SCHEDULE 7

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 2

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE MANUFACTURE OR ASSEMBLY OF INVESTIGATIONAL MEDICINAL PRODUCTS

8. The holder of the authorisation shall keep readily available for examination by a person authorised by the licensing authority the samples of each batch of bulk formulated products referred to in Article 11(4) of Commission Directive 2003/94/EC.