


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

21 - 47 High Street, Feltham, Middlesex, TW13 4UN, UK

|                                                                                                                               |                                                                                           |                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>Accredited to<br/>ISO/IEC 17025:2005</p> | <h3>Quality Control North West</h3> <p>Issue No: 018    Issue date: 30 September 2010</p> |                                                                                                                                                                                                                                                                                   |
|                                                                                                                               | <p><b>Stepping Hill Hospital</b><br/>Poplar Grove<br/>Stockport<br/>SK2 7JE</p>           | <p><b>Contact: Mr I M Beaumont</b><br/>Tel: +44 (0)161 419 5011<br/>Fax: +44 (0)161 419 5394<br/>E-Mail: <a href="mailto:ian.beaumont@stockport-tr.nwest.nhs.uk">ian.beaumont@stockport-tr.nwest.nhs.uk</a><br/>Website: <a href="http://www.qcnw.nhs.uk">www.qcnw.nhs.uk</a></p> |
| <p><b>Testing performed by the Organisation at the locations specified below</b></p>                                          |                                                                                           |                                                                                                                                                                                                                                                                                   |

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

| Location details                                                                                                                                                                                                                                                                                                                                                     | Activity                                                                                                                                                                                                                                                                                                 | Location code |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| <p><b>Address</b><br/>Quality Control North West<br/>Stepping Hill Hospital<br/>Poplar Grove<br/>Stockport<br/>SK2 7JE</p> <p><b>Local contact</b><br/>Mr I M Beaumont<br/><br/>Tel: +44 (0)161-419 5011<br/>Fax: +44 (0)161-419 5394<br/>Email: <a href="mailto:ian.beaumont@stockport-tr.nwest.nhs.uk">ian.beaumont@stockport-tr.nwest.nhs.uk</a><br/>Website:</p> | <p><b>Testing:</b><br/>Chemical and Physical<br/>Microbiological<br/>Bacterial endotoxin test<br/>Customer site work</p> <p><b>Support Functions:</b><br/>Co-ordination of SLAs with internal customers and contract review.<br/>Co-ordination and administration of activities on clients' premises</p> | S             |
| <p><b>Address</b><br/>Quality Control North West<br/>Pharmacy Practice Unit<br/>70 Pembroke Place<br/>Liverpool<br/>L69 3GF</p> <p><b>Local contact</b><br/>Mr M Jackson<br/>Tel: +44 (0)151-794 8110<br/>Fax: +44 (0)151-794 8108<br/>Email: <a href="mailto:mark.jackson@lrippu.nhs.uk">mark.jackson@lrippu.nhs.uk</a><br/>Website:</p>                            | <p><b>Testing:</b><br/>Chemical and Physical<br/>Microbiological<br/>Bacterial endotoxin test<br/>Customer site work</p> <p><b>Support Functions:</b><br/>Co-ordination and administration of activities on clients' premises<br/>Group document control and maintenance of suppliers list</p>           | L             |
| <p><b>Address</b><br/>Quality Control North West<br/>Pharmacy Department<br/>Royal Preston Hospital<br/>Sharoe Green Lane<br/>Preston<br/>PR2 9HT</p> <p><b>Local contact</b><br/>Mrs R Barnes<br/><br/>Tel: +44 (0)1772 522898<br/>Fax: +44 (0)1772 522805<br/>Email: <a href="mailto:ruth.barnes@lthtr.nhs.uk">ruth.barnes@lthtr.nhs.uk</a><br/>Website:</p>       | <p><b>Testing:</b><br/>Microbiological<br/>Customer site work</p>                                                                                                                                                                                                                                        | P             |



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**Site activities performed away from the locations listed above:**

| Location details                                                                            | Activity                                                                                                                                        | Location code |
|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Pharmaceutical manufacturing premises and associated clean rooms and workplace environments | Sampling of air, surfaces and water at clients premises<br><br>Testing air quality for physical and microbiological quality at clients premises | Site          |



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DETAIL OF ACCREDITATION

| Materials/Products tested            | Type of test/Properties measured/Range of measurement                                                                              | Standard specifications/ Equipment/Techniques used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Location Code                                                                        |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| DRUGS, MEDICINES AND PHARMACEUTICALS | <u>Chemical and Physical Tests</u><br><br>As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph | Specifications and methods detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur), and/or the US Pharmacopoeia (USP), supplemented by Documented In-House methods and procedures where appropriate, using the following techniques and/or equipment:                                                                                                                                                                                                                                                                                                                 |                                                                                      |
|                                      | Identification Tests<br>Assay of active and non-active ingredients:<br>Related substances tests<br>Qualitative reactions and tests | a) Atomic absorption and emission spectroscopy (excluding graphite furnace)<br><br>b) Infra-red spectroscopy with reference to GP(T)2<br><br>c) Ultra-violet and visible spectroscopy with reference to GP(T)1<br><br>d) Thin layer Chromatography<br><br>e) HPLC with UV detection<br><br>f) Gas chromatography with FID or TCD detection<br><br>g) Gas chromatography with FID detection<br><br>h) Gravimetric techniques<br><br>i) Volumetric techniques:<br>Non-aqueous titration<br>Potentiometric titration<br>Complexometric titration<br>Acid base titration<br>Iodometric titration | L<br><br>S & L<br><br>S & L<br><br>S & L<br><br>S<br><br>L<br><br>S & L<br><br>S & L |
|                                      | Colorimetric tests                                                                                                                 | Visual comparative technique as documented in Pharmacopoeial Monographs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | S & L                                                                                |



