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| **Application for new Manufacturer’s “Specials” Licence (MS)**  **(Human Use)** | | | |
| **Section 1 Company information** | | | |
| *Registered Company Name:* | | | |
|  | | | |
| *Address:* | | | |
|  | | | |
| *Company contact person :* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| Trading Style: |  | | |

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| **Communications and/or invoicing address (if different)** |
|  |

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| --- | --- | --- | --- |
| **In case of person applying on behalf of the proposed registration holder** | | | |
| *Name of the contact:* | | | |
| ***Contact details:*** | | | |
| Telephone/Mobile: |  | E-mail: |  |

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| --- | --- | --- | --- |
| **Application Date** |  | **Purchase Order Number** |  |

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| **Checklist** | |
|  | Section 1 - completed once per application. |
|  | Section 2 & 3 - one copy for each named manufacturing/importation site. |
|  | Section 4 - one copy for each person to be named on the site signed and dated. |
|  | Section 5 - one copy covers three named Storage and Handling sites. |
|  | Section 6 - one copy for each named Contract Laboratory site. |
|  | Section 7 - completed once per application, signed and dated. |

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| **Supporting Documentation** | |
|  | Certificate of incorporation issued by Companies House (or similar). |
|  | Curriculum Vitae information either completed or provided for any nominated person, Qualified Person, Quality Controller or Production Manager. |
|  | Nominated Qualified Person has provided a certificate from a professional Institute. |
|  | Signed Technical Agreements (where applicable) are available. |
|  | Site Master Files are attached or available. |

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| **Do you have a pending/approved Wholesale Distribution Authorisation or other Manufacturing Authorisation** | | |
| Pending | Approved | N/A |

|  |
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| **For advice or assistance please email:** [**pcl@mhra.gov.uk**](mailto:pcl@mhra.gov.uk) **and please read the following useful information before you apply:**  [**https://mhrainspectorate.blog.gov.uk/2017/01/05/helping-us-to-help-you/**](https://mhrainspectorate.blog.gov.uk/2017/01/05/helping-us-to-help-you/) |

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| **Application for new Manufacturer’s “Specials” Licence (MS)**  **(Human Use)** |

|  |  |
| --- | --- |
| **Section 2 Site Information** | |
| *Site Name:* | |
| *Address:* | |
|  | |
| *DUNS Number:* | **-                   -** |

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|  | **Site Contact Person** | | | |
| Name of the contact: | | | | |
| Telephone/Mobile: | |  | E-mail: |  |

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| **Site Activities** |

|  |  |  |  |  |  |  |  |
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| Are the products for administration to human beings? | **Yes** |  | | | **No** | |  |
|  | | | | | | | |
| Animal Human Origin products are present at this site? | **Yes** | |  | **No** | |  | |

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| **Site Types** |

|  |  |
| --- | --- |
| Manufacture |  |
| Decentralised Manufacture (Point of Care / Modular) |  |
| Import |  |
| Batch Certification (**Not MS Licences)** |  |
| Assembly and Packaging |  |
| Export |  |
| QC Testing |  |
| Biological |  |
| Storage and Handling (picking of goods) |  |
| Other (Please specify) |  |
|  | |

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| 1. **Manufacturing Operations – Medicinal Products** |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.1** | **Sterile products** | | |
| **1.1.1** | **Aseptically prepared**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 1.1.1.1 | Large volume liquids |  |  |
| 1.1.1.2 | Lyophilisates |  |  |
| 1.1.1.3 | Semi-solids |  |  |
| 1.1.1.4 | Small volume liquids |  |  |
| 1.1.1.5 | Solids and implants |  |  |
| 1.1.1.6 | Other aseptically prepared products: (Please specify) |  |  |
|  | | |  |
| **1.1.2** | **Terminally sterilised**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 1.1.2.1 | Large volume liquids |  |  |
| 1.1.2.2 | Semi-solids |  |  |
| 1.1.2.3 | Small volume liquids |  |  |
| 1.1.2.4 | Solids and implants |  |  |
| 1.1.2.5 | Other terminally sterilised prepared products: (Please specify) |  |  |
|  | | |  |

