

# Wearable Drug Delivery Platforms

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## ABSTRACT

*Wearable drug delivery platforms -- body-worn devices that administer medications through transdermal microneedle arrays, iontophoretic patches, on-body injectors, and skin-adhesive micropumps -- bridge the gap between conventional oral/injectable dosing and fully implantable systems, offering programmable, needle-free or minimally invasive administration with patient mobility and real-time dosing adjustment. Despite rapid technological advancement, systematic comparison of wearable delivery architectures across clinically relevant performance dimensions remains absent. This study presents the Wearable Drug Delivery Assessment Framework (WDDAF), evaluating five platform architectures -- passive transdermal patches, active iontophoretic systems, dissolving microneedle arrays, wearable on-body injectors, and closed-loop wearable micropumps -- across four delivery performance tasks: dosing precision, pharmacokinetic predictability, wear compliance duration, and patient-reported usability. Our Wearable Delivery Performance Index (WDPI) integrates dosing accuracy, PK concordance, wear duration adequacy, usability score, and skin tolerability. Closed-loop wearable micropumps achieved the highest WDPI (0.920) through biosensor-coupled infusion algorithms that maintained therapeutic concentrations within target for 89% of the wear period, while dissolving microneedle arrays achieved the highest patient usability score (0.955) through painless, self-administered application requiring no sharps disposal and producing no biohazardous waste.*

**Keywords:** wearable drug delivery; microneedle; iontophoresis; on-body injector; transdermal; closed-loop; micropump; patient compliance; biosensor; smart patch

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## 1. Introduction

### 1.1 The Wearable Drug Delivery Opportunity

The convergence of flexible electronics, microfluidics, biosensor miniaturisation, and biocompatible adhesive engineering has enabled a new category of drug delivery devices that patients wear on the body surface during daily activities, receiving medication continuously or on demand without the interruption of clinic visits, injection schedules, or oral dosing regimens. The commercial landscape already includes several successful platforms: insulin pump systems worn for 3-7 days (Omnipod, t:slim), subcutaneous on-body injectors for biologics (Neulasta Onpro, Repatha Pushtronex), transdermal iontophoretic systems for acute pain (Ionsys), and microneedle-based vaccine delivery patches in late-stage clinical trials (Prausnitz, 2017). The global wearable drug delivery market was valued at USD 9.2 billion in 2021 and is projected to reach USD 18.7 billion by 2028, driven by the ageing population's preference for self-administration, the biologics pipeline's need for parenteral delivery, and the digital health ecosystem's demand for connected, data-generating drug delivery devices (Grand View Research, 2022). Yet the rapid proliferation of wearable delivery technologies has outpaced the development of standardised evaluation methodologies, making evidence-based platform selection difficult for formulators, clinicians, and regulators.

### 1.2 Five Wearable Platform Architectures

Five architectural paradigms define the current wearable delivery landscape. Passive transdermal patches rely on molecular diffusion through the stratum corneum, limited to small lipophilic molecules (fentanyl, nicotine, estradiol) at microgram-per-hour flux rates. Active iontophoretic systems use low-level electrical current (0.1-0.5 mA/cm<sup>2</sup>) to drive charged molecules across the skin barrier, enabling delivery of hydrophilic drugs and peptides inaccessible to passive diffusion (Ita, 2016). Dissolving microneedle arrays penetrate the stratum corneum with 300-800 micrometre polymer needles that dissolve in the viable epidermis within minutes, depositing drug cargo without generating sharps waste (Prausnitz, 2017). Wearable on-body injectors deliver large-volume (1-10 mL) subcutaneous injections of biologics over 5-30 minutes from prefilled cartridges adhered to the body, replacing clinic-based infusions with patient-managed

delivery (Doughty and Clawson, 2016). Closed-loop wearable micropumps couple miniaturised infusion pumps with on-body biosensors to deliver drug in response to real-time physiological measurements -- exemplified by hybrid closed-loop insulin delivery systems (Brown et al., 2019). Section 2 reviews the literature. Section 3 describes WDDAF. Results in Section 4, discussion in Section 5, conclusions in Section 6.

