**Quality information checklist for UK manufactured Specials**

This checklist is provided to assist with obtaining information to support quality assessments for UK manufactured Specials.

It is available in an edited Word format to facilitate copying and editing in local documentation.

For guidance on how to interpret the information please refer to our article about [evaluating the quality of UK manufactured Specials](https://www.sps.nhs.uk/articles/evaluating-the-quality-of-uk-manufactured-specials).

A separate checklist for imported Specials can be found in our article about [evaluating the quality of imported Specials.](https://www.sps.nhs.uk/articles/evaluating-the-quality-of-imported-specials)

**Quality information checklist for UK manufactured Specials**

* Manufacturer name & address
* Supplier, if different from the manufacturer
* Specials manufacturing licence number of manufacturer
* Wholesale distribution authorisation number of wholesaler, if not supplied directly by the Specials manufacturer
* Manufacturer’s product specification. This should include all of the following information; if not it should be requested separately
  + Name, generic name, strength, quantity/volume per container and presentation
  + Excipients
  + Intended route of administration
  + Method of manufacture: brief description including method of sterilisation (if relevant) and in process controls
  + Release criteria
  + Storage conditions
  + Shelf life, including in-use shelf life if applicable
  + Stability information and justification for shelf life
* Certification (or an example certificate for another batch of the same product if the product to be purchased has not yet been made)
  + Certificate of Analysis (C of A) for the batch, if finished product testing is performed
  + Certificate of Conformity (C of C) if no finished product testing is performed
* Photographs of all faces of carton and primary container. If photographs cannot be obtained, label proofs and details of all packaging and labelling
* If a cold chain product, details of maintenance of the cold chain in delivery

***Additional questions for aseptically prepared medicines (these may also be in the product specification)***

* A brief description of the facilities used, types of clean air devices and method of transfer sanitisation
* An outline of the programme of finished product testing and end of session media filling