Target Product Profile for Misoprostol and Mifepristone Point-of-Care Quality Testing

Disease Area: Medical Abortion
Intervention: (near) point-of-care quality detection devices

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Table of Contents

1 Background

1.1 General

Comprehensive abortion care relies on access to quality-assured, affordable medical abortion medicines — mifepristone, misoprostol, and co-packaged mifepristone-misoprostol (combi-pack) — including for self-managed abortion. Increasing the availability of these medicines is essential to improve access and depends on medicines policies and regulation, procurement and distribution, as well as health worker and end-user knowledge. Ensuring the quality of abortion medicines, such as mifepristone and misoprostol, is essential for their safe and efficacious use.

Both quality assurance and quality control play crucial roles in this process, though they serve distinct functions. Quality assurance is a proactive, process-driven approach that ensures abortion medicines are manufactured, stored, and distributed under strict regulatory standards. It includes compliance with Good Manufacturing Practices (GMP), supplier qualification, and continuous monitoring of production systems to prevent quality issues before they arise. Quality assurance helps ensure that only safe and efficacious products enter the supply chain. Quality control, in contrast, is a product-focused process that involves testing medicines at different points in the supply chain to verify they meet established standards. This includes analyzing samples for active pharmaceutical ingredient (API) content, detecting impurities, and assessing stability. Quality control is critical to confirming that mifepristone and misoprostol tablets meet quality standards at the time they reach the end-user.

Abortion medicines are distributed through diverse channels, including pharmacies, clinics, telemedicine services (via post and internet services), and community health programs. In some settings, they are legally regulated, while in others, access is restricted due to legal and social barriers. To ensure that good quality medical abortion medicines are used, there is a need to advance quality testing methods and technologies. The current approach to conducting quality surveys is to sample medicines in the field and send those samples to a laboratory for quality testing. Several studies have been conducted in the last decade, identifying substandard misoprostol and mifepristone in multiple countries, which can lead to inadequate efficacy (lower amount of API leading to reduced effectiveness) and safety concerns (such as impurities leading to increased risk of adverse reactions)[1–3]. Stigmatized products such as medical abortion medicines are also more likely to be falsified. Indeed, falsified products that do not contain any API have been found in circulation and remain a critical concern [4]. However, all these quality survey studies are time-consuming and costly, using high-performance liquid chromatography, and do not readily inform local decision-making, especially at the point of care. In addition, in some regulatory settings, resources may be limited and a national or certified laboratory may not be available to test suspected substandard medicines. While samples can sometimes be sent to laboratories in neighboring countries, obtaining results may take considerable time; in such situations, a quantitative device capable of providing numerical values of the API content in a tablet could offer valuable preliminary information. Having tools for quality control at the point of care would be valuable for real-time monitoring that enables prompt action and decision-making to remove substandard and falsified products from the supply chain. However, there are currently no methods for testing mifepristone and misoprostol at this level.

Point-of-care (POC) or near POC technologies have been developed for a range of medicines, including infectious disease medicines, and could be applied to abortion medicines[5,6]. Currently, fingerprint technologies are available to identify whether a given API is present in a finished pharmaceutical product (FPP) and spectroscopy can be used to evaluate an FPP by comparing it to a reference formulation. These technologies, however, are qualitative and do not quantify the API content of the product, a critical parameter to ensure product quality, adequate dosing and, ultimately, efficacy.

1.2 Purpose of this Target Product Profile

Target product profiles (TPPs) specify the minimum and optimal requirements for new health products, including diagnostic tests [7–11]. They are used by WHO and other international organizations to address major public health gaps, including the need to spur development and accelerate implementation of health products[7–11]. TPPs are an important resource for funders, researchers, product developers, manufacturers and regulators[12]. They guide key stakeholders on the characteristics required of new health products to meet pre-specified clinical and public health needs. They inform research and development strategies, help frame product dossiers, streamline communication with regulatory agencies and help funders set targets[13]. In addition, medical products approved by the US Food and Drug Administration that addressed pre-specified TPPs have been linked to more rapid regulatory review[14].

There are currently no TPPs available for POC or near POC technologies that test the quality of medical abortion medicines. Availability of POC devices that can test the quality of medical abortion tablets would facilitate the implementation of safer and more effective access to abortion care. Development of this TPP provides clear and consistent requirements to help drive innovation, research, and implementation of an accessible quality testing device for medical abortion medicines that meet global health needs.

2 Summary: Intervention Indication and Target Users

This TPP focuses on quality testing of **misoprostol** as a priority use-case because it is more widely used and distributed than mifepristone, including for medical abortion and postpartum hemorrhage management. Misoprostol is also chemically less stable, degrading quickly when exposed to heat and humidity, and its low active ingredient content (measured in micrograms) makes accurate quality testing technically challenging. In contrast, mifepristone is more stable and typically manufactured and distributed through more controlled channels**.** Therefore, developing a robust, field-appropriate quality testing method for misoprostol addresses a greater public health need and it would pave the way for mifepristone quality testing in the near future.

In developing a TPP for a medical abortion product testing device, we recognize that users at different points along the supply chain have different needs and product requirements. We have therefore created two separate TPPs.

TPP 1 (Upper level of supply chain) – for use by individuals involved in the procurement and wholesale distribution of medical abortion products (e.g. Ministries of Health, county governments, large distributors, and other centralized supply agencies). In addition, the device can be used by regulatory authorities for field screening.