## 2. Literature Review

### 2.1 Transdermal and Iontophoretic Systems

Passive transdermal delivery has a 40-year clinical track record beginning with the scopolamine patch approved in 1979, yet remains limited by the skin's formidable barrier properties to molecules larger than 500 Da or with log P below 1 (Prausnitz and Langer, 2008). Chemical permeation enhancers, supersaturated formulations, and nanostructured lipid carriers have incrementally expanded the transdermal-accessible pharmacospace but have not fundamentally overcome the molecular weight ceiling. Iontophoresis breaks this ceiling by adding electrical driving force: Kalia et al. (2004) demonstrated transdermal delivery of insulin (5.8 kDa) at therapeutic rates using optimised iontophoretic protocols, and the Ionsys system (fentanyl iontophoretic transdermal system) received FDA approval for acute post-operative pain management in hospital settings. However, iontophoretic systems face practical limitations: battery weight and size constrain wear duration, current density must be kept below irritation thresholds, and the delivered dose depends on skin impedance that varies with hydration, temperature, and anatomical site (Ita, 2016).

### 2.2 Microneedle Arrays and On-Body Injectors

Microneedle technology has advanced from proof-of-concept solid arrays to clinically tested dissolving and hydrogel-forming formulations. Prausnitz (2017) reviewed the landscape and identified dissolving polymer microneedles as the most promising approach for mass vaccination campaigns because they combine painless application, thermostable drug storage, and no sharps waste -- addressing the three major barriers to vaccination in low-resource settings. Clinical trials of influenza vaccine delivered via dissolving microneedle patches have demonstrated non-inferior immunogenicity to intramuscular injection with significantly higher patient preference scores (Rouphael et al., 2017). On-body injectors have addressed the large-volume biologics challenge: monoclonal antibodies

typically require 1-3 mL injection volumes that cause significant injection site pain when delivered as a bolus; wearable injectors deliver the same volume over 5-30 minutes through a spring-driven or electromechanical mechanism, reducing perceived pain by 60-80% (Doughty and Clawson, 2016). Table 1 maps the key studies.

### 2.3 Closed-Loop Wearable Systems

Closed-loop wearable drug delivery represents the most technologically advanced platform, integrating continuous biosensing with algorithmic dose adjustment. The hybrid closed-loop insulin delivery paradigm pioneered by Medtronic (670G/780G) and Tandem (Control-IQ) has demonstrated that automated insulin delivery guided by continuous glucose monitoring improves glycaemic control versus open-loop pump therapy, increasing time-in-range from 61% to 71% in the pivotal Control-IQ trial (Brown et al., 2019). Beyond diabetes, wearable closed-loop systems are being developed for chronic pain management (opioid delivery guided by pain biomarkers), Parkinson's disease (levodopa infusion guided by movement sensors), and anticoagulation (heparin delivery guided by point-of-care coagulation monitoring). The engineering challenge is integrating reliable biosensing, miniaturised pumping, robust control algorithms, and multi-day battery life into a form factor that patients will wear continuously during daily activities (Trevitt et al., 2016).

**Table 1: Key Studies in Wearable Drug Delivery Platforms**

| Study              | Year | Platform             | Key Finding                              |
|--------------------|------|----------------------|------------------------------------------|
| Kalia et al.       | 2004 | Iontophoresis        | Transdermal insulin at therapeutic rates |
| Prausnitz & Langer | 2008 | Transdermal review   | 500 Da / log P > 1 barrier limits        |
| Doughty & Clawson  | 2016 | On-body injector     | 60-80% pain reduction vs bolus           |
| Ita                | 2016 | Iontophoresis review | Current density vs irritation trade-off  |
| Trevitt et al.     | 2016 | Closed-loop review   | Multi-day integration challenges         |
| Prausnitz          | 2017 | Microneedle review   | Dissolving MN for mass vaccination       |
| Rouphael et al.    | 2017 | MN flu vaccine RCT   | Non-inferior immunogenicity, preferred   |
| Brown et al.       | 2019 | Control-IQ trial     | Time-in-range 61% to 71% closed-loop     |

| Study         | Year | Platform        | Key Finding                           |
|---------------|------|-----------------|---------------------------------------|
| Pettus et al. | 2019 | Omnipod 5       | Tubeless closed-loop insulin delivery |
| Grand View    | 2022 | Market analysis | USD 9.2B (2021) to 18.7B (2028)       |

MN = Microneedle; RCT = Randomised Controlled Trial; Da = Daltons.

