Document type: **Format**		
RWANDA FDA Rwanda Food and Drugs Authority	Title: **DRUGS TESTING SCOPE**	Doc. Number: LSD/DT/FMT/003 Revision number: 0 Revision Date: 21.07.2025 Effective date: 24/07/2025

DRUGS TESTING DIVISION

1. FINISHED PHARMACEUTICAL PRODUCTS

S/N	Products	Parameters /and test method
1	**Tablets and Capsules**	Identification test by HPLC
2		Identification test by UV/VIS
3		Identification test by HPTLC
4		Identification by GC
5		Assay by UV/VIS
6		Assay by HPLC
7		Assay by Titration
8		Dissolution test by Dissolution apparatus paired to UV/VIS
9		Dissolution test by Dissolution apparatus paired to HPLC
10		Content of uniformity by UV/VIS
11		Content uniformity by HPLC
12		Related substances/impurities by HPLC
13		Uniformity of dosage unit by weight variation
14		Uniformity of dosage unit Disintegration test
15		Friability test by Friability tester
16		Physical appearance by visual inspection
17	**Syrups**	Physical appearance by visual inspection
18		Identification by HPLC
19		Identification by TLC
20		Identification by Uv-vis
22		Assay by HPLC
22		Assay by Uv-vis
23		Related substances or impurities by GC
24		pH
25	**Oral suspension**	Physical appearance by visual inspection
26		Identification test by HPLC
27		Identification by Uv-vis
28		Identification by TLC

29		Assay by HPLC
30		Assay by Uv-vis
31		Related substances/impurities by GC
32		pH
INJECTABLES (SMALL & LARGE VOLUME PARENTERAL) + DRY POWDER FOR INJECTIONS		
33		Visible particulate matter
34		Identification by HPLC
35		Identification by TLC
36		Identification by Uv-vis
37		Assay by HPLC
38		Assay by Uv-vis
39		Impurities by ICP or AAS
40		pH
41		Sterility test
42		Bacterial endotoxins
2. Active Pharmaceutical ingredients (API) Testing scope is under construction		

N.B: The following methods are used for the analysis of medicinal products:

1. Pharmacopoeia Methods including:
    - United states pharmacopoeia (USP),
    - British pharmacopoeia (BP),
    - International pharmacopoeia (Ph.int.),
2. Manufacturer-Specified Methods
3. In house methods