities - Limits as published in PF 47(1). IPEC-Americas appreciates the opportunity to provide comments for the proposed revision.

### ***IPEC-Americas Background***

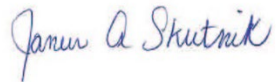
IPEC-Americas represents more than 50 excipient manufacturers, distributors and pharmaceutical/biopharma companies to support the safe production and use of excipients. This letter represents the IPEC-Americas membership. A complete list of IPEC-Americas member companies can be found at: <https://ipecamericas.org/what-ipec-americas/member-companies>. IPEC-Americas is dedicated to working closely with regulatory authorities, industry organizations and scientific bodies (globally) to advance public health on matters relating to the quality, safety, manufacture, distribution, use and functionality of excipients. IPEC is the sole association representing excipients.

### ***IPEC-Americas Comments***

Pharmacopeial harmonization is very important for industry. IPEC-Americas appreciates the publication of the proposed revisions to General Chapter <232> in alignment with ICH Q3D(R2) step 3. Continued collaboration between ICH, USP, Ph. Eur., BP, JP, and other pharmacopeia will ensure alignment and facilitate a globally consistent approach. IPEC-Americas requests that USP does not implement the proposed limits for the cutaneous and transcutaneous routes prior to ICH Q3D(R2) reaching step 5.

IPEC-Americas recognizes the efforts of the USP and other pharmacopeias, to continually improve, harmonize, and modernize excipient monographs. We look forward to continued collaboration on the development of global standards which ensure the quality and safety of excipients.

Respectfully yours,

A handwritten signature in blue ink that reads "Janeen A. Skutnik". The signature is written in a cursive, flowing style.

Janeen Skutnik-Wilkinson  
Chair, IPEC-Americas