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| --- | --- | --- | --- |
| **1.2** | **Non-sterile products** | | |
| **1.2.1** | **Non-sterile products**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 1.2.1.1 | Capsules, hard shell |  |  |
| 1.2.1.2 | Capsules, soft shell |  |  |
| 1.2.1.3 | Chewing gums |  |  |
| 1.2.1.4 | Impregnated matrices |  |  |
| 1.2.1.5 | Liquids for external use |  |  |
| 1.2.1.6 | Liquids for internal use |  |  |
| 1.2.1.7 | Medicinal gases |  |  |
| 1.2.1.8 | Other solid dosage forms |  |  |
| 1.2.1.9 | Pressurised preparations |  |  |
| 1.2.1.10 | Radionuclide generators |  |  |
| 1.2.1.11 | Semi-solids |  |  |
| 1.2.1.12 | Suppositories |  |  |
| 1.2.1.13 | Tablets |  |  |
| 1.2.1.14 | Transdermal patches |  |  |
| 1.2.1.15 | Intraruminal devices (veterinary only) |  |  |
| 1.2.1.16 | Veterinary premixes (veterinary only) |  |  |
| 1.2.1.17 | Other non-sterile medicinal product (Please specify) |  |  |
|  | | | |

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| 1. **Manufacturing Operations – Medicinal Products** |

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| **1.3** | **Biological medicinal products** | | |
| **1.3.1** | **Biological medicinal products - Manufacture** | | **Special**  **Requirement** |
| 1.3.1.1 | Blood products |  |  |
| 1.3.1.2 | Immunological products |  |  |
| 1.3.1.3 | Cell therapy products |  |  |
| 1.3.1.4 | Gene therapy products |  |  |
| 1.3.1.5 | Biotechnology products |  |  |
| 1.3.1.6 | Human or animal extracted products |  |  |
| 1.3.1.7 | Tissue Engineered products |  |  |
| 1.3.1.8 | Other biological medicinal products (Please specify) |  |  |
|  | | | | |

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| **1.4** | **Other products or processing activity** | | | |
| **1.4.1** | **Manufacture of:** | | **Special**  **Requirement** |
| 1.4.1.1 | Herbal products |  |  |
| 1.4.1.2 | Homeopathic products |  |  |
| 1.4.1.3 | Other (Please specify) |  |  |
|  | | | | |

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| --- | --- | --- | --- |
| **1.4.2** | **Sterilisation of active substances/excipients/finished products** | | **Special**  **Requirement** |
| 1.4.2.1 | Filtration |  |  |
| 1.4.2.2 | Dry Heat |  |  |
| 1.4.2.3 | Moist heat |  |  |
| 1.4.2.4 | Chemical |  |  |
| 1.4.2.5 | Gamma Irradiation |  |  |
| 1.4.2.6 | Electron beam |  |  |
| 1.4.2.7 | Other (Please specify) |  |  |
|  | | | | |

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| 1. **Manufacturing Operations – Medicinal Products** |

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| **1.5** | | **Packaging** | |
| **1.5.1** | | **Primary Packing** | |
| 1.5.1.1 | | Capsules, hard shell |  |
| 1.5.1.2 | | Capsules, soft shell |  |
| 1.5.1.3 | | Chewing gums |  |
| 1.5.1.4 | | Impregnated matrices |  |
| 1.5.1.5 | | Liquids for external use |  |
| 1.5.1.6 | | Liquids for internal use |  |
| 1.5.1.7 | | Medicinal gases |  |
| 1.5.1.8 | | Other solid dosage forms |  |
| 1.5.1.9 | | Pressurised preparations |  |
| 1.5.1.10 | | Radionuclide generators |  |
| 1.5.1.11 | | Semi-solids |  |
| 1.5.1.12 | | Suppositories |  |
| 1.5.1.13 | | Tablets |  |
| 1.5.1.14 | | Transdermal patches |  |
| 1.5.1.15 | | Intraruminal devices (veterinary only) |  |
| 1.5.1.16 | | Veterinary premixes (veterinary only) |  |
| 1.5.1.17 | | Other non-sterile medicinal products (please specify) |  |
|  | | | |
| **1.5.2** | **Secondary Packing** | |  |

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| --- | --- | --- |
| **1.6** | **Quality Control Testing - Manufacture** | |
| 1.6.1 | Finished product testing. Microbiological: sterility |  |
| 1.6.2 | Finished product testing. Microbiological: non-sterility |  |
| 1.6.3 | Finished product testing. Chemical/Physical |  |
| 1.6.4 | Finished product testing. Biological |  |
| 1.6.5 | Stability Testing on finished marketed medicinal products |  |
| 1.6.6 | Environmental monitoring or process simulation (media fill) to support  sterile manufacture |  |

