





## SUMMARY AND CONCLUSION

The summary of deficiencies is given in section 6 of this short report. All deficiencies were pointed out during the inspection and were discussed during the closing meeting on 28-Sept-2012.

During the inspection one major deficiency was detected. That's why you are asked to respond in writing within 14 days to this major deficiency listed in section 6.2. Please

send your answer including an obligatory timeframe. Corrective and preventive actions should be taken as soon as possible.

You are asked to respond in writing to the above listed deficiencies in section 6.3. Please send your answer within 6 weeks including an obligatory timeframe.

Your answers will be evaluated by RP Darmstadt. The Qualified Person according to section 15 German Drug Law of the responsible importer, STADA Arzneimittel AG, will be asked by RP Darmstadt upon the outcome of her or his assessment of the corrective and preventive actions taken at Nizhpharm.



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28-Sept-2012



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28-Sept-2012