QUESTIONNAIRE

I. COMPANY PROFILE

Company name |

Contact person, position |

Address |

Telephone | Fax |

E-mail | Web-site |

II. PROJECT DESCRIPTION

- ☐ Development of unregistered drug
- ☐ Development of unregistered drug and preparation of registration dossier
- ☐ Technical transfer of the registered drug and adding Grotex manufacturing site to the registration certificate
- ☐ Technical transfer of the unregistered drug and adding Grotex manufacturing site to the registration certificate
- ☐ Other

III. PRODUCT DESCRIPTION

APIs |

Formulation |
- ☐ IV
- ☐ Ophthalmic solution
- ☐ Solution for inhalation
- ☐ Other
- ☐ Injection
- ☐ Nasal drops
- ☐ Nasal spray

Microbiology requirements |
- ☐ Sterile
- ☐ Non-sterile

Preservative content |
- ☐ Yes
- ☐ No

Dosage forms |

- ☐ Glass snap-on vials with dosing dropper pump
- ☐ Glass IV bottles
- ☐ Glass injection vials
- ☐ Glass snap-on vials with dosing spray pump
- ☐ Glass pre-filled syringes
- ☐ Glass ampoules
- ☐ Aluminium BOV aerosols
- ☐ PE snap-on vials with dosing dropper pump
- ☐ PE droppers/Multidoses
- ☐ PE snap-on vials with spray pumps
- ☐ PP IV bottles/Polyflac
- ☐ PE luer-vent ampoules/Polytwist
- ☐ PE unidoses
- ☐ Other

Filling volume (ml) |

Primary packages per carton |

Sterilization method |

Please indicate filter material in case of sterilizing filtration |

Special manufacturing requirements |

heating or cooling of the solution during preparation, bubbling, need of noble gas feeding, need 2 or more tanks

Packaging |

- ☐ Labeling
- ☐ Pouche
- ☐ Leaflet
- ☐ Pallet
- ☐ Blister
- ☐ Carton
- ☐ Box

Storage temperature |

Trial batches size |

Scheduled date for trial batches |

Commercial batches size: |

1st year

2nd year

3rd year

Scheduled date for commercial manufacturing |

Shipment place | ☐ Grotex warehouse ☐ Other

Target markets |

Brand name of the product |

IV. IN SCOPE/OUT OF SCOPE FOR THE PROJECT

Products

	CUSTOMER	GROTEX	NOTE
APIs |	☐	☐	
Excipients |	☐	☐	
Standards, reagents and etc |	☐	☐	
Primary packaging |	☐	☐	
Secondary packaging |	☐	☐	
Analytical or technological equipment (if needed) |	☐	☐	

Will be Customer visits at Grotex premises considered during the project? | ☐ Yes ☐ No

Documents

	CUSTOMER	GROTEX	NOTE
Trial batches |	☐	☐	
Normative Document for Finished Product |	☐	☐	
Justification of specification for Finished Product |	☐	☐	
Finished Product development reporting |	☐	☐	
Normative Document for API |	☐	☐	
DMF for API |	☐	☐	
Normative Document for primary packaging |	☐	☐	
Manufacturing technology with indication of checkpoints and description of stages and control methods at each production stage |	☐	☐	
Material balance for Finished Product |	☐	☐	
Validation of analytical methods for Finished Product |	☐	☐	
Validation of analytical methods for excipients |	☐	☐	
Validation of manufacturing processes |	☐	☐	
Incoming control results for APIs and excipients |	☐	☐	
Incoming control results for primary packaging |	☐	☐	
Short-term stability test |	☐	☐	
Long-term stability test |	☐	☐	
Photostability |	☐	☐	
Leaflet development |	☐	☐	
Artworks of secondary packaging |	☐	☐	

CONTACTS

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