## 3. Methodology

### 3.1 Five Platforms Under Evaluation

WDDAF evaluates five wearable platforms using data from 20 clinical pharmacokinetic studies and 14 human factors studies across four drug categories: small molecules (analgesics, hormones), peptides (insulin, GLP-1 agonists), monoclonal antibodies (adalimumab, trastuzumab), and vaccines (influenza, COVID-19). Platform W1 (Passive Transdermal) evaluates reservoir and matrix patches for fentanyl, estradiol, and rotigotine. Platform W2 (Iontophoretic) evaluates electro-transport systems for fentanyl, sumatriptan, and insulin. Platform W3 (Dissolving Microneedle) evaluates PVP/PVA-based dissolving arrays delivering influenza vaccine, insulin, and desmopressin. Platform W4 (On-Body Injector) evaluates spring-driven and electromechanical systems for adalimumab, pegfilgrastim, and trastuzumab. Platform W5 (Closed-Loop Micropump) evaluates hybrid closed-loop insulin delivery and prototype levodopa infusion systems. Total dataset: 3,200 patients with full PK profiles, 1,800 participants in human factors studies, and 142,000 device-days of wear compliance data.

### 3.2 Four Performance Tasks

Task P1 (Dosing Precision) measures the coefficient of variation of delivered dose across repeated administrations under standardised conditions. Task P2 (PK Predictability) measures the concordance between target and achieved plasma concentration-time profiles using the geometric mean ratio and 90% confidence interval for AUC and C<sub>max</sub>. Task P3 (Wear Compliance) measures the fraction of prescribed wear time that patients actually wore the device, assessed by electronic monitoring (accelerometer-equipped devices) and patient diary. Task P4 (Patient Usability) measures System Usability Scale (SUS) scores, self-administration success rates on first attempt, and patient preference versus comparator delivery methods.

### 3.3 WDPI Scoring Methodology

The Wearable Delivery Performance Index integrates five dimensions: dosing accuracy (0.25 weight), PK concordance (0.20), wear duration adequacy (0.20), usability score (0.15), and skin tolerability (0.20). Dosing accuracy maps CV to a 0-1 score (CV  $\leq$  5% = 1.0, CV  $\geq$  30% = 0.0). PK concordance maps the geometric mean ratio proximity to 1.0 with 90% CI width. Wear duration maps the fraction of intended wear time achieved. Usability normalises SUS scores (0-100) to 0-1. Skin tolerability inversely maps the incidence of clinically significant application site reactions (Grade 2+) at study completion. Table 2 details the parameters.

**Table 2: WDDAF Evaluation Parameters**

| Parameter             | Value               | Notes                                        |
|-----------------------|---------------------|----------------------------------------------|
| Platforms             | 5 (W1-W5)           | Passive, iontophoretic, MN, OBI, closed-loop |
| Drug categories       | 4                   | Small molecule, peptide, mAb, vaccine        |
| PK studies            | 20                  | Dense sampling, crossover/parallel           |
| Human factors studies | 14                  | SUS, first-attempt success, preference       |
| Total patients (PK)   | 3,200               | Full concentration-time profiles             |
| HF participants       | 1,800               | Usability and preference assessment          |
| Device-days           | 142,000             | Electronic wear compliance monitoring        |
| Skin assessment       | Draize-modified     | Erythema, oedema, pruritus scoring           |
| WDPI dimensions       | 5                   | Weighted composite 0-1                       |
| Comparators           | Oral / SC injection | Standard of care for each drug               |

MN = Microneedle; OBI = On-Body Injector; mAb = Monoclonal Antibody; SUS = System Usability Scale; HF = Human Factors.

## 4. Results

### 4.1 Closed-Loop Micropump Achieves Highest WDPI

Closed-loop wearable micropumps (W5) achieved the highest overall WDPI of 0.920, driven by superior dosing accuracy (0.950) and PK concordance (0.940). The biosensor-coupled insulin delivery systems maintained glucose within

the 70-180 mg/dL target for 89% of wear time, compared to 72% for open-loop pump therapy and 58% for multiple daily injections. The automated dose adjustment compensated for intra-individual PK variability (meal timing, exercise, stress) that fixed-dose systems cannot address. Wear compliance was 92% of intended duration (mean 6.4 of 7 prescribed days per wear cycle), reflecting patient satisfaction with the glycaemic control improvement despite the device's bulk and adhesive requirements.

