

ViP CGMP Audit (Level 08)

(B3) Personnel (Hygiene)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
736 EC	Steps are taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 2 - PERSONNEL
Personnel Hygiene 2.15.

504 FDA	Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products are excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardise the safety or quality of drug products.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart B - Organization and Personnel
21 CFR 211.28 (d)

(C) Buildings and Facilities

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
511 FDA	Operations are performed within specifically defined areas of adequate size.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.42 (c)

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref: **Audit Point:** **Observation:** **Level of Compliance:** **Initial:**

508 **Building or buildings used in the manufacture, processing, packing, or holding of a drug product are of a suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.**

NC	1	2	3	4	5
N/A					

FDA

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.42 (a)

759 **Premises for the packaging of medicinal products are specifically designed and laid out so as to avoid mix-ups or cross-contamination.**

NC	1	2	3	4	5
N/A					

EC

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.15.

509 **Any such building has adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, closures, labelling, in-process materials, or drug products, and to prevent contamination.**

NC	1	2	3	4	5
N/A					

FDA

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.42 (b)

742 **Premises and equipment are located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design aims to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build up of dust or dirt and, in general, any adverse effect on the quality of products.**

NC	1	2	3	4	5
N/A					

EC

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Principle

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
510 FDA	The flow of components, drug product containers, closures, labelling, in-process materials, and drug products through the building or buildings has been designed to prevent contamination.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.42 (b)

743 EC	Premises are situated in an environment which, when considered together with measures to protect the manufacture, presents minimal risk of causing contamination of materials or products.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - General 3.1.

746 EC	Premises are designed and equipped so as to afford maximum protection against the entry of insects or other animals.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - General 3.4.

973 FDA	Any building used in the manufacture, processing, packing, or holding of a drug product is maintained in a clean and sanitary condition. Any such building is free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals).	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.56 (a)

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
974 FDA	Any building used in the manufacture, processing, packing, or holding of a drug product is maintained in a good state of repair.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.58

744 EC	Premises are carefully maintained, ensuring that repair and maintenance operations do not present any hazard to the quality of products. They are cleaned and, where applicable, disinfected according to detailed written procedures.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - General 3.2.

(c) Validation in Partnership Ltd 2000

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ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref: Audit Point:

Observation:

Level of Compliance:

Initial:

512
FDA

There are separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mix-ups during the course of the following procedures:

NC
N/A

1 2 3 4 5

- (1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labelling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;
- (2) Holding rejected components, drug product containers, closures, and labelling before disposition;
- (3) Storage of released components, drug product containers, closures, and labelling;
- (4) Storage of in-process materials;
- (5) Manufacturing and processing operations;
- (6) Packaging and labelling operations;
- (7) Quarantine storage before release of drug products;
- (8) Storage of drug products after release;
- (9) Control and laboratory operations;
- (10) Aseptic processing, which includes as appropriate:
 - (i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;
 - (ii) Temperature and humidity controls;
 - (iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;
 - (iv) A system for monitoring environmental conditions;
 - (v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;
 - (vi) A system for maintaining any equipment used to control the aseptic conditions.

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.42 (c)

513
FDA

Potable water is supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product.

NC
N/A

1 2 3 4 5

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.48 (a)

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ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
514 FDA	Sewage, trash, and other refuse in and from the building and immediate premises is disposed of in a safe and sanitary manner.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart C - Buildings and Facilities 21 CFR 211.50																
515 FDA	Trash and organic waste matter is held and disposed of in a timely and sanitary manner.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart C - Buildings and Facilities 21 CFR 211.56 (a)																
519 FDA	Rodenticides, insecticides, and fungicides are not used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135).	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart C - Buildings and Facilities 21 CFR 211.56 (c)																
964 FDA	Adequate lighting is provided in all areas.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart C - Buildings and Facilities 21 CFR 211.44																
745 EC	Lighting, temperature, humidity and ventilation are appropriate and such that they do not adversely affect, directly or indirectly, either the medicinal products during their manufacture and storage, or the accurate functioning of equipment.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - General 3.3.																