Upper level of supply chain scenario:
When a shipment of misoprostol tablets is received, stakeholders at the upper level of the supply chain can sample and test tablets on-site with this device, or it can be used at storage facilities to measure the quality before further distribution. If the device indicates that a batch contains substandard levels of the active ingredient, the stakeholders can take immediate action: the suspect batch can be quarantined or rejected outright instead of being distributed. The stakeholder may then invoke quality safeguards – for example, renegotiating with the manufacturer or supplier based on the test findings, or enforcing contract clauses that require acceptable quality before payment is finalized. Such proactive measures strengthen accountability in the supply chain by signaling to manufacturers that substandard products will not be tolerated. Furthermore, any batch flagged as substandard by the device should be withheld from downstream distribution.
While this device is not a replacement for compendial laboratory testing, its findings can serve as an early warning: regulatory bodies can be notified to investigate and perform formal analytical testing on the suspected products.

TPP 2 (Lower level of supply chain) – for use by individuals involved at point of distribution or use of medical abortion products (e.g. pharmacies, hospitals, community centers).

Lower level of supply chain scenario:
When a pharmacy, clinic, or community health center receives misoprostol tablets—especially from informal or non-centralized sources—the provider can use this device to test a sample tablet on-site before dispensing it to patients. If the device indicates that the tablet contains insufficient active ingredient, the provider can immediately set aside the suspect stock and avoid selling or using it. They may also contact the distributor to report the issue, request a replacement or refund, and choose to source from a different supplier in the future. In some cases, the result may prompt the provider to stop working with a supplier altogether. This enables frontline health workers to play an active role in ensuring medicine quality, even in settings where regulatory oversight is weak or formal quality assurance is lacking.

The device can also be used as a spot-check tool to verify the quality of products already in stock, or to build trust with patients concerned about counterfeit or ineffective medicines. While the tool is not a substitute for official regulatory testing, it empowers providers to detect substandard products early and take action to protect patient safety.

Upper-level supply chain settings (ministries of health, large distributors, etc.) generally have more budget, more controlled environments, better technical infrastructure and trained staff. By contrast, lower-level supply chain settings (pharmacies, clinics or community health care centers) need a low-cost, portable, easy-to-use screening tool with minimal training. Regulatory and distribution contexts might also differ: in some countries medical abortion medicines are strictly channeled through official systems, while in others they circulate informally. Because quality problems are common, having two TPPs lets us tailor requirements for each level – such as balancing cost, training level, and portability for centralized procurement sites/ labs versus point-of-care settings.

The testing device is intended for use by various stakeholders across the supply chain to assess the quality of medical abortion medicines. It does not replace the formal analytical testing required for regulatory approval or official quality certification, but supports flagging potential substandard or falsified products.

3. TPP 1 (Upper level of supply chain): Core Variables

Variable	Minimum	Optimum	Annotations
Product Overview & Target Context			
1: **Intended use**	A device to assess the presence of sufficient active pharmaceutical ingredient (API) of misoprostol in a tablet at the near point-of-care.	A device to assess the presence of sufficient active pharmaceutical ingredient of misoprostol and mifepristone in a tablet at the near point-of-care.	In practical use, when a shipment of misoprostol tablets is received, stakeholders at the upper level of the supply chain can sample and test tablets on-site with this device. If the device indicates that a batch contains substandard levels of the active ingredient, the stakeholders can take immediate action: the suspect batch can be quarantined or rejected outright instead of being distributed. The stakeholder may then invoke quality safeguards – for example, renegotiating with the manufacturer or supplier based on the test findings, or enforcing contract clauses that require acceptable quality before payment is finalized. Such proactive measures strengthen accountability in the supply chain by signaling

Variable	Minimum	Optimum	Annotations
			to manufacturers that substandard products will not be tolerated. Furthermore, any batch flagged as substandard by the device should be withheld from downstream distribution. While this device is not a replacement for compendial laboratory testing, its findings can serve as an early warning: regulatory bodies can be notified to investigate and perform formal analytical testing on the suspected products. Letrozole is excluded from the list of target products prioritized for measurement in this TPP because additional evidence is needed on its safety, effectiveness, and acceptability.
2: **Target Use Setting**	Upper level of the supply chain, including procurement and wholesale distribution settings of medical abortion products (e.g. Ministries of Health, county governments, large distributors, and other centralized supply agencies). In addition, the device can be used by regulatory authorities for field screening.	Same as minimum	The tablets can be tested before being distributed to the abortion care providers (healthcare facilities, pharmacies)

Variable	Minimum	Optimum	Annotations
3: **Target operator and skills**	Individuals working at upper-level supply chain settings, including the procurement level/ wholesale distributor's location or associated laboratories Requires a basic skill set and training depending on the background of person and technology	Same as minimum Requires minimal skill set and training, depending on background of person and technology	The responsibility of quality testing cannot be shifted onto users themselves, especially when dealing with sensitive medications such as abortion drugs, where individuals may not have the means, knowledge, or safe conditions to verify quality. Users must be able to trust that the medicines they obtain are genuine and effective, without facing the added burden of testing or uncertainty. • No skills: Lay person with no healthcare or technical background • Minimal skills: Lay person or staff member after brief demonstration • Basic skills: Trained pharmacy or healthcare support staff. • Advanced skills: Healthcare professional • Specialist skills: Laboratory-qualified professional
Product Design & Functionality			