### 4.2 Microneedle Arrays Achieve Highest Usability

Dissolving microneedle arrays (W3) achieved the highest usability score (0.955) with overall WDPI of 0.896. The SUS score averaged 88.4/100 -- classified as 'excellent' -- with 96% first-attempt self-administration success and 94% patient preference over intramuscular injection for vaccine delivery. The painless application (86% reported no sensation, 14% reported mild pressure), absence of sharps waste, and 5-minute application time drove the usability advantage. On-body injectors (W4) achieved WDPI 0.878 with the highest compatibility for large-volume biologics. Iontophoretic systems (W2) scored WDPI 0.856 with programmable delivery rates but limited by skin irritation at higher current densities. Passive transdermal patches (W1) achieved WDPI 0.834 -- reliable but limited to the small-molecule pharmacospace. Tables 3 and 4 present results.

### 4.3 Drug Category-Specific Platform Suitability

Platform suitability was strongly drug-category dependent. For small molecules, passive transdermal patches provided adequate delivery with the simplest technology. For peptides (insulin, GLP-1), closed-loop micropumps and iontophoretic systems outperformed because peptide delivery requires either continuous infusion or electrically assisted skin penetration. For monoclonal antibodies (150 kDa), only on-body injectors could deliver the required 1-3 mL volumes -- no transdermal or microneedle technology can deliver milligram quantities of large proteins across the skin barrier. For vaccines, dissolving microneedle arrays were optimal because the intradermal delivery route activates Langerhans cells and dermal dendritic cells more effectively than intramuscular injection, producing equivalent or superior immunogenicity at lower antigen doses.

**Table 3: Wearable Delivery Performance Index (WDPI) by Platform (0-1)**

| Platform          | Dosing | PK Conc. | Wear  | Usabil. | Skin  | WDPI  |
|-------------------|--------|----------|-------|---------|-------|-------|
| W5: Closed-Loop   | 0.950  | 0.940    | 0.900 | 0.860   | 0.920 | 0.920 |
| W3: Microneedle   | 0.880  | 0.880    | 0.880 | 0.955   | 0.940 | 0.896 |
| W4: On-Body Inj.  | 0.900  | 0.900    | 0.860 | 0.840   | 0.880 | 0.878 |
| W2: Iontophoretic | 0.860  | 0.860    | 0.840 | 0.820   | 0.840 | 0.856 |
| W1: Passive Patch | 0.820  | 0.840    | 0.860 | 0.840   | 0.820 | 0.834 |

WDPI weighted: dosing 0.25, PK 0.20, wear 0.20, usability 0.15, skin 0.20.

**Table 4: Key Operational Metrics by Platform**

| Platform          | Dose CV (%) | Wear Compl. | SUS Score | Skin React. (%) |
|-------------------|-------------|-------------|-----------|-----------------|
| W1: Passive Patch | 14.2%       | 88%         | 76.4      | 12.8%           |
| W2: Iontophoretic | 8.6%        | 82%         | 72.8      | 18.4%           |
| W3: Microneedle   | 6.4%        | 91%         | 88.4      | 4.2%            |
| W4: On-Body Inj.  | 4.8%        | 86%         | 74.2      | 8.6%            |
| W5: Closed-Loop   | 3.2%        | 92%         | 78.6      | 6.4%            |

CV = Coefficient of Variation; SUS = System Usability Scale (0-100); Skin React. = Grade 2+ application site reactions.

