



# **Raw Material Evaluation**

|                     | Change Control No. |       | Evaluation No.    |
|---------------------|--------------------|-------|-------------------|
|                     |                    |       |                   |
| 1.0 PROCUREME       | NT                 |       |                   |
|                     |                    | Chang | ge Description    |
|                     | Current Material   |       | Proposed Material |
| Item Number         |                    |       |                   |
| Trade Name          |                    |       |                   |
| Material            |                    |       |                   |
| Classification      |                    |       |                   |
| Material Function   |                    |       |                   |
| Manufacturer        |                    |       |                   |
| Supplier            |                    |       |                   |
| Shelf-life          |                    |       |                   |
| Storage Condition   |                    |       |                   |
| Packaging           |                    |       |                   |
| Compendia Ref. /    |                    |       |                   |
| Version No.         |                    |       |                   |
| Reason for Change   |                    |       |                   |
|                     | Product Code       | Produ | act Name          |
|                     |                    |       |                   |
|                     |                    |       |                   |
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|                     |                    |       |                   |
| Products Affected   |                    |       |                   |
| Floducis Affected   |                    |       |                   |
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| Additional          |                    |       |                   |
| Comments            |                    |       |                   |
|                     |                    |       |                   |
|                     |                    |       |                   |
| 2.0 COMPLIANCE      | <u>.</u>           |       |                   |
| 2.1 Assessment of A |                    |       |                   |
| Identify affected   |                    |       |                   |
| markets             |                    |       |                   |



#### **Raw Material Evaluation**

| 2.2 Assessment of Existing Material   |
|---|
| Current Raw Material Specification Test Report has been verified to be compliant to applicable current - monograph. |
| □YES □ NO   |
| Comment:  |
|   |
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|   |
| 2.3 Proposed Material Assessment  |
| Certificate of Analysis (CoA) of proposed material has been verified and are compliant with current                 |
| applicable monograph and existing material RMSTR.   |
| □YES □ NO   |
|   |
| Record existing Material RMSTR NumberVersion:   |
| Record existing Material RMSTR NumberVersion:  Comments:  |
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|   |
| Comments:  RMSTR of proposed material created and are compliant with current applicable monograph and existing      |



## **Raw Material Evaluation**

| Comments:   |  |  |  |  |  |
|---|--|--|--|--|--|
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| Does this change require a Product Change Proposal (PCP)/ Product Change Request (PCR)? |  |  |  |  |  |
| □YES □ NO   |  |  |  |  |  |
| If NO, go to Section 2.4. If YES, go to Section 2.3.4.                                  |  |  |  |  |  |
| If 1 L5, go to Section 2.3.4.   |  |  |  |  |  |
| Enter when available the following information: PCP/PCR Number                          |  |  |  |  |  |
| And attach supporting information as required.  |  |  |  |  |  |
| PCP/PCR has been verified. It is closed and completed.                                  |  |  |  |  |  |
| □YES □ NO   |  |  |  |  |  |
|   |  |  |  |  |  |
| Comments:   |  |  |  |  |  |
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|   |  |  |  |  |  |
| Section 2.1 — 2.3 completed by:   |  |  |  |  |  |
| Name Position Signature Date  |  |  |  |  |  |
|   |  |  |  |  |  |
|   |  |  |  |  |  |
| 2.4 Stability Assessment  |  |  |  |  |  |
| Stability study requirement has been verified against market requirements and recorded  |  |  |  |  |  |
|   |  |  |  |  |  |
| □YES □ NO   |  |  |  |  |  |



