

INSPECTION REPORT

Nova Laboratories Ltd
 Martin House
 Gloucester Crescent
 Wigston
 Leicester
 LE18 4YL

Medicines and Healthcare Products Regulatory Agency
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Head Office:
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GMP INSPECTION OF Nova Laboratories Ltd

SECTION A INSPECTION REPORT SUMMARY

Inspection requested by: Routine fee based re-inspection

Scope of Inspection: EU Guide to GMP

Licence or Reference Number: MIA, MIA(IMP), MS and ManSA 13581

Licence Holder/Applicant: Nova Laboratories Ltd

Details of Product(s)/ Clinical trials/Studies:
 Variety of aseptically prepared sterile products, for Clinical Trials or hospital specials.
 Extemporaneously prepared non-sterile products as specials.

Activities carried out by company:

	Y/N
Manufacture of Active Ingredients	N
Manufacture of Finished Medicinal Products	Y
Manufacture of Intermediate or Bulk	Y
Packaging	Y
Importing	N
Laboratory Testing	Y
Batch Certification and Batch Release	Y
Other: <i>Specials and IMP activities</i>	Y

Name and Address of site(s) inspected: Nova Laboratories Ltd
 Martin House, Gloucester Crescent,
 Wigston Leicester LE18 4YL

Site Contact: Dr Peter White peter.white@novalabs.co.uk


Date(s) of Inspection: 11-15th July 2011

Lead Inspector: Vicki Pike

Accompanying Inspector(s): N/A

References: Insp GMP/IMP 13581/4097-0015

Final Conclusion/Recommendation:
 The site operates to a satisfactory level of GMP. A GMP certificate shall be issued. Please refer to Annex 1 for re-inspection frequency.

Name and Dated Signature of Lead Inspector:
 Signed:  Dated: 16/08/11