

Questionnaire

for product development / licensing / manufacturing offer



In order to estimate time and costs for the activities of interest, please fill in the right column of the table below. It is not mandatory to complete every line, but the more information is given, the better we can calculate the necessary work load.

Item	Example	Demand
Dosage form of interest	Edible film/ patch	
Active drug substance	Nicotine	
Indication	Smoking cessation	
Reference product / dosage form	Nicotinelle® patch Nicotinelle Chewing gum	
Standard doses (dosage form)	7mg/24hrs; 14mg/24hrs; 21mg/24hrs (patch)	
Target dose for development	14mg/24hrs	
Application interval	1 pc. every 24hrs	
Maximum size	20 cm ²	
Printing on product required	No	
Minimum acceptable shelf life	24 months	
Drug product / medical product / food supplement / etc.	Drug product	
Rx / OTC / Consumer product	OTC	
Territory of interest (or individual countries)	Europe	
Desired time to market	3 years	
Registration strategy, e.g. NDA (originator), ANDA (generic)	Generic (bioequivalent to Nicotinell®)	
Workscope (full program or only individual parts)	Formulation & Analytical method development, Scale-up, Manufacture of clinical trial supplies, ICH stability testing, Validation, Prep.of CMC part of registration dossier, etc.	
Manufacturing site (tech transfer to own facility or toll manufacturing in Karlsruhe)	Toll manufacturing in Karlsruhe	
Estimated sales volume per year (yrs. 1-3)	1 st year: 0.8 Mio. patches 2 nd year: 2.1 Mio. patches 3 rd year: 2.5 Mio. patches	

Date and Company Name: