Alcohol-Based HandRub (ABHR) local procurement QA guidance summary

Product description: Alcohol-Based Hand Rub, Ethanol 80%± 5% v/v OR Isopropyl 75%± 5%v/v[1] *100ml/500ml/1L with flap closure/dosing pump*

This quick guide shows the evaluation criteria for the domestic procurement of ABHR to be used in the context of covid-19. For each criteria the corresponding Supporting document/information to be requested to the bidders are indicated as well as the information to be checked by UNDP Country Offices to assure compliance.

Evaluation criteria:	Supporting document/information to request (Requirements for bidders):	What to check by UNDP Country Office:
➢ **REGULATORY COMPLIANCE**	Registration status of the product (in SRA[2] or in the country where it will be used)	Verify product listing in: ECHA List of active substances and suppliers or, US FDA National Drug Code Directory or, Confirm registration according to the local national requirements (of the country where the product will be used)
➢ **QUALITY COMPLIANCE**	GMP certificates or manufacturing certificate/authorization according to the local national requirements (of the country where the product is manufactured)	Verify that the production of ABHR is in the scope of the manufacturer registration/certificate
➢ **TECHNICAL SPECIFICATIONS**	Product information, datasheet or Finished Product Specifications	Active ingredient(s) is/are relevant and appropriate Avoid products with unnecessary appetizing scents or colors which may promote accidental ingestion *Recommended:* Contaminants of concern does not exceed acceptable values: Methanol NMT* 200 ppm** , Benzene NMT 2 ppm, Acetaldehyde and acetal NMT 10 ppm, Sum of all other impurities NMT 300 ppm
➢ **CHEMICAL ANALYSIS**	Certificate of Analysis (CoA) or Lab report on chemical analysis	The batch number and expiry date on the CoA matches with the one on the product Confirms the active ingredient and its' concentration indicated on the label *Recommended:* Contaminants of concern does not exceed acceptable values: Methanol not more than (NMT) 200 ppm, Benzene NMT 2 ppm, Acetaldehyde and acetal NMT 10 ppm, Sum of all other impurities NMT 300 ppm
➢ **PRODUCT PRESENTATION AND PACKAGING**	Clear images of the product, packaging, labels, and any artwork (information must be clearly readable)	Information on the label complies with the national regulation and may include: - Brand name and manufacturer information including address and phone number - Product identifier such as NDC number, BPR code, or local assigned ID - Product claim and indication - Active and inactive ingredients - Batch number and expiration date - Instruction and warnings Avoid packaging which resembles food pouches, water, or beverage bottles Avoid packaging bigger than 1L.
➢ **AUTHENTICITY** **(In case the manufacturer is not the supplier)**	Letter of Authorization (LoA, issued to the supplier by the manufacturer, authorizing it as official distributor (Exclusive or not))	Share with the manufacturer the LoA received, the product picture, batch number and expiry date to confirm their authenticity.

*NMT: Not More Than; **ppm: parts per million

The following documents are considered common for any manufacturer having a quality system in place and consistently implementing good manufacturing practices, it is therefore recommended to require them although depending on the manufacturer quality they might be unavailable.

- ➢ Safety datasheet (SDS or MSDS) if shipping and transporting is required
- ➢ Lab report(s) on efficacy testing: Not all ABHRs are proven to be effective even at the recommended concentrations. Inactive ingredients and various additives can alter the performance of the alcohol. While efficacy data should always be part of the assessment, the tests can be costly and may not always be feasible in low resource areas.

Table 3. Examples of test standards but not limited to

	Reference standards	Test type	Acceptance reduction
Bacteria	EN 1500	In vivo, fingertip	30-60 sec. result ≥ propan-2-ol 60% (active control)
	ASTM E 2755	In vivo, fingertip	Non-inferiority to active control (0.5 lg margin)
Viruses	EN14476	In vitro, suspension test	30-120 sec. log reduction 4
	ASTM 1838	In vivo, fingerpad	Non-inferiority to active control (0.5 lg margin)

If a chemical analysis is planned, products should be sampled at the supplier facility. Testing should be required only to ISO 17025 certified labs

[1] Guide to local production: WHO-recommended handrub formulations; Technical specifications of personal protective equipment for COVID-19

[2] SRA, Stringent Regulatory Authority according to WHO definition: https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs