

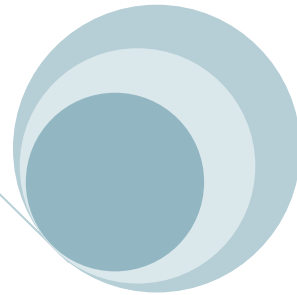
www.stabicon.com

Stabicon Life Sciences Pvt. Ltd.

Business Services Portfolio

Business Development Team

Stabicon 2017



Index

Sr. No	Business Segment Services Portfolio	Page No
1	In-Vitro Services	3-4
2	Formulation And Development Services	5-6
3	Laboratory Services	7-13
4	Setting up Dedicated Operational Formulation development & Laboratory	14-14



Section -1) Business Segment: In-vitro Services Portfolio**Section-1a: In-vitro binding studies for non systematic drugs**

Sr. No	Molecule	Route	Applications
1	Cholestyramine (Light/Regular)	Suspension/ Oral	Anti-cholesterol (Bile acid Sequestrate)
2	Colesevelam	Tablet/Suspension: oral	Anti-cholesterol (Bile acid Sequestrate)
3	Colestipol	Granule; Oral	Anti-cholesterol (Bile acid Sequestrate)
4	Sevelamer	Suspension; Oral	Renal (Phosphate Binding)
5	Sevelamer Carbonate	Tablet/Suspension; Oral	Renal (Phosphate Binding)
6	Lanthanum Carbonate	Chewable Tablets/Oral	Renal (Phosphate Binding)
7	Calcium Acetate	Tablets/Oral	Renal (Phosphate Binding)
8	Sodium polystyrene sulfonate	Powder; oral/rectal	Renal (K+ Binding)
9	Calcium polystyrene sulfonate	Powder; oral/rectal	Renal (K+ Binding)

Section-1b: In-vitro studies for quantitative capsule rupture test (QCRT)

Sr. No	Molecule	Route	Applications
1	Ergocalciferol	Capsule Oral	Vitamin D
2	Omega-3 Acid Ethyl Esters	Capsule Oral	To treat Hyperlipidemias
3	Omega-3 Carboxylic Acids	Capsule Oral	To treat Hyperlipidemias
4	Ethyl eicosapentaenoic acid	Capsule Oral	To treat Hyperlipidemias

Section -1c: Nasogastric and gastronomy (NG) tube in- vitro studies

Sr. No	Molecules	Route	Applications
1	Lansoprazole DR Capsule	Delayed Release Capsule/Oral	Proton pump inhibitor
2	Esomeprazole Strontium DR Capsule	Capsule, Delayed Release; Oral	Proton pump inhibitor
3	Esomeprazole magnesium DR Capsule	Capsule, Delayed Release Pellets; Oral	Proton pump inhibitor
4	Morphine Sulfate	Extended Release Capsule; Oral	Pain management
5	Rivaroxaban	Tablet; Oral	Anticoagulant

Section-1d: Topical and transdermal in-vitro release testing (IVRT)

In vitro release of API from topical and transdermal products, and subsequent permeation through a membrane, can be tested in a vertical diffusion cell (i.e. Franz diffusion cell). In this apparatus, formulation is applied or put in contact with a membrane that is in contact with a receiving medium. The receiving medium is sampled as a function of time and API is quantities to determine a permeation/flux profile. Membrane materials include synthetic polymer, tissue constructs. The choice of membrane is driven by the purpose of the test (i.e. development vs. quality control) and robustness of the model. This technique is applicable not only to externally applied topical formulations, but also to products that deliver via the vaginal, rectal, buccal, or nasal routes.

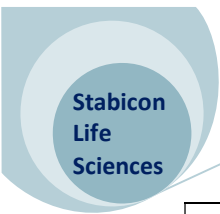
Section-1e: Micro bail In-Vitro evaluation:

In-vitro microbial kill rate study as per USFDA guidance

In-Vitro Evaluation of the Antimicrobial properties for various application

Section: 2) Business segment: Formulation and development services portfolio

Sr. No	Drug delivery system	Type	Dosage form
1	Oral Delivery through Digestive tract(enteral)	Solids	Pill
			Tablet
			Capsule
			Lozenges & Pastille
			Buccal & sub lingual Tablets
			Osmotic delivery system (OROS)
			Granules, Powder
2	Ophthalmic /Otologic / Nasal	Solid/Liquid	Spray
			Drops
			Ointment
			Hydrogel
			Nano sphere suspension
			Insufflation
			Mucoadhesive microdisc (microsphere tablet)
3	Urogenital	Solid/Liquid	Ointment
			Pessary (vaginal suppository)
			Extra-amniotic infusion
			Tablets
			Intravesical infusion
4	Rectal (enteral)	Solid/Liquid	Ointment
			Suppository
			Enema
			Solution
			Hydrogel
			Murphy drip
			Nutrient enema
5	Dermal	Solid/Liquid	Ointment
			Topical gel
			Liniment
			Paste



