CHECKLIST FOR PROTOCOL OF ANALYSIS (POA)

- British Pharmacopoeia (BP) 2018 or the edition thereafter shall be used as the main references.
- Photocopies from pharmacopoeias shall not be accepted.
- Specify the reference and edition of the method used.

No.	TEST	INFORMATION REQUIRED
1	Total Viable Aerobic Count (Total Aerobic Microbial Count (TAMC) & Total Yeasts and Moulds Count (TYMC))	a) Detailed test procedure for Total Viable Aerobic Count should consist of: - Method used (Example of method: Plate Count, Membrane Filtration method) - Preparation of test sample (including neutralizing of preservatives for samples that contain preservatives) b) Detailed test procedure and test report for growth promoting properties of media
2	Test for Specified Microorganism	a) Detailed test procedure for each specific microorganism tested b) Detailed test procedure and test report for growth promoting, inhibitory and indicative properties of media
3	Semi-Quantitative Test for Bile-Tolerant Gram Negative Bacteria	Detailed test procedure for Semi-Quantitative Test for Bile-Tolerant Gram Negative Bacteria
4	Semi-Quantitative Test for *Escherichia Coli*	Detailed test procedure Semi-Quantitative Test for *Escherichia Coli*

CHECKLIST FOR ANALYTICAL METHOD VALIDATION (AMV)

- List of the traditional samples (batch number, expiry date and MAL number) used for the validation tests shall be provided.

TEST	MICROBIAL CONTAMINATION TEST (TOTAL VIABLE AEROBIC COUNT)	
PARAMETER	No.	DOCUMENTS REQUIRED
Accuracy	1	Validation method
	2	Acceptance criteria
	3	Minimum six (6) products for the matrix applied
	4	Minimum one (1) spiking level at the lowest specification range for the matrix applied Example of spiking level: TAMC: at $<10^2$ CFU TYMC: at $<10^1$ CFU
	5	Cover microorganisms for TAMC and TYMC as specified in British Pharmacopoeia
	6	Raw data and result
Intermediate Precision	1	Validation method
	2	Acceptance criteria
	3	Minimum six (6) products for the matrix applied
	4	Minimum two (2) spiking level covering the specification range of TAMC & TYMC for the matrix applied and minimum six (6) replicates for each spiking level Example of spiking level: TAMC: at $<10^2$ CFU and $>10^7$ CFU TYMC: at $<10^1$ CFU and $>10^5$ CFU
	5	Cover microorganisms for TAMC and TYMC as specified in British Pharmacopoeia
	6	Cover at least 2 parameters among variation of analyst, date, equipment and batch of media

	7	Raw data and result

TEST	**DETECTION OF SPECIFIC MICROORGANISM**	
PARAMETER	No.	DOCUMENTS REQUIRED
Limit of Detection	1	Validation method
	2	Acceptance criteria
	3	Minimum six (6) products for the matrix applied
	4	Concentration of spiking: 1 cfu into sample preparation. The specific microorganism must be recovered and confirmed by confirmation test
	5	Raw data and result

TEST	**SEMI-QUANTITATIVE TEST FOR BILE-TOLERANT GRAM NEGATIVE BACTERIA**	
PARAMETER	No.	DOCUMENTS REQUIRED
	1	Validation method
	2	Acceptance criteria
	3	Minimum six (6) products for the matrix applied
	4	Inoculate *Escherichia* coli and *Pseudomonas aeruginosa* individually. Concentration of spiking: not more than 100 CFU per gram or milliliter of product. Perform the test using the shortest incubation period. The dilution corresponding to 0.1 g or 0.1 mL of product must be positive.
	5	Raw data and result

TEST	**SEMI-QUANTITATIVE TEST FOR *ESCHERICHIA COLI*** (intended for the preparation of infusions and decoctions using boiling water only)	
PARAMETER	No.	DOCUMENTS REQUIRED
	1	Validation method
	2	Acceptance criteria
	3	Minimum six (6) products for the matrix applied
	4	Concentration of spiking: not more than 100 CFU per gram or milliliter of product. Perform the test using the shortest incubation period. The dilution corresponding to 0.1 g or 0.1 mL of product must be positive.
	5	Raw data and result

*Raw data must comprise name, strength and dosage form of product, type of media, batch no of product/media, name and strain of spiked microorganisms, passage number of microorganisms, expiry date of microorganisms/culture, date of test commencement and completion, observation in every interval period, wherever applicable. Actual data must be provided.