General parameters for Pharmaceuticals Analysis	
S.No.	**Test Parameters**
A1	**Acidity and Alkalinity**
A2	**Ash Value**
A3	**Assay**
i	GLC Assay
	a) GLC (Normal)
	b) GLC (Headspace), (Capillary)
	GC – Headspace with MS Detection for OVIs / Residual Solvents' Confirmation
	GC – Headspace with Photo-Ionization Detector for ppb level detection of volatile impurities
	c) GC-MS (EI/NCI/PCI Mode)
	Single Scan (m/z determination of primary ion)
	Identification & m/z of daughter ion)
	d) GC – Purge & Trap
	GC – Purge & Trap with FID for ppb level detection of volatile impurities *(for VOCs in Water as per WHO, EPA, EU)*
	GC – Purge & Trap with PID for ppt/sub-ppb level detection of volatile impurities *(for VOCs in Water as per WHO, EPA, EU)*
ii	Gravimetric Assay
iii	HPLC Assay only
	HPLC – UV/RI Detector
	HPLC – ECD/PDA/FLD Detector
	LC – MS/MS (ESI Mode / APCI Mode)
iv	Infra Red Assay (Simethicone)
v	Microbiological Assay (Vitamins / Antibiotics)
vi	Photofluorometric Assay (B1, B2)
vii	Steroid Assay

viii	Titrimetric Assay
	Aqueous Titration
	Argentimetric
	Ceric Ammonium Sulphate / Chloride
	Complexometric
	Non Aqueous Titration (Perchloric Acid Titration)
	Potentiometric Titration
	Tetra Butyl Ammonium Hydroxide Titration
	Titanium Chloride Titration
ix	UV/Vis Spectrophotomeric Assay
A4	**Average Net Content of Capsules / Injection Tubes**
A5	**Average Weight of Tablets / Capsules**
B1	**Bacterial Endotoxin Test (LAL Test)**
B2	**Boiling Range/ Distilling Range**
C1	**Clarity and Colour of Solutions**
C2	**Congealing Range or Temperature**
C3	**Consistency test**
D1	**Density**
D2	**Disintegration time**
D3	**Dissolution Test (06 Individual Units) ****
i	UV/Vis Spectrophotometric - Single Point - IP
ii	HPLC (Isocratic) - Single Point - IP
E1	**Element Analysis By AAS**
i	Atomic Absorption Spectrophotometer - Flame Ionizer (Each Element)
	(Al, Ba, Be, Mo, Si)
	(Au, V, Ca, Cd, Cr, Fe, K, Mg, Mn, Na, Ni, Pb, Se, Si, Zn)
ii	Atomic Absorption Spectrophotometer - Graphite Furnace / Hydride Generator (Charges per Element)
	(Al, As, Ba, Ca, Co, Cr, Cu, Fe, Mn, Mo, Ni, Pd, Sb, Se, Si)
	(Ag, Au, Cd, K, Mg, Na, Pb, Zn)
	(Hg)
	For Multiple Extraction Stages (charges per extraction)
iii	Chemical method (Each Element)
iv	Flame photometer (Each Element)
E2	**Ethanol content**
i	By Distillation
ii	By GC

F1	**Fatty acid composition (By GC)**
F2	**Freezing Point**
F3	**Friability**
I 1	**Identification Tests**
i	Chemical identification
ii	FTIR (Raw Material)
iii	FTIR (Finished Product)
iv	HPLC (Only identification, by Isocratic)
v	Melting point
vi	Paper chromatography
vii	Steroids identification
viii	TLC
ix	UV/Vis spectrophotometer (Complete spectrum)
x	UV/Vis spectrophotometer (Single wavelength)
I 2	**Impurities**
i	TLC (Each Impurity)
ii	HPLC (Each Impurity)
J1	**Jelly strength**
L1	**Limit test for**
i	Arsenic (Chemical Method))
ii	Chlorides
iii	Free formaldehyde
iv	Heavy metals
v	Iron
vi	Lead
vii	Sulphates
viii	Arsenic as per BP (by AAS)
ix	Arsenic as USP (by colorimetric as per USP)
x	Lead as BP / USP (by AAS)
xi	Selenium as per USP (colorimetric)
L2	**Loss on drying**
i	Simple LOD
ii	Vacuum LOD
L3	**Loss on Ignition**
M1	**Melting point / range**
M2	**Microbial Count ,except for Salmonella & Shigella (Each)**
	Microbial Count – Salmonella & Shigella (Each)
M3	**Minimum Inhibitory Concentration (per micro-organism)**
O1	**Optical Rotation / Specific Optical Rotation**
O2	**Organic Volatile Impurities** (By GC - Headspace / Capillary Col.)
P1	**Peroxide Value**
P2	**pH value**