			Film
			DMSO drug solution
			Hydrogel
			Liposomes
	Dermal		Transfer some vesicles
			Cream
			Lotion
			Medicated shampoo
			Dusting Powder



Section -3: Business Segment: Laboratory services portfolio

Section-3a: Physical tests

Sr. No	Test Parameter
1	Uniformity of Weight / Weight Variation
2	Uniformity of Dosage Units (by weight)
3	Uniformity of Dispersion
4	Diameter / Thickness / Length / Width (For each)
5	Hardness
6	Disintegration test
7	Friability test
8	Loss on Drying / LOD
9	Dispersion
10	Bulk density
11	Jelly strength
12	Particle size(Microscopic)
13	Specific surface area
14	Bloom strength
15	Crystallinity
16	Particulate matter
17	Redispersability
18	Deliverable volume
19	Content of packed dosage form
20	Wetting time
21	Volume in container
22	Tapped density (Manual)
23	Sieve analysis per sieve /30 mesh size,20 mesh size



Section-3b: Chemical tests

Sr. No	Evaluation parameter
1	Loss on Ignition / sup hated Ash
2	Heavy metals
3	Arsenic
4	Melting point / melting range
5	Acidity / alkalinity
6	Total hardness
7	Total dissolved solids
8	Color / Clarity of Solution (Chemical)
9	Chlorides, by Titration
10	Chlorides (qualitative test)
11	Sulphates/Sulphites , by Titration / Gravimetry
12	Sulphates/sulphites (qualitative test)
13	Solubility in water
14	Solubility in solvents (each)
15	Density /Specific gravity (weight per ml)
16	Identification by Chemical
17	Distilling range
18	Assay by chemical
19	Residue on evaporation
20	Assay by aqueous titration
21	Assay by Non Aqueous Titration
22	Uniformity of Content by Chemical
23	Iodine value
24	Saponification value
25	Acid value
26	Peroxide value
27	Volatile oil content
28	Cyanide content
29	Potassium content
30	Sodium content
31	Freezing point
32	Nitrogen determination-Kjeldhal method

33	Reducing sugars (Reducing sugars before hydrolysis) (Based on Method)
34	Aldehydes and reducing substances (Based on Method)
35	Reducing sugars after hydrolysis (Based on Method)
36	Esters
37	Lead
38	Nickel
39	Congeaing temperature
40	Sucrose analysis by Titration (Based on Method)
41	Calcium and Magnesium
42	Fluoride (Based on Method)
43	Ammonium
44	Reducing impurities
45	Dextrins

Section-3c: Instrumental tests

Sr. No	Evaluation parameter
1	Identification by HPLC -UV detector
2	Identification by HPLC -RI detector
3	Identification by GC-FID detector
4	Amino acid analysis by HPLC-UV detector
5	Identification by IR
6	Identification by TLC
7	Identification by UV
8	Optical Rotation by Digital Polari meter (Specific optical rotation)
9	Assay by HPLC -UV detector (for one active)
10	Assay by HPLC -RI detector (for one active)
11	Assay by GC-FID detector with head space (one active)
12	Assay by GC-FID detector without head space (one active)
13	Assay by UV
14	Assay by TLC
15	Dissolution by HPLC, for Single Time Point
16	Dissolution by UPLC, for Single Time Point
17	Dissolution by UV / Chemical, for Single Time Point
18	Preservative content by UPLC
19	Preservative content by HPLC-UV detector
20	Preservative content by HPLC-RI detector

21	Uniformity of content by UPLC
22	Uniformity of Content by HPLC-UV detector
23	Uniformity of Content by HPLC-RI detector
24	Uniformity of Content by UV / Chemical
25	Related substances / Compounds by HPLC UV detector (for one active)
26	Related substances / Compounds by HPLC RI detector (for one active)
27	RS by GC FID Detector with head space
28	RS by GC FID Detector without head space
29	Organic Volatile Impurities (Up to four) by GC-FID detector
30	Potentiometric titration
31	Related substances/TLC
32	Forced Degradation Study as per ICH (5 degradation Pathways)

Section-3d: Microbiological Tests

Sr. No	Evaluation parameter
1	Microbial Limit Tests (TBC, TAC, 4 pathogens)
2	Microbial Limit Test- Per Additional Pathogen
3	Preservative Efficacy Testing (Five Microorganisms with five intervals)
4	MLT Validation (Per Microorganism)
5	MLT Verification(Per Microorganism)
6	Sterility
7	BET
8	Environmental Monitoring Analysis
9	Sterility Validation & Verification
10	BET Validation & Verification
11	Organism Identification (Gram staining -per colony)
12	Organism Identification (Lacto phenol cotton blue staining -per colony)
13	Organism Identification (Acid fast staining -per colony)
14	Water analysis(Raw water, Untreated process water, Treated Process water)
15	Preservative Efficacy Testing per pathogen

