



CYCLOLAB
Cyclodextrin Research & Development Laboratory Ltd.
Mail address: Budapest, P.O.Box 435, H-1525 Hungary
Location: Illatos út 7., Budapest, H-1097 Hungary
TEL: (361) 347-60-60 or -70, FAX: (361) 347-60-68
E-mail: cyclolab@cyclolab.hu
Homepage: www.cyclolab.hu
VAT No.: HU 10678970



Questionnaire for compilation of a working program at CycloLab Ltd

As a future partner of CycloLab Cyclodextrin Research and Development Laboratory Ltd we kindly ask you to complete the following questionnaire so that our colleagues can provide you with a custom, comprehensive and well defined working program proposal of our services. This document will also serve as a guide that enables you to follow the quotations offered for each particular step of the study.

Name:

Company:

Position:

E-mail:

Phone:

Short description of the subject and purpose:

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Description of activity	Include in the proposal? (Y/N)		Quotation (EUR)
General Items			
Project Management	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Compilation of specification or monograph	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Consultancy (regular teleconference, written discussions)	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Regular informal status report	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Regular official status report	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Compilation of literature data, investigation of IP environment	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Compilation of patent	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Other:	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
GMP production			
GMP production (single or multiple batches)	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Compilation of corresponding documentation	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Accelerated stability study	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Long-term stability study	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Regulatory document filing or compilation of equivalent documentation	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Associated reports	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
The sponsor provides the following materials for the study:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Other:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Scale-up and process validation			
Scale-up to batch size of:	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Associated analysis	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Feasibility (engineering) batch	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	



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Associated analysis	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Manufacture of three validation batches	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Associated analysis	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Terminal sterilization cycle validation	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Media fill validation (extractable volume)	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Associated reports	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
The sponsor provides the following materials for the study:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Analytical development and validation			
Setting IPC controls and validation	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Investigation of the suitability of pharmacopeial methods for analysis	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Method development and/or testing for:			
Appearance/discoloration, Clarity of solution	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
pH, Conductivity, Water content	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Residual solvents	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Assay	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Stability indicating method	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Identification of main degradation products	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Specified impurities:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Unspecified impurities	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Formulation specific analytical tests	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Bioburden:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Endotoxin content	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Other:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Method transfer needed for the following methods:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
.....			
Cross-validation of the following methods:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
.....			
Comprehensive method validation needed for the following methods:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
.....			



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Packaging interaction study	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Stability test			
ICH conform	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Temperature (Humidity):.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Duration:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Associated reports	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
The sponsor provides the following materials for the study:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	
Other:.....	Y: <input type="checkbox"/>	N: <input type="checkbox"/>	

Your cooperation in completing this form is highly appreciated. One of our colleagues will revert you shortly in case further questions arise and will send the individual working program proposal established based on your requests.

We are looking forward to a productive cooperation with you in this field.

Please forward this form to info@cyclolab.hu.