Variable	Minimum	Optimum	Annotations
4: **Portability**	Moveable by one person, a small table-top device that can be carried/moved with or without the help of a cart.	Handheld device.	Handheld is the optimistic option for maximum access. Minimum target for the benchtop device is based on the current weight and dimension of a mobile mini-laboratory [15], and airline allowed weight for check-in luggage. Optimistic weight has been based on the maximum recommended weight for a woman to manually lift [16]. Minimum target for the handheld device is based on the current weight and dimension of a Handheld Raman Analyzer [17]. Optimistic weight and dimensions are based on a smartphone.
5: **Required accessories**	None	None	Reducing dependence on companion parts simplifies deployment, especially in rural areas with limited supply chains or import restrictions. Additional accessories could include for example a probe, sample holder, or UV viewing box. These accessories do not relate to those needed for sample preparation
6: **Training requirements**	Basic operation (instrument handling, sample preparation, running measurements): maximum 2 day of hands-	Basic operation (instrument handling, sample preparation, running measurements): maximum 1 day of remote or self-training (for example	

Variable	Minimum	Optimum	Annotations
	on training is sufficient for someone with prior lab experience. Data interpretation and routine quality control use: requires maximum 2 weeks to get comfortable with	online video instructions) is sufficient for someone with prior lab experience. Data interpretation and routine quality control use: requires maximum 1 week to get comfortable with	
7: **Languages required for operating**	English Language of target countries	Same as minimum	
8: **Results display and interpretation**	Requires companion device provided by the user (no onboard display or result output) Result is displayed immediately e.g. as yes/no or as % API detected. Results are easy and intuitive to interpret.	Integrated display with onboard result interpretation or companion device is not needed for result display. Result is displayed immediately e.g. as yes/no or as % API detected. Results are easy and intuitive to interpret.	
9: **Connectivity**	Test results can be transferred to a laptop/ tablet using a cable or by using Bluetooth.	Same is minimum	There is a need to transfer results to device (computer/ tablet/smartphone), in order to ensure adequate storage of the test results and printing if needed. The output should be universal, e.g. USB3

Variable	Minimum	Optimum	Annotations
10: **Internal results storage**	100 tests	500 tests	Requirement on the minimum numbers of results that can be stored within the device before it runs out of storage capacity. *Only applicable for multi use devices
11: **Data security**	Reference libraries, algorithms and generated data should be appropriately protected.	Same as minimum	*Only applicable for multi use devices
12: **Software - Interoperability standards and format**	Software runs on commonly available operating systems including their older versions. Data output is given in several appropriate file formats, including .csv. Software updates are provided free of charge	Device can be operated by a smartphone or no software for analysis of results required. Data output is given in several appropriate file formats, including .csv. Software updates are provided free of charge and are available for older versions of commonly available operating systems.	*Only applicable if software is required.
13: **Software functionality & user access**	Single-user application with basic interface; fixed data output. No differentiation between user types. No automatic data sharing through a centralized dashboard.	Multi-user platform with role-based access Includes data sharing between (inter-) national users, centralized dashboard to view aggregated results, and automatic notifications/alerts when substandard products are detected.	*Only applicable if software is required. For example, users at higher-level settings can access detailed analytical data, and exportable reports (e.g., PDFs for data filing), while lower-level users receive simplified outputs (e.g., pass/fail or semi-quantitative).

Variable	Minimum	Optimum	Annotations
14: **Support**	Full support through a website chat box, WhatsApp/Wechat assistance, with email replies guaranteed within 24 hours	Full support through a website chat box, WhatsApp/Wechat assistance, and a toll-free number, with email replies guaranteed within 24 hours	
15: **Sample preparation**	Minimal destruction of tablet sample is needed for the device to measure the quality. Tablet must be free from packaging (box and blister) Could require simple sample preparation (e.g. no usage of solvent use besides distilled water or alcohol, maximum three steps). Sample preparation can be done using basic laboratory equipment, such as a mortar, pestle and vortex mixer	No destruction of tablet sample is needed for the device to measure the quality. Tablet must be free from packaging (box only, measurement through blister) No additional sample preparation required.	Misoprostol tablets are typically sealed individually in aluminum blister packs, which protect them from moisture and humidity, as the tablets are highly sensitive to moisture. Primary packaging consists of aluminum blisters, while secondary packaging typically includes a small cardboard box.
16: **Reagents Requirement**	Reagents might be required, but are easily accessible in LMIC	No reagents are required.	As mentioned under 'sample preparation', reagents may include distilled water or alcohol, which in general are available at basic pharmacies
17: **Measurement Time**	Under 10 minutes	Under 5 minutes	The measurement time does not include sample preparation

Variable	Minimum	Optimum	Annotations
Technology & Performance			
Single use device			
18A: **Target product**	Device can only be used for misoprostol tablets	Same as minimum Plus: Device can be used for mifepristone tablets	This TPP focuses on misoprostol for the quality testing device as a priority because it is more widely used and distributed than mifepristone, including medical abortion and postpartum hemorrhage management. Misoprostol is also chemically less stable, degrading quickly when exposed to heat and humidity, and its low active ingredient content (measured in micrograms) makes accurate quality testing technically challenging. A single use device is defined as a disposable one time use only
19A: **Quantitation**	Semi-quantitative	Same as minimum	The device is not intended to replace the formal analytical testing required for regulatory approval or official quality certification. **Definitions**

Variable	Minimum	Optimum	Annotations
			• **Semi-quantitative:** provides a yes/no or range rather than an exact amount. • **Quantitative:** provides an exact numerical measurement of the API amount present. For a single-use device, operation and interpretation should be as simple as possible, giving a clear binary result: • **Yes** — tablet contains sufficient misoprostol API. • **No** — tablet contains insufficient misoprostol API.
20A: **Analytical specificity/ selectivity**	No interference from other excipients commonly used in the target product (misoprostol tablets or mifepristone tablets) formulations.	Same as minimum	
21A: **Limit of Detection (LOD)**	90% of the label claim	90% of the label claim	Misoprostol tablets for medical abortion are labeled to contain 200 micrograms of API. International quality standards require 90–110% of the label claim, corresponding to 180–220 micrograms. → Tablets containing less than 180 micrograms (90%) of misoprostol API are considered substandard products.

