



Schedule of Conditions Applicable to the Manufacture of Therapeutic Goods

The following conditions form part of Licence No. **MI-08122004-LI-000289-1** issued in respect of:

Sphere Healthcare Pty Ltd
10-12 Church Street
MOOREBANK NSW 2170
Australia

Under the Therapeutic Goods Act, 1989

The manufacture of registered medicines is restricted to complementary medicines and solutions for topical application only.

Where manufacture of tablets and hard shell capsule medicines is required to comply with the uniformity of content requirements set out in 'Therapeutic Goods Order Number 56 -- General standard for tablets, pills and capsules' the manufacturer must provide the TGA with copies of validation protocols and records, batch manufacturing records and quality control records, for each of the first three batches of each such medicine manufactured prior to their release.

Persons currently nominated as having control under Section 37 of the *Therapeutic Goods Act, 1989*:

Production: **Cecil J Finley**

Quality Control: **Frank Galluzzo**

Originally Issued: **31/03/2005** Date Revised: **12/04/2007**

Signed:

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Delegate of the Secretary

