HAFFKINE BIO-PHARMACEUTICAL CORPORATION LTD.

(Govt. of Maharashtra Undertaking)
Acharya Donde Marg, Parel, Mumbai – 400 012.
Telefax: 022-24147564 Board Line: 022 – 24129320-22 Ext. 232
E-mail: mm@vaccinehaffkine.com

Specification for scope of Services to be offered by Formulation & Development vendor (including method development, validation/verification, MMD, and process validation on one scale-up batch) –

Following operations to be performed & information should be provided by the vendor for the product development services;

A	**DRUG SUBSTANCE**
1	**General Information**
1a	Nomenclature
1b	Structure
1c	General properties
1d	Name and contact details of API and Excipients suppliers
2	**Control of Drug Substance**
2a	Specification
2b	Analytical Procedures
2c	Validation/verification of Analytical Procedures-(Assay only)
2d	Batch Analyses (one batch of API received)
2e	Justification of Specification
3	**Reference Standards or Materials- to be supplied or cost reimburse by** Service Recipient.
4	**DRUG PRODUCT**
5	**DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT**
6	**Pharmaceutical Development (using one batch of API)**
7	**Components of the Drug Product**
7a	Drug Substance
7b	Excipients
8	**Drug Product**

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8a	Formulation Development
8b	Overages
8c	Physicochemical and Biological Properties
9	**Manufacturing Process Development**
10	**Container Closure System**
11	**Microbiological Attributes**
12	**Compatibility (API-Excipients compatibility study -30days)at** 25C/60%RH, open and close container 40C/75%RH, open and close container 50C, open and close container; Following studies are performed; Appearance, milard reaction, IR, pH, LOD, assay.
13	**Manufacture**
13a	Batch Formula
13b	Description of Manufacturing Process and Process Controls
13c	Controls of Critical Steps and Intermediates
13d	Process Validation and/or Evaluation- will be performed using one scale up production batch at client's site.
14	**Control of Excipients**
14a	Specifications
14b	Analytical Procedures
14c	Justification of Specifications
14d	Excipients of Human or Animal Origin
14e	Novel Excipients
15	**Control of Drug Product**
15a	Specification(s)
15b	Analytical Procedures- Vendor will develop the method for assay and dissolution tests.

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15c	Validation of Analytical Procedures- Vendor will validate/verify assay and dissolution method of finished product.
15d	Batch Analyses- Vendor will provide two R and D scale (3-4kg) batch data and one production scale up batch data.
15e	Characterization of Impurities- to be tested only as per monograph.
15f	Justification of Specification(S)
16	Reference Standards or Materials- List of reference std to be provided. Actual std to be supplied or cost reimburse by Service Recipient.
17	Container Closure System
18	Stability (will be performed for 6months at real time and accelerated conditions on 2 batches of F&D scale i.e. 3kg -4kg and one batch of production scale.
18a	Stability Summary and Conclusions
18b	Stability Data
18c	Ref listed products- to be supplied by Service Recipient or cost to be reimbursed. If RLD is not used/available, Service Recipient to supply Name and other details of alternative products to be used.
18d	Comparative dissolution study (MMD) using RLD.
19	Vendor is required to submit the draft index of the CTD that will be prepared by the vendor for submission to HBPCL.
20	The vendor shall provide document support in such a way that HBPCL will get FDA approval for commencing the production of the concerned product
21	The vendor should include the costing of the services in two parts; One for Indian market & other for International market (WHO / UNISEF/ COPP/ ROW)
22	The products shall be developed on Fluid Bed processor for wet granulation & on Roll compactor for dry granulation
23	Vendor to identify the products to be manufactured on FBP and / or Roll compactor