Variable	Minimum	Optimum	Annotations
			The Limit of Detection (LOD) is the lowest amount that a device can detect. For example, considering the label claim of misoprostol is 200 micrograms per tablet: • **90% LOD:** 180 micrograms is the lowest amount that the device can detect. • **50% LOD:** 100 micrograms is the lowest amount that the device can detect. • **10% LOD:** 20 micrograms is the lowest amount that the device can detect. To enable a semi-quantitative device that indicates whether a misoprostol tablet is of good quality (using the cut-off value of 180 micrograms), the LOD should be set at 90%.
22A: **Limit of Quantification (LOQ)**	Not applicable for semi-quantitative devices	Not applicable for semi-quantitative devices	*Only applicable for quantitative tests
23A: **Sensitivity and specificity for detecting the target**	Sensitivity 80 % Specificity 80 %	Sensitivity 95% Specificity 95%	A minimum sensitivity and specificity of ≥80% is acceptable because it reflects a reasonable balance between technical feasibility and public health benefit—allowing the device to identify most severely substandard tablets

Variable	Minimum	Optimum	Annotations
substance at the limit of detection			(well below the 90–110% label claim) while recognizing that some margin of error is tolerable in low-resource settings. This level is consistent with established benchmarks for triage or first-line tools in global health, where perfect accuracy is not always achievable but early detection still provides significant value. At the optimal level, ≥95% sensitivity and specificity ensures the device can reliably distinguish between very low-API tablets and those within or near the acceptable range. This higher threshold supports confident decision-making, minimizes false positives and negatives, and aligns with standards used for high-quality diagnostics intended to trigger regulatory or supply chain action.
24A: **Calibration**	Calibration of the device is not needed	Calibration of the device is not needed	
25A: **Robustness**	Method should be robust to different analytical procedure parameters, ambient temperature, humidity and duration of the procedure.	Same as minimum	
26A: **Reproducibility**	Method should give reproducible results when device is used by a different person,	Same as minimum	

Variable	Minimum	Optimum	Annotations
	on a different day and in a different place after transport.		
27A: **Maintenance Requirements**	No maintenance needed	Same as minimum	
28A: **Internal Control/ Reference**	Optional internal control/ reference items (e.g. values, standards) are either included or inexpensive and readily available in LMIC.	No internal control or reference items needed	Built-in controls improve reliability, ensure test validity, and enhance user trust—particularly critical when devices are used in decentralized settings.
29A: **Companion equipment**	No companion equipment is required	No companion equipment is required	Eliminating reliance on external equipment simplifies implementation and improves usability in clinics with limited infrastructure and in home settings.
Multi use device			
18B: **Target product**	Device can only be used for misoprostol tablets Device has the potential to measure other APIs	Same as minimum Plus: Device can be used for mifepristone tablets Device can be used for testing other API, for which methodologies and reference libraries exist (or can be developed)	For higher end technologies, such as the NIR (Near-Infrared) or Raman technologies, methods could be developed and validated to measure other API's using the same device.

Variable	Minimum	Optimum	Annotations
19B: **Quantitation**	Semi-quantitative	Quantitative	The device is not intended to replace the formal analytical testing required for regulatory approval or official quality certification. A quantitative version of the device could be useful at upper levels settings, where users may include Ministries of Health, procurement agencies, and regulators. In some settings, access to accredited laboratory facilities may be limited or unavailable, meaning tablets cannot easily be sent for confirmatory testing. In such situations, a more precise numerical result can support evidence-based decisions on product acceptance, distribution, investigation of suspected substandard medicines, and supply chain quality monitoring. **Definitions** • **Semi-quantitative:** provides a yes/no or range rather than an exact amount. • **Quantitative:** provides an exact numerical measurement of the API amount present.
20B:	No interference from other excipients commonly used in the target product	Same as minimum	

Variable	Minimum	Optimum	Annotations
Analytical specificity/ selectivity	(misoprostol tablets or mifepristone tablets) formulations.		
21B **Limit of Detection (LOD)**	90% of the label claim	10% of the label claim (assuming a quantitative device)	Misoprostol tablets for medical abortion are labeled to contain 200 micrograms of API. International quality standards require 90–110% of the label claim, corresponding to 180–220 micrograms. → Tablets containing less than 180 micrograms (90%) of misoprostol API are considered substandard products. The **Limit of Detection (LOD**) is the lowest amount that a device can detect (provide yes/no). The **Limit of Quantification (LOQ)** is the lowest amount that a device can measure (provide a number) For example, considering the label claim of misoprostol is 200 micrograms per tablet: • **90% LOD/LOQ:** 180 micrograms is the lowest amount that the device can detect (LOD) or measure (LOQ). • **50% LOD/LOQ:** 100 micrograms is the lowest amount that the device can detect (LOD) or measure (LOQ).

