AUDIT – REFERENCES

1. PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME. AIDE-MEMOIRES - INSPECTION OF BIOTECHNOLOGY MANUFACTURES. PI 024-1.16 December 2005.

2. WHO technical report series; no. 961. Annex 6 WHO good manufacturing practices for sterile pharmaceutical products.

3. FDA Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice. September 2004. Guidance for Industry.

4. Parenteral Drug Association. “Elements of a Code of Conduct for Data Integrity”

5. ISO 19011:2011(E). Guidelines for auditing management systems.

6. International Conference on Harmonization, *Guidance for Industry. Q10*, “Pharmaceutical Quality System,” June 2008.

7. Auditing as a Component of a Pharmaceutical Quality System. T. Fields. Journal of GXP Compliance. Autumn 2008 Volume 12 Number 5.

8. Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements. GHTF/SG4/N28R4:2008.