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Importance Considering ISR for Bioanalysis

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In bioanalysis, the validity of analytical validation, standard samples to prepare standard curve and validity of quality control using standard sample and so on were carried out. However, analytical validity using the real biosamples was not always reproducible due to matrix effect. Un-uniformity distribution of the interest in the real sample matrix, contamination during sampling, interference by specific compounds in the biosamples and unknown metabolites of the interest contributed to the interference of the analysis. ISR (Incurred samples reanalysis) was done reanalysis on the different days using different biosample units to confirm reproducibility of the analysis. By carrying out the ISR, reproducibility was confirmed and thus result of analysis was reliable. If it cannot be confirmed reproducibility by ISR, the cause was investigated and must be diminished the cause.

In general, in the major pharmacokinetics test to utilize endpoint test, ISR was conducted for each different matrix sample. For example, toxicokinetics test was carried out to the different animals in case of non-clinical study. In clinical study, healthy male volunteers and volunteers who have inferiority in kidney function or liver function was carried out representative several trials based on phamacokinetics test and biologically equivalence test.

Samples conducting ISR were many different unit samples. They should include samples of normal maximum blood concentration and trace level of blood concentration. ISR was conducted within stability confirmed. The real sample numbers used for ISR was ca10% within 1000 samples and ca5% for more than 1000 samples.

For evaluation of ISR, rate of deviation was utilized. Rate of deviation was obtained as follows.

[(A, Amount of determined by ISR) – (I, Initial determined amount)]/average of A and I

Rate of deviation must be within ± 20% for more than 2/3 samples conducted ISR. If not satisfied within ± 20% for more than 2/3 samples, the cause must be surveyed and necessary countermeasure must be taken considering the effect on the analysis of real biosamples.

ISR was conducted to evaluate degree of variation, in individual sample, even if ISR was beyond ± 20%, the initial determination was not replace re-analysis amount or not rejected.

ISR is an important factor to handle biosample analysis. Because biosample has so much matrix effect, so it is quite complicated sample. The interests in blood, serum, plasma are quite difficult to be free from admixtures in body fluids. In that sense, biosamples must not apply directly to HPLC or GLC to prevent insufficient separation, clogging the analytical column by deproteinization from biosamples and so on. In that sense, automated SPE (sold phase extraction) was recommended to conduct as pre-treatment (manual type SPE was not recommended due to variation of pressure) and I recommend refer to SPE paper I published so far.

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