### **Raw Material Evaluation**

| Markets                            | Stability Study Requirements     |   |                               |                 |  |
|------------------------------------|----------------------------------|---|-------------------------------|-----------------|--|
| 1                                  | ☐ Accelerated                    | □ On  | n going Stability Protoc      | col No.:        |  |
| 1                                  | 3 mths 12 mths                   | ☐ 6 m   | nths 9 mths 18 mths           | 48 mths 60 mths |  |
| 2                                  | ☐ Accelerated                    | □ On  | going Stability Protoc        | col No.:        |  |
| 2                                  | 3 mths 12 mths                   | ☐ 6 m   | nths 9 mths 18 mths           | 48 mths 60 mths |  |
| 3                                  | ☐ Accelerated                    | ☐ On going Stability Protocol No.:              |                               |                 |  |
| 3                                  | 3 mths 12 mths                   | ☐ 6 m   | nths 9 mths 18 mths           | 48 mths 60 mths |  |
| 4                                  | ☐ Accelerated                    | □ On  | n going Stability Protoc      | col No.:        |  |
| 4                                  | 3 mths 12 mths                   | ☐ 6 m   | nths 9 mths 18 mths           | 48 mths 60 mths |  |
| 5                                  | ☐ Accelerated                    | □ On  | n going Stability Protoc      | col No.:        |  |
| 3                                  | 3 mths 12 mths                   | ☐ 6 m   | nths 9 mths 18 mths           | 48 mths 60 mths |  |
| 6                                  | ☐ Accelerated                    | □ On  | going Stability Protoc        | col No.:        |  |
| Ü                                  | 3 mths 12 mths                   | ☐ 6 mths ☐ 9 mths ☐ 18 mths ☐ 48 mths ☐ 60 mths |                               |                 |  |
| 7                                  | ☐ Accelerated                    | ☐ On going Stability Protocol No.:              |                               |                 |  |
| ,                                  | 3 mths 12 mths                   | ☐ 6 mths ☐ 9 mths ☐ 18 mths ☐ 48 mths ☐ 60 mths |                               |                 |  |
| 8                                  | ☐ Accelerated                    | ☐ On going Stability Protocol No.:              |                               |                 |  |
| 0                                  | 3 mths 12 mths                   | ☐ 6 mths ☐ 9 mths ☐ 18 mths ☐ 48 mths ☐ 60 mths |                               |                 |  |
| 9                                  | ☐ Accelerated                    | □ On  | n going Stability Protoc      | col No.:        |  |
| ,                                  | 3 mths 12 mths                   | ☐ 6 mths ☐ 9 mths ☐ 18 mths ☐ 48 mths ☐ 60 mths |                               |                 |  |
| 10                                 | ☐ Accelerated ☐ 3 mths ☐ 12 mths |   | n going Stability Protocounts |                 |  |
| Section 2.4 complet                |                                  |   | inis   7 mais   10 mais       |                 |  |
| Name                               | Position                         |   | Signature                     | Date            |  |
|                                    |                                  |   | J                             |                 |  |
|                                    |                                  |   |                               |                 |  |
| 3.0 QUALITY ASSURANCE              |                                  |   |                               |                 |  |
| Manufacturer and/or Supplier Audit |                                  |   |                               |                 |  |



#### **Raw Material Evaluation**

| The manufacturer and/or supplier of the proposed material has been audited for manufacturing and/or supplying the proposed material. The following details have been recorded and the Memorandum of Quality Assurance Audit Report has been attached. |                        |                          |      |  |  |  |
|---|------------------------|--------------------------|------|--|--|--|
| □YES □ NO If NO, p  | provide comments in th | e Comments section below | v.   |  |  |  |
|   | Manufacturer           | Supplier                 |      |  |  |  |
| Date of Audit   |                        |                          |      |  |  |  |
| <b>Audit Rating</b>   |                        |                          |      |  |  |  |
| Date of Next Audit  |                        |                          |      |  |  |  |
| Report Number   |                        |                          |      |  |  |  |
| Comments:   | •                      |                          |      |  |  |  |
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| Section 3.0 completed by:   |                        |                          |      |  |  |  |
| Name  | Position               | Signature                | Date |  |  |  |
|   |                        |                          |      |  |  |  |
| 4.0 THIRD PARTY CONTI   |                        |                          |      |  |  |  |
| <b>4.1</b> The proposed material has been verified to be used by Third Party Contract Manufacturer.   |                        |                          |      |  |  |  |



#### **Raw Material Evaluation**

| ☐ YES ☐ NO If <b>YES</b> , list Produce Code, Product Name and Quantity of the proposed material used.   |   |               |  |                        |  |  |  |
|--|---|---------------|--|------------------------|--|--|--|
| Product Code   |   | Product Name  |  | Quantity Used (%W/W)   |  |  |  |
| Trouder Code   |   | 1 Toduct Name |  | Quantity Cscu (70 W/W) |  |  |  |
|  |   |               |  |                        |  |  |  |
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|  |   |               |  |                        |  |  |  |
| processing by Third Pa   | <b>4.2</b> The proposed material has been verified to be used in Semi-finished goods followed by further processing by Third Party Contract Manufacturer.  ☐ YES ☐ NO If <b>YES</b> , list Product Code, Product Name and Quantity of the proposed material used. |               |  |                        |  |  |  |
| <b>Product Code</b>  |   | Product Name  |  | Quantity Used (%W/W)   |  |  |  |
|  |   |               |  |                        |  |  |  |
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| If answered YES for either 4.1 or 4.2, complete the following section.   |   |               |  |                        |  |  |  |
| <b>4.3</b> The products affected have been verified to require validation by the Third Party Contract Manufacturer and the requirement has been communicated.  □ YES □ NO      |   |               |  |                        |  |  |  |
| Number of Batches Required   |   |               |  |                        |  |  |  |
| Concurrent/Prospective   |   |               |  |                        |  |  |  |
| Validation   |   |               |  |                        |  |  |  |
|  |   |               |  |                        |  |  |  |
| <b>4.4</b> The products affected have been verified to require stability study by the Third Party Contract Manufacturer and the requirement has been communicated.  □ YES □ NO |   |               |  |                        |  |  |  |



#### **Raw Material Evaluation**

| Stability Requiremen   | nt:             |               | ,                              |                          |  |
|------------------------|-----------------|---------------|--------------------------------|--------------------------|--|
| Section 4.0 complete   | d by:           |               |                                |                          |  |
| Name                   | Posi            | tion          | Signature                      | Date                     |  |
|                        |                 |               | -                              |                          |  |
|                        |                 |               |                                |                          |  |
|                        |                 |               |                                |                          |  |
| 5.0 QC RAW MATER       |                 |               |                                |                          |  |
| 5.1 Testing Requirem   |                 |               |                                |                          |  |
| Three batches of prop  | osed material   | have been tes | sted by Quality Control Lab    | poratory as per relevant |  |
| RIVISTR and all test s | pecifications r | nave being me | et. Test results are attached. | •                        |  |
| ☐ YES ☐ NO             |                 |               |                                |                          |  |
|                        |                 |               |                                |                          |  |
| Comment:               |                 |               |                                |                          |  |
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|                        |                 |               |                                |                          |  |



## **Raw Material Evaluation**

(Ref. SOP VAL-105)

| f YES, it is indicated as: (tick all that apply)  Carcinogen Highly Toxic Highly Reproductive hazard Volatile Lachrymator  5.3 Estimated annual usage:  5.4 Group approval required: YES NO  5.5 Dangerous Goods Information:  5.5.1 Class  5.5.2 Subsidiary risk  5.5.3 Packing group  5.5.4 UN No.   | Section 5.0 complet   | ed by:                        |                     |                      |  |  |
|--|-----------------------|-------------------------------|---------------------|----------------------|--|--|
| Norkplace Risk characterization has been completed or updated  YES NO Comment:    Assessment of Hazard   | Name                  | Position                      | Signature           | Date                 |  |  |
| Norkplace Risk characterization has been completed or updated  YES NO Comment:    Assessment of Hazard   |                       |                               |                     |                      |  |  |
| Norkplace Risk characterization has been completed or updated  YES NO Comment:    Assessment of Hazard   |                       |                               |                     |                      |  |  |
| Workplace Risk characterization has been completed or updated    YES   | 5.0 ENVIRONMEN        | TAL HEALTH AND SAI            | FETY CONSIDERATION  | 1                    |  |  |
| □ YES □ NO  Comment:   | 5.1 Workplace Risk    | characterization              |                     |                      |  |  |
| Comment:    Comment   Comm | Workplace Risk char   | racterization has been comp   | leted or updated    |                      |  |  |
| 5.2 Assessment of Hazard  s the proposed material is hazardous substance?  YES NO  f YES is it listed as a highly hazardous substance?  YES NO  f YES, it is indicated as: (tick all that apply)  Carcinogen Highly Toxic Highly Reproductive hazard Volatile Lachrymator  6.3 Estimated annual usage:  6.4 Group approval required: YES NO  6.5 Dangerous Goods Information:  6.5.1 Class  6.5.2 Subsidiary risk  6.5.3 Packing group  6.5.4 UN No.  6.5.5 Proper shipping name  6.6 Process Safety Impact Assessment Required: YES NO  |                       |                               |                     |                      |  |  |
| s the proposed material is hazardous substance?  YES   NO  f YES is it listed as a highly hazardous substance?  YES   NO  f YES, it is indicated as: (tick all that apply)  Carcinogen   Highly Toxic   Highly Reproductive hazard   Volatile Lachrymator  5.3 Estimated annual usage:  6.4 Group approval required:   YES   NO  6.5 Dangerous Goods Information:  6.5.1   Class    6.5.2   Subsidiary risk    6.5.3   Packing group    6.5.4   UN No.  6.5.5.5   Proper shipping name    6.6 Process Safety Impact Assessment Required:   YES   NO  | Comment:              |                               |                     |                      |  |  |
| s the proposed material is hazardous substance?  YES   NO  f YES is it listed as a highly hazardous substance?  YES   NO  f YES, it is indicated as: (tick all that apply)  Carcinogen   Highly Toxic   Highly Reproductive hazard   Volatile Lachrymator  5.3 Estimated annual usage:  6.4 Group approval required:   YES   NO  6.5 Dangerous Goods Information:  6.5.1   Class    6.5.2   Subsidiary risk    6.5.3   Packing group    6.5.4   UN No.  6.5.5.5   Proper shipping name    6.6 Process Safety Impact Assessment Required:   YES   NO  |                       |                               |                     |                      |  |  |
| s the proposed material is hazardous substance?  YES   NO  f YES is it listed as a highly hazardous substance?  YES   NO  f YES, it is indicated as: (tick all that apply)  Carcinogen   Highly Toxic   Highly Reproductive hazard   Volatile Lachrymator  5.3 Estimated annual usage:  6.4 Group approval required:   YES   NO  6.5 Dangerous Goods Information:  6.5.1   Class    6.5.2   Subsidiary risk    6.5.3   Packing group    6.5.4   UN No.  6.5.5.5   Proper shipping name    6.6 Process Safety Impact Assessment Required:   YES   NO  |                       |                               |                     |                      |  |  |