P3	**Pyrogen**
R1	**Refractive Index**
R2	**Related Substances**
i	GLC
ii	HPLC
	Isocratic
	Gradient
iii	TLC
R3	**Residual Solvents**
	Residual Solvents (Upto 4 in a single scan)
	Ethylene oxide and 1,4-dioxane
R4	**RWC (Rideal Walker Coefficient) + SA (Staphylococcal Aureus Coefficient) Each**
S1	**Saponification Value**
S2	**Skin Sensitization Test**
S3	**Solubility Test**
S4	**Sterility**
i	Direct Filtration
ii	Membrane Filtration
S5	**Sulphated Ash**
T1	**Total Bacterial Count**
T2	**Toxicity**
i	3 days
ii	5 days
U1	**Uniformity of Content ****
i	Titrimetric
ii	UV/ Colorimetric
iii	HPLC
V1	**Viscosity**
i	Brookfield Viscometer (Dynamic Viscosity)
ii	Ostwald Viscometer (Kinematic Viscosity)
W1	**Water content**
i	Dean Stark Method
ii	K.F.Autotitrator
iii	By GC-TCD (Acetone)
W2	**Weight per ml/ Relative Density**
W2	**Weight Variation Test of Tablets/ Capsules**

	Special Focus Areas
1	***Accelerated Storage for Stability Analysis ******
	Storage – Per Sample (Test Unit) / Per Month
	Stability - Analytical Only
2	***Bio-burden Studies***
	Air monitoring and surface monitoring of manufacturing area
3	***Compatibility Test (Container & Content)***
4	***Glass Containers for Injectable Preparations (IP)***
	Hydraulic Resistance
	Distinction Between Type 1 & Type 2
	Arsenic, As (Limit Test)
5	***Metal Containers for Eye Ointment (IP)***
	Metal Particles
6	***Plastic Container for Non-injectable Preparations (IP)***
	Collapsibility Test
	Clarity of Aqueous Extract
	Non-Volatile Residues
7	***Plastic Container for injectable Preparation (IP)***
	Leakage Test
	Collapsibility Test
	Transparency
	Water-Vapour Permeability
	Extractable di(2-ethylhexyl) pthalate
	Barium, Ba
	Heavy Metals, as Pb
	Tin, Sn
	Zinc, Zn
	Residue on Ignition
	Appearance
	Light Absorption
	pH
	Buffering Capacity
	Oxidizable Substances
	Non-Volatile Matter
	Biological Tests – Systemic Injection
	Biological Tests – Intracutaneous test

8	***Plastic container for Ophthalmic Preparations (IP)***
	Leakage Test
	Collapsibility Test
	Clarity and Colour of Solutions
	Non volatile residue
	Systemic injection test
	Intracutaneous test
	Eye Irritation test
9	***Rubber Closures for Containers for Injectable Preparations (IP)***
	Sterilization test
	Fragmentation test
	Self sealability
	Clarity and colour of aqueous extract
	pH aqueous extract
	Light Absorption
	Reducing substances
	Heavy Metals, as Pb
	Residue on evaporation
10	***Biological tests***
	TEST A
	TEST B
	Sample volume shall be as per pharmacopoeia. The below mentioned is indicative only.
a	Tablets / Capsules = 2 * 30 units
b	Powders = 2 * 5 gms
c	Liquids = 2 * 100 ml
d	For Sterility 2 * 40 vials / sets are required.