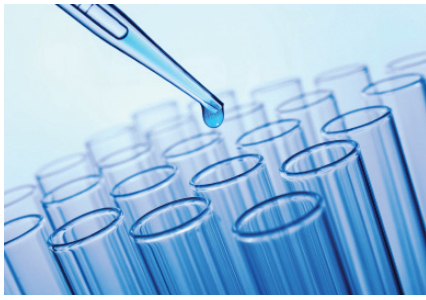
APSM

Association of Pharmaceutical Specials Manufacturers

What to look for in a Specials manufacturer

Quality commitment from a licenced Specials manufacturer

APSM members have invested more than £150 million in quality and infrastructure in the last 5 years.



All members should offer:

- Premises inspected by MHRA for compliance to GMP (Good Manufacturing Practice)
- A pharmaceutical quality assurance system, e.g. pharmacopoeial monograph, stability tests
- Batch testing / Certificates of Analysis provided
- Certificates of Compliance (for single products)
- Best practice labelling
- Customer support line
- Unique codes on all products
- Innovation – e.g. clearer patient labelling
- Yellow card adverse event reporting
- Investment in facilities for medicines manufacture

In the UK, the majority of Specials are manufactured and prepared by Specials manufacturers who are licensed, regulated and inspected by the MHRA and must comply with the principles of Good Manufacturing Practice (GMP) adopted by the EU Commission.

These licensed manufacturers provide additional assurances of quality. A certificate of analysis is provided for batch manufactured Specials as evidence that critical parameters have been met through physical, chemical or microbiological analysis of the final product. Where individual or bespoke Specials are prepared, the manufacturer will provide a certificate of conformity to show that the product meets the specification.

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In addition, (ALL) APSM members voluntarily undertake to apply the Yellow Card reporting scheme for their Specials (unlicensed medicines). This is the same pharmacovigilance process adopted by manufacturers of licensed pharmaceuticals.

Pharmacovigilance involves the continuous monitoring of medicines for any adverse side effects. In the UK, this process is managed under the Yellow Card scheme whereby patients, doctors and health professionals can report any potential side effects.

In this way, any adverse events related to unlicensed medicines produced by APSM members would be brought to the attention of the MHRA and therefore fully monitored and investigated in the same way as any licensed medicine.