Section-3e: Comparative dissolution profiles

Sr. No	Evaluation parameter
1	Development of discriminating dissolution Method by HPLC per media
2	Development of Discriminating Dissolution Method by UV per media
3	CDP (Test & Reference), 4 Time Points up to 4 media, BY HPLC
4	CDP (Test & Reference), 4 Time Points up to four media, BY UV

Section-3f: Method development

S.N	Evaluation parameter
1	Method Development for Assay / UOC by HPLC
2	Method Development for Assay / UOC by UV
3	Method Development for Dissolution by HPLC
4	Method Development for Dissolution by UV
5	Method Development for Related Substances / Compounds by HPLC
	Forced Degradation, by HPLC
6	Method Development for Related Substances / Compounds by HPLC, without Forced Degradation, by HPLC

Section 3g: Method validation, as per ICH

Sr. No	Evaluation parameter
1	Method validation for Assay by HPLC, with Forced Degradation
2	Method validation for Assay by HPLC, without Forced Degradation
3	Method validation for Dissolution / Preservative Content / Content by HPLC
4	Method validation for Assay / Dissolution / Preservative Content / Content by UV
5	Method validation for Related Substances / Compounds by HPLC, with Forced Degradation
6	Method validation for Related Substances / Compounds by HPLC, without
	Forced Degradation
7	Method validation by GC

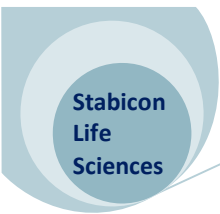
Section-3h: Method development & validation as per ICH

Sr. No	Evaluation parameter
1	Method development & validation for assay by HPLC, with Forced degradation
2	Method development & validation for Assay by HPLC, without forced Degradation
3	Method development & validation for Dissolution / Preservative content / Colorant / UOC by HPLC
4	Method development & validation for assay / dissolution / preservative content / colorant / UOC by UV
5	Method development & validation for Related Substances / compounds by HPLC, with Forced Degradation

Section-3i: Method transfers / verifications

Sr. No	Evaluation parameter
1	Assay by HPLC
2	Assay by UV / Chemical
3	Assay by Microbiology / Antibiotic Assay
4	Dissolution by HPLC, for Single Time Point
5	Dissolution by UV, for Single Time Point
6	Related Substances / Compounds by HPLC

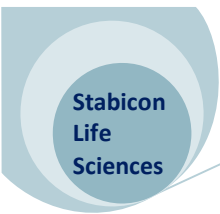




Section-3j: Stability Storage

Sr. No	Evaluation parameter
1	Storage - ICH Conditions, Per Batch Per Pack Per Condition Per Month
2	Storage - Photo stability, Per Batch,
3	Full Chamber (18K Liters, 48 Trays), Per Condition Per Year
4	Full Chamber (18K Liters, 48 Trays), Per Condition Per Month
5	Half Chamber (9K Liters, 24 Trays), Per Condition Per Year
6	Half Chamber (9K Liters, 24 Trays), Per Condition Per Month
7	Quarter Chamber (4.5K Liters, 12 Trays), Per Condition Per Year
8	Quarter Chamber (4.5K Liters, 12 Trays), Per Condition Per Month
9	Full Tray (Dimensions: 90cm X 80cm X 8cm), Per Condition Per Year
10	Full Tray (Dimensions: 90cm X 80cm X 8cm), Per Condition Per Month
11	Storage - Freeze thaw stability, Per Batch,
12	Storage - Sync accelerated stability, Per Batch,
13	Full time equivalent service model and Fixed rate contract service model
14	Retention sample /Backup storage/Disaster management storage
15	Controlled substance & Products evaluation
16	Import License (Per ten products)





Section -4 Business Segment: Setting up dedicated operational center for F & D and Laboratory

We provide concept-to-completion design laboratory and formulation development centre for pharmaceutical industry. Our experts will understand your business, possess experience implementing best practices, and will leverage that expertise to enhance your lab's and R&D efficiency. Whether it's for research or routine testing, our experts can recommend and provide the right solution to address laboratory and development process challenges, helping you drive decisions, maximize resources, and increase productivity. Our operational set up services will ensure regulatory compliance and efficient workflows within a facility. Details of services as follow.

Sr. No	Services
1	Needs assessment
2	Process Improvement
3	Complete Automation of process
4	Plan & setting up operation center
5	Multicenter integration process
6	Training programs
7	Expert Laboratory Personnel Training

We will be pleased to talk to you through voice or email, for better understanding of your requirements.



For any query please contact:

- 👤 Mr. Vaidyanathan, Business Development
- ☎️ +91 7022281068, +918041285405
- ✉️ vaidyanathan.r@stabicon.com; info@stabicon.com

THANK YOU

