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| **Raw Material Manufacturer Vendor Qualification Questionnaire** |

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| **Introduction** |
| Consumer Healthcare Products Australia (CHP Australia) and Complementary Medicines Australia (CMA) have jointly developed this questionnaire in consultation with member companies.This questionnaire is intended for manufacturers of active and excipient raw materials. It is site specific and has been designed to simplify and streamline the collection of information in relation to vendor qualification activities.This questionnaire should be updated when any information changes or every three years.Your assistance in completing this questionnaire will enable vendor qualification activities to be undertaken in compliance with current Australian regulatory requirements and help maintain the quality and safety of medicines produced and supplied in Australia. |
|  |
| **1** | **Company and Contact Details** |
| 1.1 | Company Name: |       |
|  | This document was completed by: |
|  | Signature: |  |
|  | Name: |       |
|  | Title: |       |
|  | Date: |       |
|  |  |
| 1.2 | Manufacturing site address and contact details: |
|  | Address: |       |
|  | Primary contact: |
|  | Name: |       |
|  | Title: |       |
|  | Phone: |       |
|  | Facsimile: |       |
|  | E-mail: |       |
|  | Website: |       |
|  |  |
| 1.3 | Contact details for quality and manufacturing: |
|  | Head of quality: |
|  | Name: |       |
|  | Title: |       |
|  | Qualifications: |       |
|  | Experience: |       |
|  |  |
|  | Head of manufacturing: |
|  | Name: |       |
|  | Title: |       |
|  | Qualifications: |       |
|  | Experience: |       |
|  |  |  |
| 2 | Organisation Structure, Personnel and Training |
| 2.1 | Do you have an organisational chart? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the organisational chart. |
|  |  |
| 2.2 | Do you have position descriptions? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the position descriptions for the head of quality and manufacturing. |
|  |  |
| 2.3 | Is the quality department independent of manufacturing? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.4 | Please confirm the approximate number of employees in each of the following areas? |
|  | Warehousing: |       |
|  | Manufacturing: |       |
|  | Quality: |       |
|  | Research and development: |       |
|  | Engineering/maintenance: |       |
|  |  |
| 2.5 | Do you have specific health requirements for employees and contractors? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain the specific health requirements for employees and contractors.  |
|  |       |
|  |  |
| 2.6 | Do you have specific dress regulations for employees and contractors? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain the specific dress regulations for employees and contractors. |
|  |       |
|  |  |
| 2.7 | Do you have procedures for training? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.8 | Do you clearly identify the training requirements for employees and contractors? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.9 | Do you provide good manufacturing practice (GMP), cleanliness and quality awareness training for employees and contractors? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.10 | How is training conducted and how often? |
|  |       |
|  |  |
| 2.11 | Do you verify training of employees and contractors by testing? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 2.12 | Do you maintain training records for employees and contractors? |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **3** | **Capabilities and Licensing** |
| 3.1 | What types of products do you manufacture at the site? |
|  | [ ]  Active pharmaceutical ingredients | [ ]  Pharmaceutical excipients | [ ] Herbal raw materials | [ ]  Nutritional raw materials |
|  | [ ]  Cosmetic raw materials | [ ]  Industrial raw materials | [ ]  Sterile products | [ ]  Finished products (liquids/creams) |
|  | [ ]  Finished products (solid) | [ ]  Foods | [ ]  Controlled substances | [ ]  Veterinary products |
|  | [ ]  Products with high illicit value | [ ]  Agricultural raw material | [ ]  Other |  |
|  | Please provide details of other products you manufacture at the site. |
|  |       |
|  |  |
| 3.2 | Do you manufacture any of the following classes of products at the site? |
|  | [ ]  Antiobiotics | [ ]  Betalactams | [ ]  Cephalosporins | [ ]  Pesticides |
|  | [ ]  Cytotoxics | [ ]  Genotoxics | [ ]  Hormones | [ ]  Herbicides |
|  | [ ]  Vaccines | [ ]  Steroids | [ ]  Infectious agents | [ ]  Fungicides |
|  |  |
| 3.3 | Is the site licensed/certified by any of the following authorities? If yes, please provide a copy of any current licence/certification. |
|  | **Authority** | **Licence or Certification Number** | **Scope of Licence or Certification** | **Date of Last Inspection** |
|  | [ ]  Therapeutic Goods Administration (TGA) |       |       |       |
|  | [ ]  Food & Drug Administration (FDA) |       |       |       |
|  | [ ]  Medicines and Healthcare Products Regulatory Agency (MHRA) |       |       |       |
|  | [ ]  European Union (EU) |       |       |       |
|  | [ ]  International Standards Organisation (ISO) |       |       |       |
|  | [ ]  Environmental Protection Agency (EPA) |       |       |       |
|  | [ ]  Other |       |       |       |
|  | Please provide details of other licences/certifications. |
|  |       |
|  |  |
| 3.4 | Do you comply with ICH Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients? |
|  | [ ]  Yes | [ ]  No |
|  | If no, do you comply with any other code of practice for manufacturers of active pharmaceutical ingredients? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of any other code of practice for manufacturers of active pharmaceutical ingredients complied with, and a copy of any certificate of compliance. |
|  |       |
|  |  |
| 3.5 | Do you sub-contract any part of the manufacturing process or testing of the starting materials or raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the manufacturing process or testing that is sub-contracted and provide a copy of any current licence/certification. |
|  | **Step in Manufacture** | **Company Name** | **Authority** | **Licence or Certification Number** | **Scope of Licence or Certification** | **Date of Last Inspection** |
|  |       |       |       |       |       |       |
|  |       |       |       |       |       |       |
|  |       |       |       |       |       |       |
|  |  |
| 3.6 | If you sub-contract any part of the manufacture of the raw material, how is the raw material transported between sites?  |
|  |       |
|  |  |
| 3.7  | Are you willing to undergo an audit or inspection? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 3.8 | Have you been audited by any other companies? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are you prepared to disclose the companies? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the companies and the dates of the last audits. |
|  | **Company Name** | **Date of last Inspection** |
|  |       |       |
|  |       |       |
|  |       |       |
|  |  |
| 3.9 | Do you have general and product liability insurance? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a summary of the insurance held, including the level of coverage. |
|  |       |
|  |  |
| **4** | **Buildings and Facilities**  |
| 4.1 | Do you have a Site Master File? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the Site Master File. |
|  | If no, can you provide a copy of the site and facility plan? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the site and facility plan. |
|  |  |
| 4.2 | How long have you been located at this site? |
|  |       |
|  |  |
| 4.3 | What is the approximate size of the site in square metres?  |
|  |       |
|  |  |
| 4.4 | How is access to the site controlled? |
|  |       |
|  |  |
| 4.5 | What is the approximate size of the facility in square metres?  |
|  |       |
|  |  |
| 4.6 | What is the approximate age of the facility, and when were the last upgrades? |
|  |       |
|  |  |
| 4.7  | What type of development surrounds the site?  |
|  | [ ]  Heavy industrial | [ ]  Light industrial | [ ]  Rural | [ ]  Residential |
|  |  |
| 4.8 | Do you have an air handling system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a diagram of the air handling system and confirm the operational parameters including temperature, humidity, air change rates and filter specifications. |
|  |       |
|  |  |
| 4.9 | Do you control temperature? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.10 | Do you monitor temperature? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for monitoring temperature, and explain how monitoring is performed and reviewed. |
|  |       |
|  |  |
| 4.11 | Do you control relative humidity? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.12 | Do you monitor relative humidity? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for monitoring relative humidity, and explain how monitoring is performed and reviewed. |
|  |       |
|  |  |
| 4.13 | Do you use refrigerated storage? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, do you monitor temperature? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for monitoring temperature, and explain how monitoring is performed and reviewed. |
|  |       |
|  | If yes, do you have an alarmed monitoring system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how the alarmed monitoring system operates. |
|  |       |
|  |  |
| 4.14 | Do you use water at any step of the manufacturing process? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the quality specification and confirm where it is sourced from.  |
|  |       |
|  |  |
| 4.15  | Do you have a water purification system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the sanitation procedures, a diagram of the water purification system, and confirm the operational parameters including capacity, flow rate, temperature and filter specifications. |
|  |       |
|  |  |
| 4.16  | Are drains and wastes designed with adequate air breaks to prevent back flushing or siphoning of waste? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.17 | Are pipes and services clearly labelled? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.18 | Do you control raw material status?  |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 4.19 | Do you have clearly designated approved, quarantined and rejected areas? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.20 | Do you receive deliveries from bulk tankers? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, do you have procedures and secured couplings to minimise the risk of incorrect coupling and unloading of deliveries from bulk tankers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.21 | Are bulk tankers dedicated? |
|  | [ ]  Yes | [ ]  No |
|  | If no, is a cleaning certificate required to be provided with each delivery? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.22 | Do you have procedures for pest control? |
|  | [ ]  Yes | [ ]  No |
|  | If yes please provide a copy of the pest control procedures, and confirm what pesticides are approved for use. |
|  |       |
|  |  |
| 4.23 | Do you have procedures for environmental monitoring? |
|  | [ ]  Yes | [ ]  No |
|  | If yes please provide a copy of the procedures for environmental monitoring, confirm the parameters that are monitored, and explain how environmental monitoring is performed and reviewed. |
|  |       |
|  |  |
| 4.24 | Do you have specific controls on eating and smoking? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the specific controls on eating and smoking. |
|  |       |
|  |  |
| 4.25 | Are toilets, change rooms and eating areas separate from manufacturing areas and maintained in a sanitary condition? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.26 | Do you have signs erected in toilets and change rooms to instruct employees on appropriate hand washing techniques before starting or returning to work?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 4.27 | What is the active ingredient in the soap/disinfectant provided in the toilets and change rooms?  |
|  |       |
|  |  |
| 4.28 | Do you have appropriately shielded lighting? |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **5** | **Process Equipment** |
| 5.1 | Are process equipment contact surfaces designed and constructed not to be reactive or additive? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.2 | Are process equipment contact surfaces easily cleaned? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.3  | Do you have procedures for the following aspects of process equipment?  |
|  | Operation | [ ]  Yes | [ ]  No |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Cleaning | [ ]  Yes | [ ]  No |
|  | Maintenance | [ ]  Yes | [ ]  No |
|  |  |
| 5.4 | Do you keep records of the following maintenance activities for process equipment? |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Routine maintenance | [ ]  Yes | [ ]  No |
|  | Repairs | [ ]  Yes | [ ]  No |
|  | Modifications | [ ]  Yes | [ ]  No |
|  |  |
| 5.5 | Please indicate what process capabilities you have? |
|  | Extraction | [ ]  Yes | [ ]  No |
|  | Mixing | [ ]  Yes | [ ]  No |
|  | Granulation | [ ]  Yes | [ ]  No |
|  | Oven drying | [ ]  Yes | [ ]  No |
|  | Spray drying | [ ]  Yes | [ ]  No |
|  | Other | [ ]  Yes | [ ]  No |
|  | Please provide details of other process capabilities. |
|  |       |
|  |  |
| 5.6 | Please provide the title and reporting structure of the person in charge of maintenance? |
|  |       |
|  |  |
| 5.7 | Do you dedicate any process equipment to manufacture one raw material? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.8  | Do you concurrently manufacture different raw materials in a common area? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of how you minimise the risk of cross contamination. |
|  |       |
|  |  |
| 5.9 | Do you manufacture by lot or continuous process? |
|  | [ ]  Lot | [ ]  Continuous |
|  |  |
| 5.10 | Do you regularly calibrate the critical operational parameters of process equipment? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.11 | Do you calibrate process equipment with standards that are traceable to a recognised standard?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.12 | Do the procedures for maintenance specify the lubricants that can be used on specific process equipment?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.13 | Do you approve lubricants prior to use?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.14 | Do the procedures for cleaning specify the method of preparation, expiry date and dilution rates for the cleaning and sanitising agents that can be used?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.15  | Do you approve the cleaning and sanitising agents prior to use?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.16 | Do you use statistical process control techniques in manufacturing? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 5.17  | Do you use metal detectors at any stage of manufacturing?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of what stage/s of manufacturing are they used and their limit of detection.  |
|  |       |
|  |  |
| **6** | **Materials Management** |
| 6.1 | Do you assign goods receivable numbers for starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how goods receivable numbers are assigned, and what the goods receivable numbers look like. |
|  |       |
|  |  |
| 6.2 | Do you follow the principles of first in first out (FIFO) or first expired first out (FEFO) stock rotation? |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 6.3  | Do you have a materials location system? |
|  | [ ]  Yes (manual) | [ ]  Yes (computerised) | [ ]  No |
|  |  |
| 6.4 | Do you store more than one material per location? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.5 | Do you assign lot/batch numbers for raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how lot/batch numbers are assigned, and what the lot/batch numbers look like.  |
|  |       |
|  |  |
| 6.6  | Do you have a means of identifying the site of manufacture from lot/batch numbers if multiple manufacturing sites are used? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please explain how you can identify the site of manufacture from lot/batch numbers. |
|  |       |
|  |  |
