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IPAC-RS RESPONSE TO THE USP GENERAL ANNOUNCEMENT "USP NEW INHALATION PRODUCT MONOGRAPHS: PROPOSED APPROACH FOR PERFORMANCE TESTS EMPLOYING NON-STANDARD APPARATUS"[1]

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The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) considered the announcement "*USP New Inhalation Product Monographs: Proposed Approach For Performance Tests Employing Non-Standard Apparatus*".

IPAC-RS in principle agrees with the proposal from USP and as a consortium involved with the development of standards and related documentation to meet those standards, fully supports standardization of analytical testing equipment by first intent. However, consistent with ICH Q6A guidance on evolving technologies, there should remain an opportunity to employ non-standard specialized equipment where it offers:

1. Additional assurance of quality e.g. improved product understanding, improved analytical method accuracy, precision and specificity

2. Improved reproducibility of methods and reduced risk of method transfer failure. As one such example, consider the Next Generation pharmaceutical Impactor (NGI) [2] developed by a pre-competitive industry consortium as an improvement to overcome some deficiencies with existing impactors, and for many years would have been considered non-standard.

For new inhalation product monographs once they have been approved and published in the USP-NF, USP propose that where the performance test employs a non-standard apparatus as the only available option, the test will be tagged as postponed, and this will render this test informational and not essential for regulatory compliance. When such a test is specified

[1] USP General Announcement "New Inhalation Product Monographs: Proposed Approach for Performance Tests Employing Non-standard Apparatus". Aug.28, 2020. https://www.uspnf.com/notices/non-standard-performance-tests-gen-announcement-20200828 (accessed 9/292020)

[2] Marple, V.A. et al. Next Generation Pharmaceutical Impactor (A New Impactor for Pharmaceutical Inhaler Testing). Part I: Design. J Aerosol Med, 2003, 16:3, 283-299.

by the sponsor as a key requirement to demonstrate the quality and safety of the product rendering this key test as “informational and not essential for regulatory compliance" seems inconsistent with USP goals.

Therefore, where a non-standardized apparatus is employed for a new product, further clarification is required on the approach to be followed where no alternate standardized test is available especially with regards to maintaining regulatory compliance. Where the non-standard test is postponed, there should be clarity within the monograph on the need of manufacturers to apply a standard apparatus and to have appropriate measurements in place to control the pertinent attribute(s) that are registered with the appropriate authority.

Additionally, in light of this new guidance, how does USP intend to accelerate adoption of new testing methodologies into general chapters and monographs?

IPAC-RS is a non-profit association of companies that develop, manufacture or market pharmaceutical products for delivery via respiratory tract - such as metered dose inhalers (MDIs), dry powder inhalers (DPIs), nasal sprays, and other product types - with the goal of advancing science-based and data-based regulations, standards, and practices for these products. A list of current members, and further information are available at http://ipacrs.org.

IPAC-RS is willing to discuss these matters further with USP as needed.

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