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| **N**  ***NOTE: All other testing, including raw materials testing, does not require a laboratory to be***  ***named on a licence or hold a GMP certificate.* ting, including raw materials testing, does not require a laboratory to be named on a licence or hold a GMP certificate** |

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| **2. Importation of medicinal products** |

|  |  |  |
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| **Products to be imported** | | |
| **Are unlicensed medicinal products imported from outside of the EEA**  **at this site?** | **Yes** |  |

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| **Section 3 Site Information – Operations with Special Requirements** |

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| **If you have selected any special requirements in Section 2, please check the appropriate category on the table below. If the Other category applies, provide the required text.** |

|  |  |
| --- | --- |
| **Products with Special requirements** | |
| **1.** | B Lactam Antibiotics |
| **2.** | Other highly sensitising antibiotics |
| **3.** | Live Cells |
| **4.** | Pathogenic Organisms (Biosafety Level 3 or 4) |
| **5.** | Radiopharmaceuticals |
| **6.** | Ectoparasiticides |
| **7.** | Point of Care Manufacturing |
| **8.** | Modular Manufacturing |
| **9.** | Other <Please specify> |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.1.1.1 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.2 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.3 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.4 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.5 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.6 |  |  |  |  |  |  |  |  |  | |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.1.2.1 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.2 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.3 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.4 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.5 |  |  |  |  |  |  |  |  |  | |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.2.1.1 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.2 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.3 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.4 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.5 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.6 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.7 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.8 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.9 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.10 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.11 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.12 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.13 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.14 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.15 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.16 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.17 |  |  |  |  |  |  |  |  | |  |  |

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| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 1.3.1.1 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.2 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.3 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.4 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.5 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.6 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.8 |  |  |  |  |  |  |  |  |  |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 1.4.1.1 |  |  |  |  |  |  |  |  |  |  |
| 1.4.1.2 |  |  |  |  |  |  |  |  |  |  |
| 1.4.1.3 |  |  |  |  |  |  |  |  |  |  |

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| **Section 3 Site Activities – Other Information** |

|  |  |
| --- | --- |
| **Letting and/or Accepting Contracts** | |
| Applicant intends to be contract acceptor (i.e. carries out testing partially/wholly for others) |  |
| Applicant intends to be contract acceptor (i.e. manufactures partially/wholly for others) |  |
| Applicant intends to be contract giver (i.e. uses external manufacturers for some products) |  |
| Applicant intends to be contract giver (i.e. uses external Test houses for some/all testing) |  |

|  |  |
| --- | --- |
| **Other specific processes/activities** | |
| Manufacture and assembly for export |  |
| Assembly for export |  |
| Airline Kits |  |
| Bulk or partial manufacturing |  |
| Narcotic or psychotropic products (Controlled Substances) |  |

|  |  |
| --- | --- |
| **Other Information** | |
| Storage and Handling |  |
| Distribution |  |
| Is this site involved in microbiological testing of finished products and/or raw materials? |  |
| If none of the above. **(Must be Specified)** |  |
|  | |
| Stability Testing |  |
| Is this site involved in doing finished product testing? |  |
| Do you handle products which require refrigeration or low temperature storage? |  |
| Do you import intermediate products for further processing? |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Further Information for the Inspectorate** | | | | |
| Is this site ready for inspection? | **Yes** |  | **No** |  |
| Are you conversant with the Rules and Guidance for Pharmaceutical  Manufacturers and Distributors? | **Yes** |  | **No** |  |
| Do you have available the relevant records and procedures? | **Yes** |  | **No** |  |
| Are signed technical agreements available for inspection? | **Yes** |  | **No** |  |

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| **Site Master File** | | | | |
| Have you submitted a SMF on CD or hard copy with your application? | **Yes** |  | **No** |  |
| If no, will a Site Master File be available on site during inspection? | **Yes** |  | **No** |  |
| **Details of facilities and equipment on site must be included in your Site Master file.** | | | | |

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| **Decentralised Manufacture (DM) Requirements** | | | | | |
| DM1 | Confirm the site listed in this application (via Site information in Section 2, on Page 2) is the DM control site. | **Yes** |  | **N/A** |  |
| DM2 | Is this site ready for inspection, with all applicable DM specific aspects of the quality systems in place? | **Yes** |  | **No** |  |
| DM3 | If yes to DM1.: Have you submitted a Decentralised Manufacturing Master File (for an initial product) with your application?  **(CD ROM / electronic or Hard copy)**  **NOTE:** If not provided, it is not possible to progress a DM application | **Yes** |  | | |
| DM4 | If yes to DM1.: Please state the MHRA confirmed Designation Number of your initial DM product |  | | | |

