Briefing on Proposed Revision
General Test “2.66 Elemental Impurities Procedures”

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Pharmaceuticals and Medical Devices Agency
Office of Review Management

Before publication of a proposed draft revision to the Japanese Pharmacopoeia (JP) general test “2.66 Elemental Impurities Procedures” for public consultation, the following background information is provided for your review.

Along with the Ministerial Notification of Supplement II to the Japanese Pharmacopoeia (JP) 17th Edition, the administrative notice[1] on the general test “2.66 Elemental Impurities Procedures” and on the general information “G1. Control of Elemental Impurities in Drug Products” was published on June 28, 2019. The Note 8 (2) in this administrative notice states that "ICH-Q3D guideline will be implemented in the JP 18th Edition with a certain grace period." In accordance with this administrative notice, the general information “G1. Control of Elemental Impurities in Drug Products” based on ICH-Q3D was integrated into the general test “2.66 Elemental Impurities Procedures”. The title of the proposed draft revision to the general test was also changed to “2.66 Elemental Impurities”.

The JP Expert Committees have discussed that a new notice about implementation and application of the revised general test should be added in the JP General Notices. The publication of the draft general notice for public consultation is scheduled for November 1, 2019 so that it will be included in the JP 18th Edition with the revised general test “2.66 Elemental Impurities”. For the information about implementation and application of the proposed draft revision to the general test, please refer to this draft general notice.

We are also coordinating length of the grace period implementing the new general notice and the revised general test.

[1] : http://www.pmda.go.jp/files/000230314.pdf (Note: Japanese only)