Variable	Minimum	Optimum	Annotations
			• **10% LOD/LOQ:** 20 micrograms is the lowest amount that the device can detect (LOD) or measure (LOQ). To enable a semi-quantitative device that indicates whether a misoprostol tablet is of good quality (using a cut-off value of 180 micrograms), the LOD should be set at 90%. To support the use case of quantitative device in the upper level settings, the LOQ could be set at 100 micrograms (50% of the label claim). This allows the device to generate reliable numerical results across a clinically and programmatically relevant range, enabling higher-level users to distinguish between compliant products, moderately degraded tablets, and clearly substandard medicines. In general, the LOD is about one tenth of the LOQ. For example, a 50% LOQ (100 micrograms) corresponds to a 5% LOD (10 micrograms). However, because misoprostol is present at very low microgram levels, a 10% LOQ is considered more feasible.
22B:	Not applicable for semi-quantitative devices	50% of the label claim	*Only applicable for quantitative tests See explanation at 'Limit of Detection (LOD)' variable

Variable	Minimum	Optimum	Annotations
Limit of Quantification (LOQ)			
23B: **Sensitivity and specificity for detecting the target substance at the limit of detection**	Sensitivity 80% Specificity 80%	Sensitivity 95% Specificity 95%	A minimum sensitivity and specificity of ≥80% is acceptable because it reflects a reasonable balance between technical feasibility and public health benefit—allowing the device to identify most severely substandard tablets (well below the 90–110% label claim) while recognizing that some margin of error is tolerable in low-resource settings. This level is consistent with established benchmarks for triage or first-line tools in global health, where perfect accuracy is not always achievable but early detection still provides significant value. At the optimal level, ≥95% sensitivity and specificity ensures the device can reliably distinguish between very low-API tablets and those within or near the acceptable range. This higher threshold supports confident decision-making, minimizes false positives and negatives, and aligns with standards used for high-quality diagnostics intended to trigger regulatory or supply chain action.
24B: Calibration	Calibration of the device is needed, can be performed by the user	Calibration of the device is needed, can be performed by the user	

Variable	Minimum	Optimum	Annotations
	Calibration time is maximum 10 minutes	Calibration time is maximum 5 minutes	
25B: Robustness	Method should be robust to different analytical procedure parameters, ambient temperature, humidity and duration of the procedure.	Same as minimum	
26B: Reproducibility	Method should give reproducible results when device is used by a different person, on a different day and in a different place after transport.	Same as minimum	
27B: Maintenance Requirements	LMIC-based third party vendors can provide maintenance. Spare parts are available within 4 weeks after placement of the order Recalibration or servicing are needed every two years	Maintenance can be performed by user itself Spare parts are available within 2 weeks after placement of the order Recalibration or servicing are needed every three years	Devices requiring minimal maintenance but with accessible support pathways are essential for long-term use in resource-limited settings. Reliance on international service may not be sustainable or responsive.
28B: Internal Control/ Reference	Optional internal control/ reference items (e.g. reference library, values, standards) are either included or inexpensive and readily available in LMIC.	No internal control needed	Built-in controls improve reliability, ensure test validity, and enhance user trust—particularly critical when devices are used in decentralized settings.
29B: Companion equipment	Small, portable, reusable tabletop devices may be required to process samples for tests.	Small, portable, reusable handheld device, or no companion equipment required.	Eliminating reliance on external equipment simplifies implementation and improves usability in clinics with limited infrastructure and in home settings.
Cost & Financial Sustainability			

Variable	Minimum	Optimum	Annotations
31: **Device cost**	**Single use device:** Under $10 **Multi use device**: Under $3000	**Single use device:** Under $5 **Multi use device:** Under $250	Upfront cost of the device/technology. Should be priced appropriately for intended markets, or supplier should be willing to negotiate on pricing.
32: **Cost per test**	If consumables and/or single use items (for example sample holder, cartridge) are required, one test should cost less than $10.	If consumables and/or single use items (for example sample holder, cartridge) are required, one test should cost less than $5. If no consumables and/or single use items are required, there are no additional costs per test	*Excluding costs for personnel
33: **Cost of software**	Software is offered at an affordable cost with discount options for low-resource settings.	Software is offered free of charge and made available open-source.	*Only applicable if software is required
34: **Accessibility**	Company provides shipment to every country with appropriate documentation for import of device and consumables.	Same as minimum	
35: **Availability**	Robust supply chain management for devices and consumables with minimized risk of stockouts in case of increased demand.	Same as minimum	

Variable	Minimum	Optimum	Annotations
	Components to operate the device are readily available from several LMIC sources.		
36: **Volume estimates**	Volumes compatible with targeted use by central procurement entities in high-need regions. This assumes initial adoption by national Ministries of Health, large distributors, and central supply agencies to test misoprostol quality for medical abortion in key markets, covering the most critical supply channels without extending to every outlet.	Volumes compatible with broad integration across supply chains for misoprostol (used for several indications including medical abortion, PPH, and gastric ulcer management). This scenario reflects uptake by procurement agencies, umbrella health facilities, NGOs, and large pharmacy networks, supported by inclusion in national quality control programs.	For higher-end analytical platforms (e.g., near-infrared spectroscopy), broader interest and purchasing willingness are expected, as these devices could later be extended to test other APIs beyond misoprostol—such as mifepristone, oxytocin, or other essential medicines—once methods are developed. While this may not directly increase initial testing volumes, it enhances value justification and procurement rationale for investing in a versatile, multi-analyte testing system.
37: **Stability / Shelf Life / Life cycle**	**Single use device:** Shelf life ≥ 1 years at 30–45°C and 75–90% RH. **Multi use device:** The lifespan of the device is approximately 5 years, depending on usage intensity, environmental conditions, and maintenance	**Single use device:** Shelf life ≥ 2 years at 30–45°C and 75–90% RH. **Multi use device:** The lifespan of the device is approximately 10 years, depending on usage intensity, environmental conditions, and maintenance	For supply chain reliability, products should remain functional across broad temperature/humidity conditions typical of LMICs. Shelf stability without cold chain simplifies logistics and minimizes stockouts. Computers and tablets, potential companion devices, usually start showing issues after 4-5 years, QC instruments have a longer life cycle but need to be replaced after a certain period of use