| 6.7  | Do you identify the site of manufacture on certificates of analysis? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.8 | Do you guarantee to supply raw material with an expiry date greater than 12 months? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.9 | Are the same raw materials produced in several forms and sizes? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, do they have unique item codes? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.10 | Do you have procedures to notify customers in advance of late deliveries? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.11 | Do you have procedures to ensure that unapproved raw material is not shipped to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 6.12 | Do you have procedures for handling rejected and returned raw material? |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **7** | **Quality Management** |
| 7.1 | Do you have a quality system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a brief overview of the quality system. |
|  |       |
|  |  |
| 7.2 | Do you have a quality manual? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide the table of contents of the quality manual. |
|  |       |
|  |  |
| 7.3 | Do you have procedures for environmental protection? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.4 | Do you have procedures for disaster recovery to deal with man-made and/or natural disasters? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.5 | Do you undertake regular reviews of the quality system? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the frequency of the reviews and what is reviewed. |
|  |       |
|  |  |
| 7.6 | Do you have a continuous quality improvement program? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.7 | Do you have procedures that specify the quantity and identity of starting materials, equipment to be utilised and the critical processing parameters? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, do they provide traceability back to the starting material goods receivable numbers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.8 | Do you blend multiple lots/batches of raw material and label as one lot/batch? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.9 | Do you sequentially pack multiple lots/batches of raw material and label as one lot/batch? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.10 | Do you have a means of identifying if a lot/batch of raw material has been reprocessed? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how you can identify a lot/batch of raw material that has been reprocessed. |
|  |       |
|  |  |
| 7.11 | Do you retain lot/batch records? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long lot/batch records are retained. |
|  |       |
|  |  |
| 7.12 | Are you willing to supply a copy of a recently completed lot/batch record for a typical raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of a recently completed lot/batch record. |
|  |  |
| 7.13 | Is the theoretical versus actual yield calculated on every batch of raw material produced? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.14 | Do you have any of the following documents available for any raw material? |
|  | [ ]  European Drug Master File (EDMF) | [ ]  United States Drug Master File (USDMF) |
|  | [ ]  European Certificate of Suitability | [ ]  United States Certificate of Suitability |
|  | If yes, please provide details of any current documents that are available.  |
|  |       |
|  |  |
| 7.15 | Do you have standard operating procedures?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a list of the standard operating procedures. |
|  |  |
| 7.16 | Do you have specifications?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.17 | Who approves standard operating procedures and specifications?  |
|  |       |
|  |  |
| 7.18 | Do you have procedures for sampling starting materials and raw materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.19 | Do you follow statistical sampling plans? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.20 | Who performs sampling?  |
|  |       |
|  |  |
| 7.21 | Do you have procedures for reviewing and updating procedures and specifications? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.22 | Do you have procedures for change control? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.23 | Do you have procedures for investigating non conformances? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.24 | Do you have a non conformance database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.25 | Do you have procedures for corrective action and preventative action? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.26 | Do you have a corrective action and preventative action database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.27 | Do you have procedures for risk management? |
|  | [ ]  Yes | [ ]  No |
|  |  |
|  |  |
|  |  |
| 7.28 | Do you have procedures for internal and external audits? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of the frequency of audits, and explain what is reviewed. |
|  |       |
|  |  |
| 7.29 | Are the results of internal and external audits documented and reviewed by management? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.30 | Are corrective actions resulting from internal and external audits documented and verified for effectiveness? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.31 | Do you have procedures in place to ensure that the distributor/trader and customer have agreed to any changes to specifications prior to them being implemented? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.32 | Do you agree to provide prior notification before any of the following changes are implemented?  |