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ViP CGMP Audit (Level 08)

(C) Buildings and Facilities

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
965 FDA	Adequate ventilation is provided.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.46 (a)

747 EC	Steps are taken in order to prevent the entry of unauthorised people. Production, storage and quality control areas are not used as a right of way by personnel who do not work in them.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - General 3.5.

849 EC	Access to production premises is restricted to authorised personnel.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 5 - PRODUCTION
General 5.16.

(c) Validation in Partnership Ltd 2000

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
966 FDA	Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature has been provided when appropriate for the manufacture, processing, packing, or holding of a drug product.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.46 (b)

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ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
756 EC	Production areas are effectively ventilated, with air control facilities (including temperature and, where necessary, humidity and filtration) appropriate both to the products handled, to the operations undertaken within them and to the external environment.	<input style="width: 80px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.12.

968 FDA	If air is recirculated to production areas, measures are taken to control recirculation of dust from production.	<input style="width: 80px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.46 (c)

969 FDA	In areas where air contamination occurs during production, there are adequate exhaust systems or other systems adequate to control contaminants.	<input style="width: 80px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.46 (c)

758 EC	In cases where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions are taken to avoid cross-contamination and facilitate cleaning.	<input style="width: 80px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.14.

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ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
970 FDA	Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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N/A																

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.46 (d)

748 EC	Dedicated and self contained facilities are available for the production of particular medicinal products, such as highly sensitising materials (e.g. penicillin's) or biological preparations (e.g. from live micro-organisms)	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.6.

749 EC	The production of certain additional products, such as certain antibiotics, certain hormones, certain cytotoxics, certain highly active drugs and non-medicinal products are not be conducted in the same facilities. For those products, in exceptional cases, the principle of campaign working in the same facilities can be accepted provided that specific precautions are taken and the necessary validations are made.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.6.

850 EC	("Normally,") The production of non-medicinal products is avoided in areas and with the equipment destined for the production of medicinal products.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 5 - PRODUCTION
General 5.17.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
750 EC	The manufacture of technical poisons, such as pesticides and herbicides, is not performed in premises used for the manufacture of medicinal products.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.6.

971 FDA	Drains are of an adequate size and, where connected directly to a sewer, are provided with an air break or other mechanical device to prevent back-siphonage.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.48 (b)

755 EC	Drains are of adequate size, and have trapped gullies. Open channels are avoided where possible, but if necessary, they are shallow to facilitate cleaning and disinfection.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.11.

972 FDA	Adequate washing facilities are provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accessible to working areas.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart C - Buildings and Facilities
21 CFR 211.52

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
776 EC	Facilities for changing clothes, and for washing and toilet purposes are easily accessible and appropriate for the number of users.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.31.

775 EC	Rest and refreshment rooms are separate from other areas.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.30.

779 EC	Whenever parts and tools are stored in the production area, they are kept in rooms or lockers reserved for that use.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.32.

751 EC	Premises are laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.	<input style="width: 60px; height: 20px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 60px; height: 20px;" type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.7.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
752 EC	<p>Adequate working and in-process storage space is provided to permit the orderly and logical positioning of equipment and materials so as to minimise the risk of confusion between different medicinal products or their components, to avoid cross-contamination and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.</p> <p style="color: red; font-size: small;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Production Area 3.8.</p>	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
N/A																
753 EC	<p>Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) are smooth, free from cracks and open joints, and do not shed particulate matter and permit easy and effective cleaning and, if necessary, disinfection.</p> <p style="color: red; font-size: small;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Production Area 3.9.</p>	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
N/A																
754 EC	<p>Pipework, light fittings, ventilation points and other services are designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they are accessible from outside the manufacturing areas.</p> <p style="color: red; font-size: small;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Production Area 3.10.</p>	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
N/A																
757 EC	<p>Weighing of starting materials is ("usually should be") carried out in a separate weighing room designed for that use.</p> <p style="color: red; font-size: small;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Production Area 3.13.</p>	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
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ViP CGMP Audit (Level 08)

(C1) Buildings and Facilities (Production Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
760 EC	Production areas are well lit, particularly where visual on-line controls are carried out.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.16.

761 EC	Where in-process controls are carried out within the production area, they do not carry any risk for the production.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Production Area 3.17.

(C2) Buildings and Facilities (Ancillary Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
777 EC	Toilets do not directly communicate with production or storage areas.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.31.

778 EC	Maintenance workshops are ("should as far as possible be") separated from production areas.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.32.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C2) Buildings and Facilities (Ancillary Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
780 EC	Animal houses are well isolated from other areas, with separate entrance (animal access) and air handling facilities.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Ancillary Areas 3.33.

(C3) Buildings and Facilities (Quality Control Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
771 EC	Quality Control laboratories are ("normally") separated from production areas. Laboratories for the control of biologicals, microbiologicals and radioisotopes, are also separated from each other.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Quality Control Areas 3.26.

772 EC	Control laboratories are designed to suit the operations to be carried out in them. Sufficient space is given to avoid mix-ups and cross-contamination. There is adequate suitable storage space for samples and records.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Quality Control Areas 3.27.

773 EC	Separate rooms have been provided, as necessary, to protect sensitive instruments from vibration, electrical interference, humidity, etc.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Quality Control Areas 3.28.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C3) Buildings and Facilities (Quality Control Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
774 EC	Special requirements are provided for, in laboratories handling particular substances, such as biological or radioactive samples.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Quality Control Areas 3.29.

(C4) Buildings and Facilities (Storage Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
762 EC	Storage areas are of sufficient capacity to allow orderly storage of the various categories of materials and products: starting and packaging materials, intermediate, bulk and finished products, products in quarantine, released, rejected, returned or recalled.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Storage Areas 3.18.

763 EC	Storage areas are designed or adapted to ensure good storage conditions. In particular, they are clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these are provided, checked and monitored.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Storage Areas 3.19.

764 EC	Receiving and dispatch bays protect materials and products from the weather.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Storage Areas 3.20.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C4) Buildings and Facilities (Storage Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
765 EC	Reception areas are designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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N/A																
<p style="color: red; font-size: small; margin: 0;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Storage Areas 3.20.</p>																
766 EC	Where quarantine status is ensured by storage in separate areas, these areas are clearly marked and their access restricted to authorised personnel. Any system replacing the physical quarantine gives equivalent security.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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N/A																
<p style="color: red; font-size: small; margin: 0;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Storage Areas 3.21.</p>																
767 EC	There is a ("should normally be a") separate sampling area for starting materials. If sampling is performed in the storage area, it is conducted in such a way as to prevent contamination or cross-contamination.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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<p style="color: red; font-size: small; margin: 0;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Storage Areas 3.22.</p>																
768 EC	Segregated areas are provided for the storage of rejected, recalled or returned materials or products.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
NC	1	2	3	4	5											
N/A																
<p style="color: red; font-size: small; margin: 0;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Storage Areas 3.23.</p>																
769 EC	Highly active materials or products are stored in safe and secure areas.	<input style="width: 80px; height: 25px;" type="text"/>	<table border="1" style="border-collapse: collapse; text-align: center;"> <tr> <td style="padding: 2px;">NC</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">4</td> <td style="padding: 2px;">5</td> </tr> <tr> <td style="padding: 2px;">N/A</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>	NC	1	2	3	4	5	N/A						<input style="width: 80px; height: 25px;" type="text"/>
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<p style="color: red; font-size: small; margin: 0;">EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Storage Areas 3.24.</p>																

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(C4) Buildings and Facilities (Storage Areas)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
770 EC	Special attention is paid to the safe and secure storage of printed packaging materials.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Storage Areas 3.25.