157
158

159

160 ## 4. TPP 2 (Lower level of supply chain): Core Variables

161

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Variable	Minimum	Optimum	Annotations
Product Overview & Target Context			
1: Intended use	A device to confirm the presence of sufficient active pharmaceutical ingredient (API) of misoprostol in a tablet at the point-of-care.	A device to confirm the presence of sufficient active pharmaceutical ingredient of misoprostol and mifepristone in a tablet at the point-of-care.	In practical use, when a pharmacy, clinic, or community health center receives misoprostol tablets—especially from informal or non-centralized sources—the provider can use this device to test a sample tablet on-site before dispensing it to patients. If the device indicates that the tablet contains insufficient active ingredient, the provider can immediately set aside the suspect stock and avoid selling or using it. They may also contact the distributor to report the issue, request a replacement or refund, and choose to source from a different supplier in the future. In some cases, the result may prompt the provider to stop working with a supplier altogether. This enables frontline health workers to play an active role in ensuring medicine quality,

Variable	Minimum	Optimum	Annotations
			even in settings where regulatory oversight is weak or formal quality assurance is lacking. The device can also be used as a spot-check tool to verify the quality of products already in stock, or to build trust with patients concerned about counterfeit or ineffective medicines. While the tool is not a substitute for official regulatory testing, it empowers providers to detect substandard products early and take action to protect patient safety. Letrozole is excluded from the list of target products prioritized for measurement in this TPP because additional evidence is needed on its safety, effectiveness, and acceptability.
2: **Target Use Setting**	Setting where the medical abortion medicines are distributed to the buyer, or the place where the medicines are being provided (e.g. pharmacies, hospitals, community centers, mobile points).	Same as minimum	The tablets can be tested before being provided to the buyer either once received at the facility or in real time.
3: **Target operator and skills**	Individuals working at pharmacies, hospitals, community centers	Same as minimum	The responsibility of quality testing cannot be shifted onto users themselves, especially when dealing with sensitive medications such as abortion drugs, where individuals may not

Variable	Minimum	Optimum	Annotations
	Requires minimal skill set and training, depending on background of person and technology	User with no laboratory, medical, pharmaceutical or other related training can operate the device/test with minimal training using clear instructions (written, visual, or digital)	have the means, knowledge, or safe conditions to verify quality. Users must be able to trust that the medicines they obtain are genuine and effective, without facing the added burden of testing or uncertainty. • No skills: Lay person with no healthcare or technical background • Minimal skills: Lay person or staff member after brief demonstration • Basic skills: Trained pharmacy or healthcare support staff. • Advanced skills: Healthcare professional • Specialist skills: Laboratory-qualified professional
Product Design & Functionality			
4: **Portability**	Handheld device, can be carried in a backpack	Handheld device, can be carried in a backpack	Handheld is the optimistic option for maximum access. Minimum target for the benchtop device is based on the current weight and dimension of a mobile mini-laboratory [15], and airline

Variable	Minimum	Optimum	Annotations
			allowed weight for check-in luggage. Optimistic weight has been based on the maximum recommended weight for a woman to manually lift [16]. Minimum target for the handheld device is based on the current weight and dimension of a Handheld Raman Analyzer [17]. Optimistic weight and dimensions are based on a smartphone.
5: **Required accessories**	None	None	Reducing dependence on companion parts simplifies deployment, especially in rural areas with limited supply chains or import restrictions. Additional accessories could include for example a probe or sample holder. These accessories do not relate to those needed for sample preparation
6: **Training requirements**	Basic operation (instrument handling, sample preparation, running measurements): maximum two days of remote or self-training (for example online video instructions) is sufficient for someone without prior lab experience.	Basic operation (instrument handling, sample preparation, running measurements): maximum ½ day of remote or self-training (for example online video instructions) is sufficient for someone without prior lab experience.	

Variable	Minimum	Optimum	Annotations
	Data interpretation and routine quality control use: requires maximum ½ week to get comfortable with	Data interpretation and routine quality control use: requires maximum 1 day to get comfortable with	
7: **Languages required for operating**	English Language of target countries	Same as minimum	
8: **Results display and interpretation**	Integrated display with onboard result interpretation or companion device is not needed for result display. Result is displayed immediately e.g. as yes/no. Results are easy and intuitive to interpret.	Same as minimum	
9: **Connectivity**	Test results can be transferred to a laptop/ tablet using a cable or by using Bluetooth.	Same is minimum	There is a need to transfer results to device (computer/ tablet/smartphone), in order to ensure adequate storage of the test results and printing if needed. The output should be universal, e.g. USB3
10: **Internal results storage**	50 test	100 tests	Requirement on the minimum numbers of results that can be stored within the device before it runs out of storage capacity. *Only applicable for multi use devices

Variable	Minimum	Optimum	Annotations
11: **Data security**	Generated data should be appropriately protected.	Same as minimum	*Only applicable for multi use devices
12: **Software - Interoperability standards and format**	Software runs on commonly available operating systems including their older versions. Data output is given in several appropriate file formats, including .csv. Software updates are provided free of charge	Device can be operated by a smartphone or no software for analysis of results required. Data output is given in several appropriate file formats, including .csv. Software updates are provided free of charge and are available for older versions of commonly available operating systems.	*Only applicable if software is required.
13: **Software functionality & user access**	Single-user application with basic interface; fixed data output. No differentiation between user types. No automatic data sharing through a centralized dashboard.	Multi-user platform with role-based access Includes data sharing between (inter-) national users, centralized dashboard to view aggregated results, and automatic notifications/alerts when substandard products are detected.	*Only applicable if software is required.
14: **Support**	Full support through a website chat box, WhatsApp/Wechat assistance, with email replies guaranteed within 24 hours	Full support through a website chat box, WhatsApp/Wechat assistance, and a toll-free number, with email replies guaranteed within 24 hours	

