報 告 書

医薬品医療機器レギュラトリーサイエンス
Pharmaceutical and Medical Device Regulatory Science
Vol. 42, No. 2, 156～176 (2011)

平成21年度「日本薬局方の試験法に関する研究」研究報告*5

輸液用ゴム栓試験法の見直し研究（第2報†）

—ゴム栓製品の三薬局方における実測値比較と国際調和を考慮した改正に向けた論点整理—

田邊 豊重*1, 高居 邦弘*1, 青木 光夫*1, 大久保 恒夫*1, 大内 正*2,
寺田 三郎*2, 柘植 英哉*2, 辰巳 治*3, 関口 道子*3, 四方田 千佳子*4

Preliminary Study on the Revision of JP General Test, Test for Rubber Closure for Aqueous Infusion (II)

Toyoshige TANABE*1, Kunihiro TAKAI*1, Mitsuo AOKI*1, Tsuneo OKUBO*1,
Tadashi OUCHI*2, Saburo TERADA*2, Hideya TSUGE*2, Osamu TATSUMI*3,
Michiko SEKIGUCHI*3 and Chikako YOMOTA*4

Summary

JP General Test＜7.03＞Test for Rubber Closure for Aqueous Infusions has not been revised since the 10th edition (published in 1981), and therefore has fallen behind Ph.Eur. and USP. The physicochemical specifications of the JP test are compared in detail with those stipulated in the relevant rubber closure tests in Ph. Eur., USP and ISO. The physicochemical specifications were well aligned among these three standards (Ph. Eur., USP and ISO), though not JP. Nine commercially available, domestic and imported rubber closures with four material types were evaluated according to the physicochemical tests of JP and Ph. Eur., as a representative of the other three standards. Based on the results, we identified issues to be addressed for the revision of JP test in the context of pharmacopoeial harmonization. The four major points are: sampling (by mass or surface area), pre-treatment of sample, extraction conditions, and control of impurities (by extractables or rubber closure itself). The test parameters (foam test, ammonium, and volatile sulfide), and the alignment of pH (acidity or alkalinity) are also highlighted. Moreover, the categorization of acceptance criteria, Type I and II, adopted in other pharmacopoeias, identification, and functionality testing are also issues to be addressed in JP. The introduction of new analytical techniques should also be investigated: for example, conductivity and TOC to substitute for residue on evaporation and potassium permanganate-reducing substances, respectively. The views of the working group on the above points are presented.

Key words

Japanese Pharmacopoeia, European Pharmacopoeia, United States Pharmacopeia, Rubber closure, Physicochemical test, Identification test, Functionality test, Harmonization, TOC, Conductivity