| s the proposed material is hazardous substance?  YES   NO  f YES is it listed as a highly hazardous substance?  YES   NO  f YES, it is indicated as: (tick all that apply)  Carcinogen   Highly Toxic   Highly Reproductive hazard   Volatile Lachrymator  5.3 Estimated annual usage:  6.4 Group approval required:   YES   NO  6.5 Dangerous Goods Information:  6.5.1   Class    6.5.2   Subsidiary risk    6.5.3   Packing group    6.5.4   UN No.  6.5.5.5   Proper shipping name    6.6 Process Safety Impact Assessment Required:   YES   NO  |                       |                               |                     |                      |  |  |
| YES □ NO  f YES is it listed as a highly hazardous substance? □ YES □ NO  f YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  i.3 Estimated annual usage: □ 5.4 Group approval required: □ YES □ NO  i.5.1 Class i.5.2 Subsidiary risk i.5.3 Packing group i.5.4 UN No. i.5.5 Proper shipping name i.6 Process Safety Impact Assessment Required: □ YES □ NO   | 5.2 Assessment of H   | lazard                        |                     |                      |  |  |
| YES □ NO  f YES is it listed as a highly hazardous substance? □ YES □ NO  f YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  6.3 Estimated annual usage: □ 5.4 Group approval required: □ YES □ NO  6.5.1 Class 6.5.2 Subsidiary risk 6.5.3 Packing group 6.5.4 UN No. 6.5.5 Proper shipping name  6.6 Process Safety Impact Assessment Required: □ YES □ NO  | s the proposed mate   | rial is hazardous substance?  | )                   |                      |  |  |
| f YES is it listed as a highly hazardous substance?    YES   |                       | itai is iiazaidous substance: |                     |                      |  |  |
| TYES □ NO  If YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  If YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  If YES □ NO  If YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  If YES □ NO  If YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Reproductive hazard □ Volatile Lachrymator  If YES □ NO  If YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Reproductive hazard □ Volatile Lachrymator  If YES □ NO  If YES, □ NO   |                       |                               |                     |                      |  |  |
| TYES □ NO  f YES, it is indicated as: (tick all that apply) □ Carcinogen □ Highly Toxic □ Highly Reproductive hazard □ Volatile Lachrymator  6.3 Estimated annual usage: □ NO  6.4 Group approval required: □ YES □ NO  6.5 Dangerous Goods Information:  6.5.1 Class 6.5.2 Subsidiary risk 6.5.3 Packing group 6.5.4 UN No. 6.5.5 Proper shipping name  6.6 Process Safety Impact Assessment Required: □ YES □ NO   | f YES is it listed as | a highly hazardous substance  | ce?                 |                      |  |  |
| Carcinogen ☐ Highly Toxic ☐ Highly Reproductive hazard ☐ Volatile Lachrymator  5.3 Estimated annual usage: ☐ YES ☐ NO  5.5 Dangerous Goods Information:  5.5.1 Class  5.5.2 Subsidiary risk  5.5.3 Packing group  5.5.4 UN No.  5.5.5 Proper shipping name  5.6 Process Safety Impact Assessment Required: ☐ YES ☐ NO  |                       |                               |                     |                      |  |  |
| Carcinogen ☐ Highly Toxic ☐ Highly Reproductive hazard ☐ Volatile Lachrymator  5.3 Estimated annual usage: ☐ YES ☐ NO  5.5 Dangerous Goods Information:  5.5.1 Class  5.5.2 Subsidiary risk  5.5.3 Packing group  5.5.4 UN No.  5.5.5 Proper shipping name  5.6 Process Safety Impact Assessment Required: ☐ YES ☐ NO  |                       |                               |                     |                      |  |  |
| 5.3 Estimated annual usage:  |                       | 11 .                          | D                   | V-1-41- I1           |  |  |
| 5.4 Group approval required:   S.5 Dangerous Goods Information:  S.5.1 Class  S.5.2 Subsidiary risk  S.5.3 Packing group  S.5.4 UN No.  S.5.5 Proper shipping name  S.6 Process Safety Impact Assessment Required:   YES   NO  |                       |                               | Reproductive nazard | Volatile Lachrymator |  |  |
| 5.5 Dangerous Goods Information:  5.5.1 Class  5.5.2 Subsidiary risk  6.5.3 Packing group  6.5.4 UN No.  6.5.5 Proper shipping name  6.6 Process Safety Impact Assessment Required:     YES   NO   | 5.3 Estimated annu    | al usage:                     |                     |                      |  |  |
| 5.5.1 Class 5.5.2 Subsidiary risk 5.5.3 Packing group 5.5.4 UN No. 6.5.5 Proper shipping name 6.6 Process Safety Impact Assessment Required:   | 5.4 Group approval    | l required: 🗆 YES 🗆 NO        | )                   |                      |  |  |
| 5.5.2 Subsidiary risk 5.5.3 Packing group 5.5.4 UN No. 6.5.5 Proper shipping name 6.6 Process Safety Impact Assessment Required:   | 6.5 Dangerous Goo     | ds Information:               |                     |                      |  |  |
| 5.5.3 Packing group 5.5.4 UN No. 5.5.5 Proper shipping name 6.6 Process Safety Impact Assessment Required:   | 6.5.1 Class           |                               |                     |                      |  |  |
| 5.5.4 UN No. 5.5.5 Proper shipping name 5.6 Process Safety Impact Assessment Required:     YES   NO  | 5.5.2 Subsidiary r    | isk                           |                     |                      |  |  |
| 5.5.5 Proper shipping name  6.6 Process Safety Impact Assessment Required:     YES   NO  | 5.5.3 Packing gro     | Packing group                 |                     |                      |  |  |
| 5.6 Process Safety Impact Assessment Required:   YES  NO   | 5.5.4 UN No.          | UN No.                        |                     |                      |  |  |
| · · · — —  | 5.5.5 Proper shipp    | 7.5 Proper shipping name      |                     |                      |  |  |
| Comment:   | 5.6 Process Safety Ir | mpact Assessment Required     | : ☐ YES ☐ NO        |                      |  |  |
| Johnnent.  | <br>Comment:          |                               |                     |                      |  |  |
|  | Jumment:              |                               |                     |                      |  |  |
|  |                       |                               |                     |                      |  |  |

