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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | |  | | | | | |
| Active Substance(s): ……………………………. | | | |  | | | | | |
| ATC Code: ……………………………….. | | | |  | | | | | |
| Proposed Product Name | | Pharmaceutical Form(s) | | | | | | Strength(s) | |
|  | |  | | | | | |  | |
|  | |  | | | | | |  | |
|  | |  | | | | | |  | |
| Legal basis of application: | | | | | | | | | |
| Art.10b | Art.10(1)  Art.10c | | Art.10(3)  Extension | | | | Art. 10c | | Art.10a |
| This is a duplicate of an ongoing or finalised procedure … | | | | | |  | | | |
| Indicate the Marketing Authorisation number of the original dossier: …. | | | | | |  | | | |
| Indicate the number of duplicates: ………………………… | | | | | |  | | | |
| **For generics only**  ***Reference medicinal product authorised for not less than 6/8/10 years in the EEA*** | | | | | | | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | | |  | | | |
| First authorisation date (yyyy-mm-dd): ……………...……... | | | | | |  | | | |
| Member State (EEA)/Union: ……..………………………..... | | | | | |  | | | |
| ***Reference medicinal product proposed for Malta*** | | | | | |  | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | | |  | | | |
| For bioequivalence study, name and address of the site: | | | | | |  | | | |
| The new product will be marketed in Malta: | | | | | | Yes No | | | |
| Name(s) and address(es) of the manufacturer(s) of active substance: …………………………………………………….. | | | | | |  | | | |
| Has a Ph.Eur. Certificate of suitability (CEP) been issued for the active substance and/or will an Active Substance Master File (ASMF) be used? | | | | | | CEP ASMF  N/A | | | |
| Applicant´s preferred submission date: ……………………. | | | | | |  | | | |
| Other information *(e.g. scientific advice received)*: | | | | | |  | | | |
| I herewith declare that product applied for is not authorised in any other Member State of the EU/EEA | | | | | | | | | |
| Applicant: ……………………………………………………. | | | | |  | | | | |
| Authorised contact person: ………………………………… | | | | |  | | | | |
| Address: ……………………………………………………… | | | | |  | | | | |
| Phone: ……………………………………………………….. | | | | |  | | | | |
| E-mail address: ……………………………………………… | | | | |  | | | | |
| Date: …………..……………………………………………… | | | | |  | | | | |