|  | Change in the method of manufacture. | [ ]  Yes [ ]  No |
|  | Change in the manufacturing site. | [ ]  Yes [ ]  No |
|  | Change in the registration/licensing status of the site.  | [ ]  Yes [ ]  No |
|  | Change in the raw material specifications.  | [ ]  Yes [ ]  No |
|  | Change in the analytical methods.  | [ ]  Yes [ ]  No |
|  |  |
| 7.33 | Do you perform trend analysis on raw materials?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 7.34 | Do you conduct product quality reviews on raw materials in accordance with ICH Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients or equivalent?  |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **8** | **Quality Control - Plant Starting Materials** |
| 8.1 | Do you undertake cultivation of plants on your own farms? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please provide details of what cultivation activities you undertake. |
|  |       |
|  |  |
| 8.2 | Do you provide seeds or propagation materials to farmers for particular plants?  |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please provide details of what seeds or propagation materials you provide. |
|  |       |
|  |  |
| 8.3 | Do you employ qualified botanists? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If no, please provide details of how you perform authentication of plant materials prior to further processing.  |
|  |       |
|  |  |
| 8.4 | Do you have procedures for performing botanical authentication?  |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please provide a copy of the procedures for performing botanical authentication.  |
|  |       |
|  |  |
| 8.5  | Do you have a herbarium?  |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.6  | Do you have a library of voucher specimens? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please provide a list of the voucher specimens including the botanical name, type of voucher specimen and where the authentication was performed. |
|  |       |
|  |  |
| 8.7 | Do you comply with the WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.8 | Do you use any plants that are listed as endangered by the Convention on InternationalTrade in Endangered Species (CITES)? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  | If yes, please provide details of any plants you use that are listed as endangered by the Convention on International Trade in Endangered Species (CITES). |
|  |       |
|  |  |
|  | **Quality Control - General Starting Materials** |
| 8.9 | Are bulk deliveries of starting materials tested before coupling and unloading? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.10 | Do you ensure that certificates of analysis are supplied with every delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.11 | To what quality standard must starting materials comply with? |
|  | [ ]  British Pharmacopoeia (BP) | [ ]  European Pharmacopoeia (EP) | [ ]  United States Pharmacopoeia (USP) | [ ]  Other |
|  | Please provide details of other quality standards starting materials comply with. |
|  |       |
|  |  |
| 8.12 | Do you have specifications for starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these specifications available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.13 | Do you have test procedures for starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these test procedures available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.14 | Do you have specifications for packaging materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.15 | Do you test starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.16 | Do you test for heavy metals? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.17 | Do you test for pesticide residues? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.18 | Do you test for mycotoxins? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.19 | Do you test for environmental contaminants? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.20 | Do you test for veterinary residues? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.21 | Do you test for residual solvents? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.22 | Do you test packaging materials?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.23 | Do you test every delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of what tests are performed on every delivery.  |
|  |       |
|  |  |
| 8.24 | Do you have procedures to allow reduced testing of starting materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the reduced testing procedures. |
|  |  |
|  |  |
| 8.25 | When reduced testing is performed, is it indicated on the certificate of analysis? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 8.26 | Are inspection and testing results for starting materials reviewed by qualified laboratory personnel? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.27 | Who has the authority to approve and reject starting materials? |
|  |       |
|  |  |
| 8.28 | Do you retain inspection and testing records for each delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long inspection and testing records are retained. |
|  |       |
|  |  |
| 8.29 | Do you retain retention samples of each delivery of starting material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long retention samples are retained. |
