

## Supplementary Data

SUPPLEMENTARY TABLE 1. STEPS TO PREVENT CONTAMINATION OF PLASMA AND URINE SAMPLES

<i>Precautions</i>	<i>Prevention steps</i>
Priming	<p>Separate rooms should be used for priming of the device, inhalation of study drug, and PK procedures</p> <p>Priming of the Respimat<sup>®</sup> inhaler should take place in a different room from where the drug inhalation takes place</p> <p>The patient should not be present in the same room during the priming procedure of the Respimat<sup>®</sup> inhaler</p> <p>Study personnel should wear laboratory coats during priming and remove them after</p> <p>Study personnel should handle the Respimat<sup>®</sup> inhaler while wearing gloves, and then change and discard their gloves immediately after priming</p>
Inhalation	<p>Patients and study personnel should handle the Respimat<sup>®</sup> inhaler while wearing gloves, and then change and discard their gloves immediately after a patient completes inhalation</p> <p>Study personnel should cover the site of cannulation (by a short piece of elastic bandage with affixed clips) while the patient is in the room where inhalation is planned</p> <p>The covering should be removed only once the patient has been moved to the room where blood sampling is planned</p> <p>No more than one patient should be in the inhalation room at the same time</p>
Preparing the blood, plasma, and urine samples	<p>The PK procedures (blood and urine sampling or sample preparation) should not take place in the same room where priming of the Respimat<sup>®</sup> inhaler or drug inhalation is taking place</p> <p>Only study personnel who are not present during priming of the Respimat<sup>®</sup> inhalers in the priming room, and who are not present during drug inhalation in the inhalation room, should be allowed to collect and process blood, plasma, and urine samples</p> <p>Study personnel should immediately discard the covering; before drawing the post-dose blood samples, study personnel should then wash their hands and put on fresh gloves (i.e., before any containers for PK samples are handled)</p> <p>They should change their gloves as soon as the PK samples are obtained</p> <p>They should also change their gloves as soon as the plasma is obtained from the blood</p> <p>Patients should be advised to wash their hands thoroughly before touching the urine containers and also after finishing urine collection</p> <p>Study personnel must change their gloves before handling urine samples</p> <p>PK tubes, pipettes, etc. should not be stored in the same room where drug inhalation is taking place</p> <p>Plasma and urine containers should be stored closed and should be opened only if necessary for collection</p>

PK, pharmacokinetic.