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| Materials/Products tested                     | Type of test/Properties measured/Range of measurement                                                                                                                                                                                                                                                                             | Standard specifications/ Equipment/Techniques used                      | Location Code |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------|
| DRUGS, MEDICINES AND PHARMACEUTICALS (cont'd) | <u>Chemical and Physical Tests</u> (cont'd)                                                                                                                                                                                                                                                                                       |                                                                         |               |
|                                               | Limit tests<br>Excluding BP tests for Aluminium, Fluoride, Heavy metals - tests E, F and G, lead in sugars and Nickel in polyols<br>Excluding USP tests for Calcium and dioxane, Mercury methods II a and b, Dimethylaniline, 4-epi-anhydrotetracycline, Lead and Selenium<br>Excluding PhEur tests for Ethylene oxide and Dioxin | Visual comparative technique as documented in Pharmacopoeial Monographs | S & L         |
|                                               | Clarity of solution                                                                                                                                                                                                                                                                                                               | Visual comparative technique as documented in Pharmacopoeial Monographs | S & L         |
|                                               | Colour of solution                                                                                                                                                                                                                                                                                                                | Visual comparative technique as documented in Pharmacopoeial Monographs | S & L         |
|                                               | Density:<br>Relative Density, Apparent Density and Weight per ml                                                                                                                                                                                                                                                                  | a) LSP 342 or SOP 006 using automated densitometers                     | S & L         |
|                                               |                                                                                                                                                                                                                                                                                                                                   | b) LSP 207 pycnometer method                                            | S             |
|                                               | Dissolution of tablets and capsules                                                                                                                                                                                                                                                                                               | Basket or paddle method                                                 | S & L         |
|                                               | Loss on drying                                                                                                                                                                                                                                                                                                                    |                                                                         | S & L         |
|                                               | Melting point                                                                                                                                                                                                                                                                                                                     | a) LSP 21 or SOP 30 using automated melting point apparatus             | S & L         |
|                                               |                                                                                                                                                                                                                                                                                                                                   | b) BP Method III                                                        | S             |
| Optical rotation                              |                                                                                                                                                                                                                                                                                                                                   | S & L                                                                   |               |



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|---------------------------------------------------|------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| DRUGS, MEDICINES AND PHARMACEUTICALS (cont'd)     | <u>Chemical and Physical Tests</u> (cont'd)                                              |                                                                                                                                                                                                                                                        |                |
|                                                   | Particulate contamination                                                                | GPT(9) Sub visible particle counting by light obscuration method                                                                                                                                                                                       | S & L          |
|                                                   | pH                                                                                       | GP(T)3 using pH meter                                                                                                                                                                                                                                  | S & L          |
|                                                   | Refractive index                                                                         |                                                                                                                                                                                                                                                        | S & L          |
|                                                   | Residue on ignition                                                                      |                                                                                                                                                                                                                                                        | S              |
|                                                   | Sulphated ash                                                                            |                                                                                                                                                                                                                                                        | S & L          |
|                                                   | Uniformity of weight                                                                     |                                                                                                                                                                                                                                                        | S & L          |
|                                                   | Viscosity                                                                                | a) Pharmacopoeial Capillary methods<br><br>b) Pharmacopoeial Rotational Viscometry using Brookfield RVT instrument                                                                                                                                     | S & L<br><br>S |
| Water content (Moisture)                          | BP Methods 1A and 1B using Karl Fischer automated titration apparatus                    | S & L                                                                                                                                                                                                                                                  |                |
| MEDICAL MATERIALS Containers                      | <u>Chemical and Physical Tests</u>                                                       | Specifications and methods detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur), and/or the US Pharmacopoeia (USP) supplemented by documented procedures where appropriate, using the following techniques and/or equipment: |                |
|                                                   | As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph |                                                                                                                                                                                                                                                        |                |
|                                                   | Light transmission                                                                       | BP and PhEur tests only                                                                                                                                                                                                                                | S              |
| Surface hydrolytic resistance of glass containers | LSP - AM 23                                                                              | S                                                                                                                                                                                                                                                      |                |