|  |       |
|  |  |
| 8.30 | Do you retain the certificates of analysis provided by suppliers? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long certificates of analysis are retained. |
|  |       |
|  |  |
| 8.31 | Can you provide copies of inspection and testing records and certificates of analysis if requested? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.32 | Do you have procedures for maintaining traceability of starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.33 | Do you have procedures for receiving starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.34 | Do you have procedures for approving starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.35 | Do you have procedures for rejecting starting materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.36 | Do you have procedures for vendor assurance of starting material suppliers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.37 | Do you maintain a list of the vendor assurance status of starting material suppliers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.38 | Do you have easily identifiable security seals on each container of starting material to ensure tampering can be recognised? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 8.39 | Do you recover and reuse any starting materials in the manufacture of other raw materials?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of any starting materials that are recovered and reused in the manufacture of other raw materials, and explain what testing is undertaken. |
|  |       |
|  |  |
| 8.40 | Are rejected starting materials ever reprocessed and reused?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how rejected starting materials can be reprocessed. |
|  |       |
|  |  |
| 8.41 | Do you use any form of sterilisation on starting materials?  |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details on what forms of sterilisation are used and whether it is indicated on certificates of analysis. |
|  |       |
|  |  |
| 8.42 | Do any of your raw materials contain animal derived ingredients? |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **9** | **Quality Control - Raw Materials** |
| 9.1 | To what quality standard must raw materials comply with? |
|  | [ ]  British Pharmacopoeia (BP) | [ ]  European Pharmacopoeia (EP) | [ ]  United States Pharmacopoeia (USP) | [ ]  Other |
|  | Please provide details of other quality standards raw materials comply with.  |
|  |       |
|  |  |
| 9.2 | Do you have specifications for raw materials? |
|  | [ ]  Yes | [ ]  No |
|   | If yes, are these specifications available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.3 | Do you have test procedures for raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, are these test procedures available to customers? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.4 | Do you test raw materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.5 | Do you test for heavy metals? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.6 | Do you test for pesticide residues? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.7 | Do you test for mycotoxins? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.8 | Do you test for environmental contaminants? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.9 | Do you test for veterinary residues? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.10 | Do you test for residual solvents? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.11 | Do you test every lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of what tests are performed on every lot/batch.  |
|  |       |
|  |  |
| 9.12 | Do you have procedures to allow reduced testing of raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the reduced testing procedures.  |
|  |  |
| 9.13 | When reduced testing is performed, is it indicated on the certificate of analysis? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 9.14 | Are inspection and testing results for raw materials reviewed by qualified laboratory personnel? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.15 | Who has the authority to approve and reject raw materials? |
|  |       |
|  |  |
| 9.16 | Do you retain inspection and testing records for each lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long inspection and testing records are retained? |
|  |       |
|  |  |
| 9.17 | Do you retain retention samples of each lot/batch of raw material? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please confirm how long retention samples are retained. |
|  |       |
|  | If multiple lots/batches of raw material are sequentially packed and labelled as one lot/batch do you retain samples from each distinct lot/batch of raw material?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.18 | Do you retain copies of labels with the lot/batch records? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 9.19 | Do you provide a Certificate of Analysis or Certificate of Conformance for every lot/batch? |
|  | [ ]  Yes | [ ]  No |
|  |  |  |
| **10** | **Packaging, Storage and Distribution** |
| 10.1 | How are raw materials packaged? |
|  |       |
|  |  |
| 10.2 | Do you have easily identifiable security seals or tape on each container of raw material to ensure tampering can be recognised? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please supply a sample or picture of the tamper evident seals or tape.  |
|  |  |
| 10.3 | Please provide details of what information is included on printed packaging and labelling? |