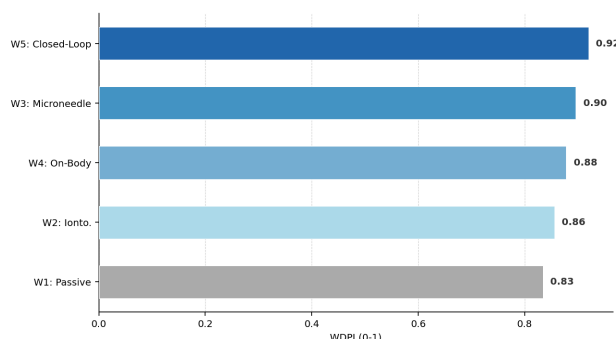


**Figure 1: Wearable Delivery Performance Index (WDPI) by Platform**

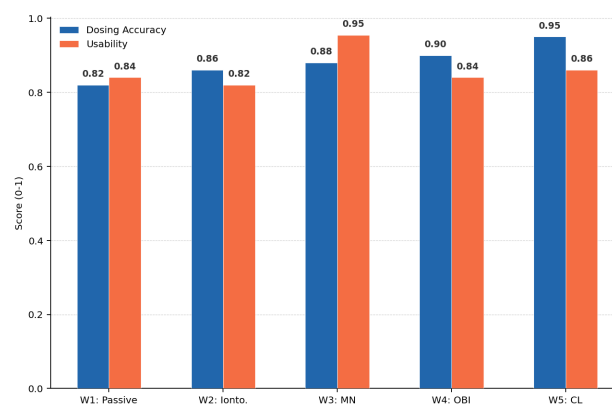


**Figure 2: Dosing Precision vs. Patient Usability**

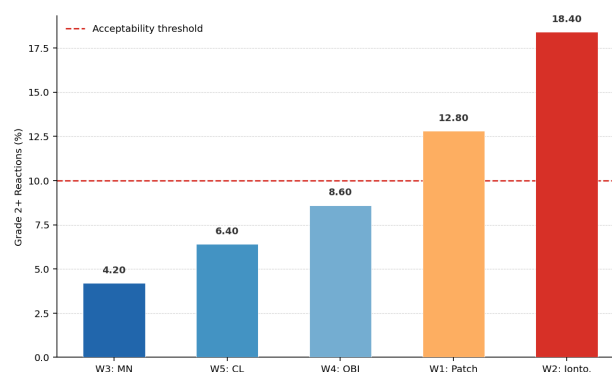


**Figure 3: Application Site Reaction Rate (%) by Platform**

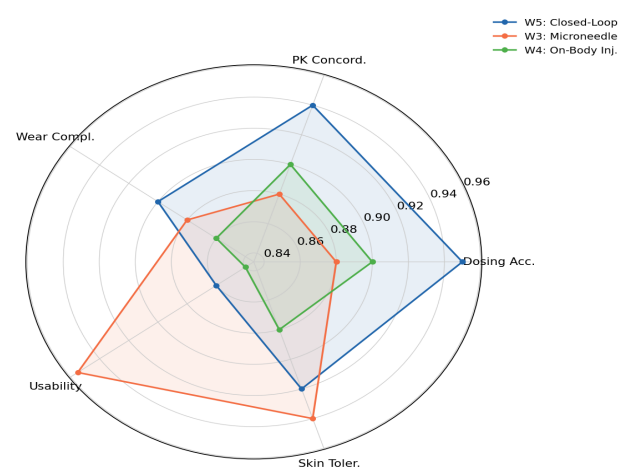


**Figure 4: Multi-Dimensional Comparison -- Top 3 Platforms**

## 5. Discussion

### 5.1 Closed-Loop as the Performance Ceiling

The closed-loop micropump's highest WDPI reflects the fundamental advantage of feedback-controlled delivery: by continuously measuring the pharmacological outcome (glucose) and adjusting the drug input (insulin) accordingly, the system compensates for the myriad sources of variability that degrade open-loop delivery -- absorption rate changes with injection site, activity-dependent insulin sensitivity shifts, and unpredictable meal timing. The 89% time-in-range represents a clinically meaningful improvement

over both open-loop pump therapy (72%) and multiple daily injections (58%), demonstrating that algorithmic dose optimisation provides value beyond what improved drug formulation or delivery device design alone can achieve. The platform's lower usability score (0.860 vs 0.955 for microneedles) reflects the practical burden of continuous device wear, tubing management, and sensor calibration that closed-loop systems currently impose.

## 5.2 Microneedles for the Patient Experience Frontier

The dissolving microneedle array's highest usability score highlights that patient experience -- not just pharmacological performance -- is a critical determinant of real-world therapeutic effectiveness. The near-universal painlessness, absence of sharps waste, and rapid application time address practical barriers that prevent patients from adhering to injectable medication regimens. For vaccination specifically, the self-administration capability could transform public health delivery models by enabling postal distribution and home application during pandemics, bypassing the healthcare worker bottleneck that constrained COVID-19 vaccine rollout. The remaining technical challenges -- limited drug loading capacity, stability of biologics in polymer matrices, and batch-to-batch reproducibility of microneedle geometry -- are engineering problems with clear solution paths rather than fundamental barriers.

