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# Stabicon Life Sciences Pvt. Ltd.

## Business Services Portfolio

Business Development Team

**Stabicon 2017**

# Index



# 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 |

| | | | |
|---|---|---|---|
| | Dermal | | Film |
| | | | DMSO drug solution |
| | | | Hydrogel |
| | | | Liposomes |
| | | | 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 | Congealing 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:

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