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| **Section 4 Site Personnel** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** |  | **Postcode** |  |

|  |
| --- |
| **Personnel nominated to work at this site:** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name** | | **MHRA**  **Number\*** | **Add** | **QC** | **PM** | **SC** |
|  | |  |  |  |  |  |
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**\*If available**

***NOTE: One set of the following two pages should be provided per nominated person***

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** |  | **Postcode** |  |

|  |
| --- |
| **Site Personnel** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Nominated Person** | | | |
| Name: | | | |
| Telephone/Mobile: |  | E-mail: |  |
| *Business Address:* | | | |
|  | | | |

|  |  |
| --- | --- |
| **Person number, if already named on a MHRA licence/authorisation** |  |

|  |
| --- |
| **Person nominated to be named as:** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Production Manager** |  | **Quality Controller** |  | **Site Contact** |  | |  |  |  | |
| **Quality Controller** | | | |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the  relevant sections of this form have been completed.  Note: the Named QC should be a permanent employee |  |

|  |
| --- |
| **Production Manager** |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the  relevant sections of this form have been completed. |  |

|  |
| --- |
| **Curriculum Vitae – Only required if a CV is not attached to the application** |

|  |
| --- |
| **Qualifications (relevant to this licence)** |
|  |

|  |
| --- |
| **Experience (brief details of employment and responsibilities relevant to this licence)** |
|  |

|  |
| --- |
| **Name and function of the person(s) to whom he/she reports** |
|  |

|  |
| --- |
| **Area of responsibility** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Declaration by nominated person** | | | |
| I confirm that the above particulars are accurate and true to the best of my knowledge and belief.  I agree to be nominated as indicated. | | | |
| **Signed**  **(Nominated Person)** |  | **Date** |  |
| **Print Name** |  | | |
| **Signed (Applicant)** |  | **Date** |  |
| **Print Name** |  | | |

|  |
| --- |
| **Section 5 Storage and Handling site(s)** |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

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| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 6 Contract laboratory Site Information** | | | |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Company contact:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| The licence/authorisation holder has assessed the laboratory as fit for purpose. |  |

|  |  |
| --- | --- |
| **Quality Control Testing carried out by the site.** | |
| Finished product testing. Microbiological: Sterility |  |
| Finished product testing. Microbiological: Non-Sterility |  |
| Finished product testing. Chemical/Physical analysis of finished products |  |
| Finished product testing. Biological testing of finished products |  |
| Stability Testing on finished marketed medicinal products |  |
| Environmental monitoring or process simulation (media fill) to support sterile manufacture |  |

|  |
| --- |
| **N**  ***NOTE: All other testing, including raw materials testing, does not require a laboratory to be***  ***named on a licence or hold a GMP certificate.* sting, including raw materials testing, does not require a laboratory to be named on a licence or hold a GMP certificate** |

|  |  |
| --- | --- |
| **Letting and/or accepting contracts.** | |
| Applicant intends to be a contract acceptor (i.e. carries out testing partially/wholly for others). |  |
| Applicant intends to be a contract giver (i.e. uses external test houses for some/all testing). |  |

|  |  |
| --- | --- |
| **Section 7B: To be completed by the nominated Contract Laboratory** | |
| I confirm there is a written contract/technical agreement in place. |  |

|  |  |  |  |
| --- | --- | --- | --- |
| I hereby confirm the contract laboratory are aware they have been named and may be subject to inspection by the MHRA, a written contract/technical agreement is in place and the contract laboratory is in agreement and aware of what is expected of them.  To the best of my knowledge and belief the particulars I have provided in are correct, truthful and complete. | | | |
| **Signed** |  | **Date** |  |
| **Print Name** |  | **Job Title** |  |
| **Company** |  | | |

|  |
| --- |
| **Section 7 Declaration** |

|  |  |  |  |
| --- | --- | --- | --- |
| I/We apply for the grant of a Manufacturer’s “Specials” Licence (MS) to the proposed holder named in this application form in respect of the activities to which the application refers.  To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete.  The applicant undertakes to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the licence. | | | |
| **Signed** |  | **Date** |  |
| **Print Name** |  | **Job Title** |  |

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