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|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| DRUGS, MEDICINES, PHARMACEUTICALS, MEDICAL DEVICES, PHARMACEUTICAL AND PURIFIED WATER | <u>Microbiological Tests</u><br>As appropriate for the product category as detailed in relevant Pharmacopoeial Monograph | Documented in-house methods based on specifications and procedures detailed in the British Pharmacopoeia (BP), the European Pharmacopoeia (PhEur) and/or the US Pharmacopoeia (USP):              |               |
|                                                                                       | Bacterial Endotoxins (Limit Test)                                                                                        | a) GP(T)5 supported by LSP 73 using gel clot technique                                                                                                                                            | S             |
|                                                                                       | Bacterial Endotoxins (quantitative)                                                                                      | b) GP(T)5 supported by SOP 389 using gel clot technique                                                                                                                                           | L             |
|                                                                                       | Bacterial Endotoxins (quantitative)                                                                                      | LSP 358, kinetic turbidimetric method (Pyros Kinetix)                                                                                                                                             | S             |
|                                                                                       | Sterility testing                                                                                                        | SOP 383 supported by SOP 352 using direct inoculation and membrane filtration techniques as appropriate for product type, and GP(T)8 to characterise any isolates                                 | L             |
|                                                                                       | Total viable aerobic colony count at 20-25 °C and at 30-35 °C                                                            | GP(T)7 using spread plate, with enrichment step in TSB for low level recovery, or membrane filtration techniques as appropriate for product type, followed by GP(T)8 to characterise any isolates | L, S, P       |
| Cytotoxic Drugs                                                                       | Sterility testing                                                                                                        | SOP 383 in conjunction with SOP 401 using direct inoculation and membrane filtration techniques as appropriate for product type, and GP(T)8 to characterise any isolates                          | L             |



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| Materials/Products tested                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Type of test/Properties measured/Range of measurement                                                                                                                                                                                                                                                                                                                                                     | Standard specifications/ Equipment/Techniques used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Location Code                                                              |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <p><b>ENVIRONMENTAL SAMPLES</b></p> <p>Samples for hygiene monitoring purposes from controlled environments for pharmaceutical manufacturing:</p> <p>Contact plates from surfaces<br/>Finger imprint plates (finger plates)<br/>Plates or strips from active air samples<br/>Settle plates</p> <p>Samples to monitor hygienic handling practices in controlled environments for pharmaceutical manufacturing:</p> <p>Universal Operator Validation Kits;<br/>Radiopharmacy generator eluates and kits;<br/>Broths for operator/ process validation</p> <p>Waters</p> <p>Working disinfectant solutions</p> | <p><u>Microbiological Tests</u></p> <p>Isolation, Enumeration and Characterisation of microbial contamination levels using Gram stain, Oxidase test, Catalase reaction, Spore stain, Motility test and methylene blue wet preparation for moulds</p> <p>Confirmation of sterility</p> <p>Assessment of microbial loading/total viable count</p> <p>Assessment of microbial loading/total viable count</p> | <p>Documented In-House Methods:</p> <p>GP(T)6 supported by local procedures for sample processing and GP(T)8 to characterise any isolates</p> <p>Local procedures for sample processing, subculture by streaking and assessment of results followed by GP(T)8 to characterise any isolates</p> <p>a) GP(T)6 incubation of 1ml spread plate supported by local procedures for sample processing and GP(T)8 to characterise any isolates</p> <p>b) GP(T)7 aerobic colony count at 20-25 °C and 30-35 °C using membrane filtration</p> <p>GP(T)7 aerobic colony count at 20-25 °C and 30-35 °C using membrane filtration and DE neutralising agar</p> | <p>L, S, P</p> <p>L, S, P</p> <p>L, S, P</p> <p>L, S, P</p> <p>L, S, P</p> |



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| ENVIRONMENTAL SAMPLES (cont'd)                                                                              | <u>Sampling for Microbiological Testing</u>                        | Documented In-House Methods:                                                                                                                                                                                       |                   |
| Taps/Wall gates in clean rooms/controlled environments                                                      | Water for assessment of microbial contamination                    | GP(T)6 using aseptic collection and spread plating onto TSA                                                                                                                                                        | Site from L, S, P |
| Clean Rooms and associated controlled environments                                                          | Air for microbial contamination                                    | GP(T)6 supported by local procedures for using MAS and RCS air samplers                                                                                                                                            | Site from L, S, P |
|                                                                                                             | Surfaces for microbial contamination                               | GP(T)6 supported by local procedures using contact plates or swab technique                                                                                                                                        | Site from L, S, P |
|                                                                                                             | <u>Physical Tests</u>                                              | Documented In-House Methods:                                                                                                                                                                                       |                   |
| Clean Rooms and associated controlled environments<br>Cytotoxic cabinets<br>LAF cabinets<br>Safety cabinets | HEPA filter integrity testing/<br>installation leak testing        | Dispersed oil particle technique documented as SOP 379, in accordance with PD 6609:2000 (BS 5295-1:1989 withdrawn) for filter installations compatible with the testing requirements of BS 5295-1:1989, Appendix C | Site from L       |
|                                                                                                             | Particle counting for classification and monitoring of clean rooms | GP(T)6 based on EN ISO 14644-1:1999 and the Orange Guide (Rules and Guidance for Pharmaceuticals Manufacturing and Distribution 2007, including Annex 1 2009) using laser particle counters                        | Site from L, S, P |
| END                                                                                                         |                                                                    |                                                                                                                                                                                                                    |                   |