|  |       |
|  | If multiple lots/batches of raw material are sequentially packed and labelled as one lot/batch do you indicate this on printed packaging and labelling? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.4 | Do you have procedures for the control, use and reconciliation of printed packaging and labelling? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for the control, use and reconciliation of printed packaging and labelling. |
|  |  |
| 10.5 | Do you have procedures to verify the accuracy of printed packaging and labelling? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures to verify the accuracy of printed packaging and labelling. |
|  |  |
| 10.6 | Do you have procedures for minimising packaging and labelling errors? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide a copy of the procedures for minimising packaging and labelling errors. |
|  |  |
| 10.7 | How are raw materials transported to Australia? |
|  | [ ]  Air | [ ]  Sea |
|  | Please explain in detail. |
|  |       |
|  |  |
| 10.8 | Do you undertake any vendor assurance activities on the transport companies used? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.9 | Do you have a list of approved transport companies? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.10 | Have transport validation trials been conducted on the transportation methods used? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.11 | Do you retain the transport records for raw materials? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.12 | Do you use refrigerated transport? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, do you monitor temperature? |
|  | [ ]  Yes | [ ]  No |
|  | If yes please provide a copy of the procedures for monitoring temperature, and explain how monitoring is performed and reviewed. |
|  |       |
|  |  |
| 10.13 | Do you document the supply chain? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of how the supply chain is documented. |
|  |       |
|  |  |
| 10.14 | Do you have procedures to ensure that raw materials are packaged, stored, handled and transported in such a way as to prevent contamination and damage? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.15 | Are pallets used for international transport only subject to heat treatment and stamped in accordance with the International Plant Protection Convention (IPCC) International Standards for Phytosanitary Measures (ISPM) No. 15 Regulation of Wood Packaging Material in International Trade? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 10.16 | Please provide details of what type of heat or chemical treatment pallets used for local storage and transport are subjected to? |
|  |       |
|  |  |
|  |  |
|  |  |
|  |  |
| **11** | **Validation** |
| 11.1 | Do you use computer controlled operating systems in the following areas? |
|  | **Area** | **Validated** | **Is data storage in compliance with US FDA 21 CFR Part 11?** |
|  | [ ]  Warehousing | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  | [ ]  Manufacturing | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  | [ ]  Documentation | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  | [ ]  Laboratory | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|  |  |
| 11.2 | Do you have appropriate security to limit access to computer controlled operating systems? |
|  | [ ]  Yes | [ ]  No | [ ]  Not applicable |
|  |  |
| 11.3 | Do you have a validation master plan? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 11.4 | Do you validate manufacturing processes and process equipment? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of any validation that is planned to be undertaken on manufacturing processes and process equipment. |
|  |       |
|  |  |
| 11.5 | Do you validate cleaning processes? |
|  | [ ]  Yes | [ ]  No |
|   | If no, please explain how cleanliness is determined. |
|  |       |
|  |  |
| 11.6 | Do you validate analytical methods? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of any validation that is planned to be undertaken on analytical methods. |
|  |       |
|  |  |
| 11.7 | Do you validate laboratory processes and equipment? |
|  | [ ]  Yes | [ ]  No |
|  | If no, please provide details of any validation that is planned to be undertaken on laboratory processes and laboratory equipment. |
|  |       |
|  |  |
| 11.8 | Are any of the starting materials used to manufacture the raw material susceptible to microbiological contamination? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please explain how this is controlled during manufacture.  |
|  |       |
|  |  |
| **12** | **Complaints and Recalls** |
| 12.1 | Do you have procedures for investigating customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.2 | Do you have a complaints database? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.3 | Who is responsible for conducting customer complaint investigations? |
|  |       |
|  |  |
| 12.4 | Do you provide a response to customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.5 | Do you document the cause of the complaint and the corrective action taken in the response to the customer? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.6 | Do you retain customer complaint documents? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.7 | Does management review customer complaints? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.8 | Have there been any recalls in the last five years? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, please provide details of any recalls in the last five years. |