Variable	Minimum	Optimum	Annotations
15: **Sample preparation**	Minimal destruction of tablet sample is needed for the device to measure the quality. Tablet must be free from packaging (box and blister) No additional sample preparation required.	No destruction of tablet sample, is needed for the device to measure the quality Tablet must be free from packaging (box only, measurement through blister) No additional sample preparation required.	Misoprostol tablets are typically sealed individually in aluminum blister packs, which protect them from moisture and humidity, as the tablets are highly sensitive to moisture. Primary packaging consists of aluminum blisters, while secondary packaging typically includes a small cardboard box
16: **Reagents Requirement**	No reagents are required.	No reagents are required.	As mentioned under 'sample preparation', reagents may include distilled water or alcohol, which in general are available at basic pharmacies
17: **Measurement Time**	Under 5 minutes	Under 1 minute	The measurement time does not include sample preparation
Technology & Performance			
Single use device			

Variable	Minimum	Optimum	Annotations
18A: **Target product**	Device can only be used for misoprostol tablets	Same as minimum Plus: Device can be used for mifepristone tablets	This TPP focuses on misoprostol for the quality testing device as a priority because it is more widely used and distributed than mifepristone, including medical abortion and postpartum hemorrhage management. Misoprostol is also chemically less stable, degrading quickly when exposed to heat and humidity, and its low active ingredient content (measured in micrograms) makes accurate quality testing technically challenging. A single use device is defined as a disposable one time use only
19A: **Quantitation**	Semi-quantitative	Same as minimum	The device is not intended to replace the formal analytical testing required for regulatory approval or official quality certification. **Definitions** • **Semi-quantitative:** provides a yes/no or range rather than an exact amount. • **Quantitative:** provides an exact numerical measurement of the API amount present. For a single-use device, operation and

Variable	Minimum	Optimum	Annotations
			interpretation should be as simple as possible, giving a clear binary result: • **Yes** — tablet contains sufficient misoprostol API. • **No** — tablet contains insufficient misoprostol API.
20A: **Analytical specificity/ selectivity**	No interference from other excipients commonly used in the target product (misoprostol tablets or mifepristone tablets) formulations.	Same as minimum	
21A: **Limit of Detection (LOD)**	90% of the label claim	90% of the label claim	Misoprostol tablets for medical abortion are labeled to contain 200 micrograms of API. International quality standards require 90–110% of the label claim, corresponding to 180–220 micrograms. → Tablets containing less than 180 micrograms (90%) of misoprostol API are considered substandard products. The Limit of Detection (LOD) is the lowest amount that a device can detect. For example, considering the label claim of misoprostol is 200 micrograms per tablet:

Variable	Minimum	Optimum	Annotations
			• **90% LOD:** 180 micrograms is the lowest amount that the device can detect. • **50% LOD:** 100 micrograms is the lowest amount that the device can detect. • **10% LOD:** 20 micrograms is the lowest amount that the device can detect. To enable a semi-quantitative device that indicates whether a misoprostol tablet is of good quality (using the cut-off value of 180 micrograms), the LOD should be set at 90%.
22A: **Limit of Quantification (LOQ)**	Not applicable for semi-quantitative devices	Not applicable for semi-quantitative devices	*Only applicable for quantitative tests
23A: **Sensitivity and specificity for detecting the target substance at the limit of detection**	Sensitivity 80% Specificity 80%	Sensitivity 95% Specificity 95%	

Variable	Minimum	Optimum	Annotations
24A: **Calibration**	Calibration of the device is not needed	Calibration of the device is not needed	
25A: **Robustness**	Method should be robust to different analytical procedure parameters, ambient temperature, humidity and duration of the procedure.	Same as minimum	
26A: **Reproducibility**	Method should give reproducible results when device is used by a different person, on a different day and in a different place after transport.	Same as minimum	
27A: **Maintenance Requirements**	No maintenance needed	Same as minimum	
28A: **Internal Control/ Reference**	Optional internal control/ reference items (e.g. values, standards) are either included or inexpensive and readily available in LMIC.	No internal control or reference items needed	Built-in controls improve reliability, ensure test validity, and enhance user trust—particularly critical when devices are used in decentralized settings.
29A: **Companion equipment**	No companion equipment is required	Same as minimum	Eliminating reliance on external equipment simplifies implementation and improves usability in clinics with limited infrastructure and in home settings.
Multi use device			
18B:	Device can only be used for misoprostol tablets	Same as minimum	For higher end technologies, such as the NIR (Near-Infrared) or Raman technologies,

Variable	Minimum	Optimum	Annotations
Target product	Device has the potential to measure other APIs	Plus: Device can be used for mifepristone tablets Device can be used for testing other API, for which methodologies and reference libraries exist (or can be developed)	methods could be developed and validated to measure other API's using the same device.
19B: **Quantitation**	Semi-quantitative	Semi-quantitative	The device is not intended to replace the formal analytical testing required for regulatory approval or official quality certification. **Definitions** • **Semi-quantitative:** provides a yes/no or range rather than an exact amount. • **Quantitative:** provides an exact numerical measurement of the API amount present. For a lower level setting, assuming users have no or limited training, operation and interpretation should be as simple as possible, giving a clear binary result: • **Yes** — tablet contains sufficient misoprostol API. • **No** — tablet contains insufficient misoprostol API.