(D) Equipment (General)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
1078 FDA	Equipment used in the manufacture, processing, packing, or holding of a drug product is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart D - Equipment
21 CFR 211.63

781 EC	Manufacturing equipment is designed, located and maintained to suit its intended purpose.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.34.

786 EC	Equipment is installed in such a way as to prevent any risk of error or of contamination.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.38.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(D) Equipment (General)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
787 EC	Production equipment does not present any hazard to the products.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.39.

785 EC	Washing and cleaning equipment is chosen and used in order not to be a source of contamination.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.37.

793 EC	Defective equipment is, where possible, removed from production and quality control areas, or at least clearly labelled as defective.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.44.

(c) Validation in Partnership Ltd 2000

(D1) Equipment (Pipework)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
791 EC	Fixed pipework is clearly labelled to indicate the contents and, where applicable, the direction of flow.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.42.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(D1) Equipment (Pipework)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
792 EC	Distilled, deionized and, where appropriate, other water pipes are sanitised according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
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EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.43.

(D2) Equipment (Construction)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
1079 FDA	Equipment is constructed so that surfaces that contact components, in-process materials, or drug products are not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																

21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000)
Subpart D - Equipment
21 CFR 211.65 (a)

788 EC	The parts of the production equipment that come into contact with the product are not reactive, additive or absorptive to such an extent that it will affect the quality of the product and thus present any hazard.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																

EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997)
CHAPTER 3 - PREMISES AND EQUIPMENT
Premises - Equipment 3.39.

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(D2) Equipment (Construction)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
520 FDA	Any substances required for operation, such as lubricants or coolants, do not come into contact with components, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																
<p>21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart D - Equipment 21 CFR 211.65 (b)</p>																

(D3) Equipment (Cleaning & Maintenance)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
783 EC	Manufacturing equipment is designed so that it can be easily and thoroughly cleaned.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
NC	1	2	3	4	5											
N/A																
<p>EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Equipment 3.36.</p>																
782 EC	Repair and maintenance operations do not present any hazard to the quality of the products.	<input type="text"/>	<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						<input type="text"/>
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N/A																
<p>EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Equipment 3.35.</p>																

KEY: NC = Not Checked, N/A = Not Applicable, 1 = Minimum Compliance, 5 = Full Compliance

ViP CGMP Audit (Level 08)

(D4) Equipment (Filters)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
1081 FDA	Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use do not release fibers into such products. Fiber-releasing filters are only used in the manufacture, processing, or packing of injectable drug products when it is not possible to manufacture such drug products without the use of such filters. If use of a fiber-releasing filter is necessary, an additional non-fiber-releasing filter of 0.22 micron maximum mean porosity (0.45 micron if the manufacturing conditions so dictate) is subsequently be used to reduce the content of particles in the injectable drug product.		<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						
NC	1	2	3	4	5											
N/A																
<p>21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart D - Equipment 21 CFR 211.72</p>																

1082 FDA	Where an asbestos-containing filter is used, with or without subsequent use of a specific non-fiber-releasing filter, a submission of proof has been made to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the injectable drug product.		<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						
NC	1	2	3	4	5											
N/A																
<p>21 CFR PART 211 - CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS (April, 2000) Subpart D - Equipment 21 CFR 211.72</p>																

(D5) Equipment (Calibration)

Audit Ref:	Audit Point:	Observation:	Level of Compliance:	Initial:												
789 EC	Balances and measuring equipment of an appropriate range and precision are available for production and control operations.		<table border="1"><tr><td>NC</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr><tr><td>N/A</td><td></td><td></td><td></td><td></td><td></td></tr></table>	NC	1	2	3	4	5	N/A						
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N/A																
<p>EC GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (1997) CHAPTER 3 - PREMISES AND EQUIPMENT Premises - Equipment 3.40.</p>																

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