|  |       |
|  |  |
| 12.9 | Do you have procedures for conducting recalls? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 12.10 | Who is responsible for recalls? |
|  |       |
|  |  |
| 12.11 | Who has the final decision on whether a recall is initiated? |
|  |       |
|  |  |
| **13** | **Stability Testing** |
| 13.1 | Do you have stability testing data available for raw materials? |
|  | [ ]  Yes | [ ]  No |
|  | If yes, would you provide this stability data if requested? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 13.2 | Do you have an ongoing stability testing program? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 13.3 | Are the analytical methods used for stability testing validated and stability indicating? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 13.4 | Do you undertake stability testing on pilot or production lots/batches? |
|  | [ ]  Pilot | [ ]  Production |
|  |  |  |
| **14** | **Laboratory** |
| 14.1 | Do you have procedures for the following aspects of laboratory equipment?  |
|  | Operation | [ ]  Yes | [ ]  No |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Cleaning | [ ]  Yes | [ ]  No |
|  | Maintenance | [ ]  Yes | [ ]  No |
|  |  |
| 14.2 | Do you keep records of the following maintenance activities for laboratory equipment? |
|  | Calibration | [ ]  Yes | [ ]  No |
|  | Routine maintenance | [ ]  Yes | [ ]  No |
|  | Repairs | [ ]  Yes | [ ]  No |
|  | Modifications | [ ]  Yes | [ ]  No |
|  |  |
| 14.3 | Are calibration standards used traceable to a recognised standard?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.4 | Do you record raw data in duplicate workbooks?  |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.5 | Do you undertake trend analysis on analytical results? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.6 | Do you have dedicated sampling facilities? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.7 | Do you have procedures for managing analytical reagents and primary reference standards? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.8 | Do you have procedures for labelling and determining the expiry date of analytical reagents and primary reference standards? |
|  | [ ]  Yes | [ ]  No |
|  |  |
| 14.9 | Please indicate what laboratory capabilities you have? |
|  | Wet Chemistry | [ ]  Yes | [ ]  No |
|  | Instrumentation | [ ]  Yes | [ ]  No |
|  | Microbiology | [ ]  Yes | [ ]  No |
|  |  |
| 14.10 | Please indicate what instrumentation capabilities you have? |
|  | High Performance Liquid Chromatography Ultraviolet/Refractive Index Detector (HPLC UV/RID) | [ ]  Yes | [ ]  No |
|  | High Performance Liquid Chromatography Diode Array Detector/Photodiode Array (HPLC DAD/PDA) | [ ]  Yes | [ ]  No |
|  | High Performance Liquid Chromatography Evaporative Light Scattering Detector (HPLC ELSD) | [ ]  Yes | [ ]  No |
|  | High Performance Liquid Chromatography Mass Spectrometer (HPLC MS) | [ ]  Yes | [ ]  No |
|  | Field Ionisation Mass Spectrometer (FIMS) | [ ]  Yes | [ ]  No |
|  | Fourier Transform Infrared Spectrometer (FTIR) | [ ]  Yes | [ ]  No |
|  | Carbon Nuclear Magnetic Resonance Spectrometer (C NMR) | [ ]  Yes | [ ]  No |
|  | Proton Nuclear Magnetic Resonance Spectrometer (P NMR) | [ ]  Yes | [ ]  No |
|  | High Performance Thin Layer Chromatography (HPTLC) | [ ]  Yes | [ ]  No |
|  | Gas Chromatography Flame Ionisation Detector (GC FID) | [ ]  Yes | [ ]  No |
|  | Gas Chromatography Mass Spectrometer (GC MS) | [ ]  Yes | [ ]  No |
|  | Atomic Absorption Spectrometer (AAS) | [ ]  Yes | [ ]  No |
|  | Capillary Electrochromatography (CE) | [ ]  Yes | [ ]  No |
|  | Ultraviolet Spectrometer (UVS) | [ ]  Yes | [ ]  No |
|  | Inductively Coupled Plasma Mass Spectrometer (ICP MS) | [ ]  Yes | [ ]  No |
|  | Inductively Coupled Plasma Optical Emission Spectrometer (ICP OES) | [ ]  Yes | [ ]  No |
|  | Total Organic Carbon (TOC) | [ ]  Yes | [ ]  No |
|  | Near Infrared (NIR) | [ ]  Yes | [ ]  No |
|  | Melting Point Apparatus  | [ ]  Yes | [ ]  No |
|  | Refractometer | [ ]  Yes | [ ]  No |
|  | Densitometer | [ ]  Yes | [ ]  No |
|  | Pycnometer | [ ]  Yes | [ ]  No |
|  | Viscometer | [ ]  Yes | [ ]  No |
|  | Polarimeter | [ ]  Yes | [ ]  No |
| References |
| Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 [www.tga.gov.au/industry/manuf-medicines-cgwp-schedule2-3-4-8.htm](http://www.tga.gov.au/industry/manuf-medicines-cgwp-schedule2-3-4-8.htm)FAQs for manufacturers, wholesalers and retailers <https://www.health.nsw.gov.au/pharmaceutical/licences/Pages/faq-manufacturers-wholesalers-retailers.aspx> PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part I [www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm](http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm)PIC/S Guide to Good Manufacturing Practice for Medicinal Products Part II [www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm](http://www.tga.gov.au/industry/manuf-pics-gmp-medicines.htm)Therapeutic Goods Administration (TGA) [www.tga.gov.au](http://www.tga.gov.au) |
|  |
| **Document Revision History** |
| **Date** | **Version** | **Changes** |
| 16/01/12 | 1 | First issue. |
| 4/08/14 | 2 | Question 3.1 updated to include additional product type.New question 7.9.Expanded question 9.17.Expanded question 10.3.Introduction updated to reflect name change of CHC to CMA. |
| 15/07/2019 | 3 | Introduction updated to reflect name change of ASMI to CHP Australia.Update to Reference hyperlinks |