BOMBAY TEST HOUSE
Testing | Inspection | Certification
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ANALYSIS OF DRUGS & PHARMACEUTICALS

MH-FDA LICENSE NO.: MH/104247

BIOLOGICAL DISCIPLINE

Ayush Products	Ayurvedic drugs	Homeopathic Drugs	Unani Drugs
	Herbal formulations	Siddha Drugs	Others

Drugs and Pharmaceuticals	Antibiotics	Drug Intermediates	Microbial limit test	Synthetic Drugs
	Bioassays of Other Products	Drug Substances(Active Pharmaceuticals Ingredients (API)	Raw Materials	Veterinary Drugs
	Chemotherapeutic Agents	Endotoxins	Sterility tests	Others

Microbial Testing	Microbial limit tests	Sterility	Bacterial Endotoxin test
	Total bacterial count	Vitamin Assays	Antimicrobial Preservative Efficacy test
	Yeast & mould	Antibiotic Assays	

CHEMICAL DISCIPLINE

Ayush Products	Ayurvedic drugs	Homeopathic Drugs	Unani Drugs
	Herbal formulations	Siddha Drugs	Others

Drugs and Pharmaceuticals	Capsules	Drops	Oral Liquids	Injectables	Nasal	Vitamins
	Creams	Gels	Oral Powders	Topical	Inhalers and other products	Others
	Drug Substance (API)	Ointment	Parenteral Preparations	Ophthalmic	Tablets	

Analytical Method Validation	Accuracy	Limits of Quantification	Range
	Precision	Limit of Detection	Robustness
	Specificity	Linearity	System suitability tests

TESTING INSIGHTS

Expertise and Services	IP/BP/USP/EP/JP	Impurity profile	Organic Volatile impurities(OVI)
	Identification of various drugs	Chromatographic purity / Related substances	Residual solvents
	Purity of pharmaceuticals	Organic & Inorganic	Dissolution Profile & Content Uniformity

General Test Analytes for Drugs & Pharmaceutical Analysis

A	
Sr No	**Test Parameters**
A1	Acidity and Alkalinity
A2	Ash Value
A3	Assay
1	GLC Assay
1 A	*GLC (Normal)*
1 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
1 C	*GC-MS (EI/NCI/PCI Mode)*
	Single Scan (m/z determination of primary ion)
	Identification & m/z of daughter ion)
1 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)*
2	Gravimetric Assay
3	HPLC Assay only
	HPLC – UV/RI Detector
	HPLC – ECD/PDA/FLD Detector
	LC – MS/MS (ESI Mode / APCI Mode)
4	Infra-Red Assay (Simethicone)
5	Microbiological Assay (Vitamins / Antibiotics)
6	Photofluorometric Assay (B1, B2)
7	Steroid Assay
8	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
9	UV/Vis Spectrophotomeric Assay
A4	Average Net Content of Capsules / Injection Tubes
A5	Average Weight of Tablets / Capsules
B	
B1	Bacterial Endotoxin Test (LAL Test)
B2	Boiling Range/ Distilling Range

	C
C1	Clarity and Color of Solutions
C2	Congealing Range or Temperature
C3	Consistency test
	D
D1	Density
D2	Disintegration time
D3	Dissolution Test (06 Individual Units)
1	UV/Vis Spectrophotometric - Single Point - IP
2	HPLC (Isocratic) - Single Point - IP
	E
E1	Element Analysis
1	ICO-OES/ICP-MS Technique: Al, Ba, Be, Mo, Si, Au, V, Ca, Cd, Cr, Fe, K, Mg, Mn, Na, Ni, Pb, Se, Si, Zn, As, Ca, Co, Cu, Mo, Sb, Si, Ag, Au, K, Hg
2	Chemical method (Each Element)
3	Flame photometer (Each Element)
E2	Ethanol content
1	By Distillation
2	By GC
	F
F1	Fatty acid composition (By GC)
F2	Freezing Point
F3	Friability
	I
I	**Identification Tests**
1	Chemical identification
2	FTIR (Raw Material)
3	FTIR (Finished Product)
4	HPLC (Only identification, by Isocratic)
5	Melting point
6	Paper chromatography
7	Steroids identification
8	TLC
9	UV/Vis spectrophotometer (Complete spectrum)
10	UV/Vis spectrophotometer (Single wavelength)
I 2	**Impurities**
1	TLC (Each Impurity)
2	HPLC (Each Impurity)
	J
J1	Jelly strength

L1	**Limit test for**
1	Arsenic (Chemical Method)
2	Chlorides
3	Free formaldehyde
4	Heavy metals
5	Iron
6	Lead
7	Sulphates
8	Arsenic as per BP (by AAS)
9	Arsenic as USP (by colorimetric as per USP)
10	Lead as BP / USP (by AAS)
11	Selenium as per USP (colorimetric)
L2	**Loss on drying**
1	Simple LOD
2	Vacuum LOD
L3	**Loss on Ignition**
	M
M1	Melting point / range
M2	Microbial Count ,except for Salmonella & Shigella (Each)
	Microbial Count – Salmonella & Shigella (Each)
M3	Minimum Inhibitory Concentration (per micro-organism)
	O
O1	Optical Rotation / Specific Optical Rotation
O2	Organic Volatile Impurities (By GC - Headspace / Capillary Col.)
	P
P1	Peroxide Value
P2	pH value
P3	**Pyrogen**
	R
R1	Refractive Index
R2	**Related Substances**
1	GLC
2	HPLC
	Isocratic
	Gradient
3	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

	S
S1	Saponification Value
S2	Skin Sensitization Test
S3	Solubility Test
S4	**Sterility**
i	Direct Filtration
ii	Membrane Filtration
S5	Sulphated Ash
	T
T1	Total Bacterial Count
T2	**Toxicity**
1	3 days
2	5 days
	U
U1	**Uniformity of Content**
1	Titrimetric
2	UV/ Colorimetric
3	HPLC
	V
V1	**Viscosity**
1	Brookfield Viscometer (Dynamic Viscosity)
2	Ostwald Viscometer (Kinematic Viscosity)
	W
W1	**Water content**
1	Dean Stark Method
2	K.F.Autotitrator
3	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.	
1	Tablets / Capsules = 2 * 30 units
2	Powders = 2 * 5 gms
3	Liquids = 2 * 100 ml
4	For Sterility 2 * 40 vials / sets are required.

Find out more about Bombay Test House Support Services:

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