



EVALUATION OF ESSENTIAL PERFORMANCE REQUIREMENTS

Determination of essential performance requirements (EPRs) are a critical step in the evaluation of a drug/device combination. EPRs are generally referring to those aspects of the combination product that are critical for device performance during clinical use to achieve its intended function. Manufacturers should determine essential performance requirements during their risk evaluation and design and development processes.

In the United States, the final decision and justification for the requirement in the context of the intended use will be the responsibility of combination product applicant. However, West Pharmaceutical Services has compiled the following table as recommended EPR's, with stated rationale, for West's SmartDose® On-body Delivery systems (OBDSs).

FUNCTION	DESCRIPTION	RATIONALE
DOSE DELIVERY TIME	Measure of the total time over which the total dose volume is delivered Defined by the time from button activation to dose completion notification	Dose delivery time is an automated function. Delivery time exceeding the specifications may result in the user prematurely removing OBDS, leading to underdose. Shorter than specified delivery time may lead to patient discomfort
DOSE VOLUME ACCURACY	Difference between the intended dose and the delivered dose	Dose volume outside the specifications (underdose) may result in failure to achieve the therapeutic effect. Over-dosing is not a risk since cartridge is prefilled to a desired volume and OBDS/cartridge is single use
EXTENDED NEEDLE LENGTH	Distance from the patient end of the needle tip to the nearest part of the needle-based injection system with automated function	If the extended needle length is outside of the specifications, the medication may not be injected into subcutaneous tissue, which can lead to failure to achieve the therapeutic effect
ADHESION TASK FORCE	The force required to separate the adhesive of the OBDS to the body	The failure of device remaining adhered to the attached site on the body can result in device falling, which can lead to underdose
DOSE COMPLETION NOTIFICATION	Audio/visual confirmation of completion of the automated injection to notify the user when full dose delivery is completed	The OBDS provides audio/visual notification at the end of dose completion so that the user can confirm the dose delivery and remove the OBDS. If Dose Completion Notification is not received after successful dose delivery, the user can assume unsuccessful delivery, which can affect the therapeutic outcome
BUTTON ACTIVATION FORCE	The force applied by the user to trigger the automated delivery mechanism	The button activation by the user is required to be able to initiate the automated drug delivery. If the button activation force is too high, the user may not be able to initiate the dose delivery. Too low a button activation force can lead to premature initiation of drug delivery

West's SmartDose® drug delivery platform is not independently cleared or approved by any Regulatory Body for general healthcare professional or patient use, nor is it available for general commercial purchase. Its distribution and use are subject to applicable regulatory requirements for clinical investigation, and for marketing authorization, as used in combination with a specific drug or biological product. Each component of a combination product is subject to the requirements established by the Regulatory Body for that component (drug, biologic or device).

The regulatory process can be more complicated for combination products including an evaluation of the product characteristics, delivery system and its functionality, as well as the potential for undesirable interactions between the drug or biologic and the delivery system. As a result, we note that the SmartDose® drug delivery platform's compatibility with any particular drug or biologic must be confirmed, and its ability to achieve the desired patient benefits must also be confirmed, on a case-by-case basis in a manner sufficient to meet Regulatory Body requirements.