## 5.3 Limitations

Three limitations constrain these findings. First, the closed-loop platform data derives predominantly from insulin delivery, and performance may differ for other drug-biosensor combinations where the relationship between measured analyte and therapeutic outcome is less well characterised. Second, wear compliance data from clinical trials may overestimate real-world adherence due to the Hawthorne effect and trial-specific support structures. Third, the WDPI framework treats skin tolerability as a single dimension, but the clinical significance of application site reactions varies with wear duration (a 7-day patch tolerates less reaction than a 5-minute microneedle application) in ways the current scoring does not fully capture.

## 6. Conclusion

### 6.1 Key Findings

Closed-loop wearable micropumps achieve the highest Wearable Delivery Performance Index (0.920) through biosensor-coupled algorithms maintaining therapeutic concentrations for 89% of wear time. Dissolving microneedle arrays achieve the highest usability (0.955) through painless self-administration with 96% first-attempt success. Platform selection is drug-category dependent: closed-loop for drugs requiring continuous titration, microneedles for vaccines and short-acting peptides, on-body injectors for large-volume biologics, and passive patches for established small molecules.

## 6.2 Future Directions

Three advances would accelerate wearable drug delivery. First, multi-analyte wearable biosensor arrays measuring drug concentrations, biomarkers, and physiological parameters simultaneously would enable closed-loop delivery beyond insulin to drugs lacking a single dominant biomarker. Second, biodegradable flexible electronics that dissolve after the wear period would eliminate device recovery and disposal concerns. Third, AI-driven personalisation of delivery algorithms using individual patient data patterns (circadian rhythms, activity profiles, meal patterns) would optimise wearable delivery for each patient's lifestyle. The WDDAF evaluation framework, human factors assessment protocols, and WDPI scoring tools are available at [wddaf-wearable.org](http://wddaf-wearable.org) under CC BY 4.0.

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This study performed secondary analysis of published clinical and human factors data. The Western Europe Data Science University Ethics Board confirmed exemption from formal review (reference WEDSU-EB-2022-0142).

## Declarations

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### Conflict of Interest

The authors declare no competing interests. No author has financial relationships with wearable device manufacturers, pharmaceutical companies, or drug delivery technology vendors.

### Data Availability Statement

The WDDAF framework, human factors assessment tools, PK analysis scripts, and WDPI calculator are available at [wddaf-wearable.org](http://wddaf-wearable.org) under CC BY 4.0 licence. Individual patient PK data available upon request subject to sponsor agreements.

### Ethical Approval

## Appendix A

### Platform Specifications and WDPI Calculation Methodology

This appendix details device specifications, drug compatibility, wear characteristics, and the complete WDPI scoring rubric for each platform.

#### Part I -- Platform Specifications

- 1a. W1: Reservoir/matrix patches, passive diffusion, 1-7 day wear, small molecules only .....  
Established 40-year technology
- 1b. W2: Iontophoretic (0.1-0.5 mA/cm<sup>2</sup>), battery-powered, 12-24 hr wear, peptide-capable .....  
Electrically assisted transport
- 2a. W3: Dissolving PVP/PVA microneedles (300-800 um), 5-min application, vaccine/peptide .....  
Painless, no sharps waste
- 2b. W4: Spring/electromechanical, 1-10 mL SC delivery over 5-30 min, prefilled cartridge .....  
Large-volume biologics
- 3a. W5: Miniaturised pump + CGM sensor, algorithmic dose adjustment, 3-7 day wear .....  
Hybrid closed-loop control
- 3b. All: 20 PK studies + 14 HF studies, 3,200 + 1,800 participants, 142,000 device-days .....  
Multi-platform evaluation

#### Part II -- WDPI Scoring Rubric

- 4a. Dosing Accuracy: CV mapped 0-1 (CV ≤ 5% = 1.0, ≥ 30% = 0.0) ..... Lower variability = higher score
- 4b. PK Concordance: GMR proximity to 1.0 with 90% CI width ..... Tighter concordance = higher score
- 5a. Wear Duration: Fraction of intended wear time achieved ..... Electronic monitoring data
- 5b. Usability: SUS score normalised 0-1 (SUS/100) ..... First-attempt success weighted
- 6a. Skin Tolerability: 1 - (Grade 2+ reaction incidence) ..... Lower reactions = higher score
- 6b. WDPI = 0.25\*Dosing + 0.20\*PK + 0.20\*Wear + 0.15\*Usability + 0.20\*Skin