Variable	Minimum	Optimum	Annotations
20B: **Analytical specificity/ selectivity**	No interference from other excipients commonly used in the target product (misoprostol tablets or mifepristone tablets) formulations.	Same as minimum	
21B: **Limit of Detection (LOD)**	90% of the label claim	90% of the label claim	The Limit of Detection (LOD) is the lowest amount that a device can detect. For example, considering the label claim of misoprostol is 200 micrograms per tablet: • **90% LOD:** 180 micrograms is the lowest amount that the device can detect. • **50% LOD:** 100 micrograms is the lowest amount that the device can detect. • **10% LOD:** 20 micrograms is the lowest amount that the device can detect. To enable a semi-quantitative device that indicates whether a misoprostol tablet is of good quality (using the cut-off value of 180 micrograms), the LOD should be set at 90%.
22B: **Limit of Quantification (LOQ)**	Not applicable for semi-quantitative devices	Not applicable for semi-quantitative devices	*Only applicable for quantitative tests

Variable	Minimum	Optimum	Annotations
23B: **Sensitivity and specificity for detecting the target substance at the limit of detection**	Sensitivity 80% Specificity 80%	Sensitivity 95% Specificity 95%	High sensitivity is crucial to minimize false negatives, ensuring that substandard or falsified drugs are detected. High specificity is essential to minimize false positives, ensuring that genuine products are not incorrectly identified as substandard.
24B: **Calibration**	Calibration of the device is needed, can be performed by the user Calibration time is maximum 5 minutes	Calibration of the device is not needed	
25B: **Robustness**	Method should be robust to different analytical procedure parameters, ambient temperature, humidity and duration of the procedure.	Same as minimum	
26B: **Reproducibility**	Method should give reproducible results when device is used by a different person, on a different day and in a different place after transport.	Same as minimum	
27B: **Maintenance Requirements**	LMIC-based third party vendors can provide maintenance. Spare parts are available within 4 weeks after placement of the order Recalibration or servicing are needed every two years	Maintenance can be performed by user itself Spare parts are available within 2 weeks after placement of the order Recalibration or servicing are needed every three years	Devices requiring minimal maintenance but with accessible support pathways are essential for long-term use in resource-limited settings. Reliance on international service may not be sustainable or responsive.

Variable	Minimum	Optimum	Annotations
28B: **Internal Control/ Reference**	Optional internal control/ reference items (e.g. reference library, values, standards) are either included or inexpensive and readily available in LMIC.	No internal control needed	Built-in controls improve reliability, ensure test validity, and enhance user trust—particularly critical when devices are used in decentralized settings.
29B: **Companion equipment**	Small, portable, reusable handheld device.	No companion equipment required.	Eliminating reliance on external equipment simplifies implementation and improves usability in clinics with limited infrastructure and in home settings.
Cost & Financial Sustainability			
31: **Device cost**	**Single use device:** Under $5 **Multi use device**: Under $1000	**Single use device:** Under $2 **Multi use device:** Under $100	Upfront cost of the device/technology. Should be priced appropriately for intended markets, or supplier should be willing to negotiate on pricing.
32: **Cost per test**	If consumables and/or single use items (for example sample holder, cartridge) are required, one test should cost less than $2.	No consumables and/or single use items are required, there are no additional costs per test	*Excluding costs for personnel
33: **Cost of software**	Software is offered free of charge and made available open-source.	Same as minimum	*Only applicable if software is required

Variable	Minimum	Optimum	Annotations
34: **Accessibility**	Company provides shipment to every country with appropriate documentation for import of device and consumables.	Company provides shipment free of charge to every country with appropriate documentation for import of device and consumables.	
35: **Availability**	Robust supply chain management for devices and consumables with minimized risk of stockouts in case of increased demand. Components to operate the device are readily available from several LMIC sources.	Same as minimum	
36: **Volume estimates**	Volumes aligned with selective deployment of testing tools at key service delivery points in high-need areas. This scenario assumes adoption by district hospitals, referral centers, and selected community health centers that routinely provide medical abortion. The goal is to ensure targeted quality assurance where misoprostol is most frequently used, without requiring broad coverage across all facilities or pharmacies.	Volumes aligned with widespread use of testing tools across frontline health service networks and retail supply points. Used for several indications including medical abortion, PPH, and gastric ulcer management. This scenario assumes routine integration in district and sub-district hospitals, community health centers, midwife-led clinics, and pharmacy chains (public and private)	For higher-end analytical platforms (e.g., near-infrared spectroscopy), broader interest and purchasing willingness are expected, as these devices could later be extended to test other APIs beyond misoprostol—such as mifepristone, oxytocin, or other essential medicines—once methods are developed. While this may not directly increase initial testing volumes, it enhances value justification and procurement rationale for investing in a versatile, multi-analyte testing system.
37: **Stability / Shelf Life / Life cycle**	**Single use device:** Shelf life ≥ 1 years at 30–45°C and 75–90% RH.	**Single use device:** Shelf life ≥ 2 years at 30–45°C and 75–90% RH.	For supply chain reliability, products should remain functional across broad temperature/humidity conditions typical of

Variable	Minimum	Optimum	Annotations
	Multi use device: The lifespan of the device is approximately 5 years, depending on usage intensity, environmental conditions, and maintenance	**Multi use device:** The lifespan of the device is approximately 10 years, depending on usage intensity, environmental conditions, and maintenance	LMICs. Shelf stability without cold chain simplifies logistics and minimizes stockouts. Computers and tablets, potential companion devices, usually start showing issues after 4-5 years, QC instruments have a longer life cycle but need to be replaced after a certain period of use

163

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