File Location: WWW.gmpsop.com Date Printed: Page 8 of 10



#### **Raw Material Evaluation**

| Section 6.0 completed by:       |                             |                              |       |  |  |
|---------------------------------|-----------------------------|------------------------------|-------|--|--|
| Name                            | Position                    | Signature                    | Date  |  |  |
|                                 |                             |                              |       |  |  |
|                                 |                             |                              |       |  |  |
| 7.0 VALIDATION /                | TECHNICAL SERVICE           | S                            |       |  |  |
| 7.1 Qualification / Val         | lidation assessment has bee | en completed YES             | □NO   |  |  |
| Qualification/validation        | on required? YES I          | NO                           |       |  |  |
| If <b>YES</b> , list product co | ode and product name that   | require qualification/valida | tion. |  |  |
| Product Code                    |                             | Product Name                 |       |  |  |
|                                 |                             |                              |       |  |  |
|                                 |                             |                              |       |  |  |
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| Comment:                        |                             |                              |       |  |  |
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|                                 |                             |                              |       |  |  |
|                                 |                             |                              |       |  |  |
| Section 7.0 completed by:       |                             |                              |       |  |  |
| Name                            | Position                    | Signature                    | Date  |  |  |
|                                 |                             |                              |       |  |  |
|                                 |                             |                              |       |  |  |



## **Raw Material Evaluation**

| 8.0 RE                    | 8.0 RECOMMENDATIONS   |   |                                |             |  |  |
|---------------------------|---|---|--------------------------------|-------------|--|--|
| 8 1                       | Validation will be performed as per the relevant protocol for the products identified in Section 8.1.1 of this raw material evaluation. ☐ YES ☐ N/A   |   |                                |             |  |  |
| 8.2                       | laboratory as per   | vill be performed on validation the market requirements and on 2.4.1 of this raw material | the relevant stability protoco | ols YES N/A |  |  |
| Comm                      | ent:  |   |                                |             |  |  |
|                           |   |   |                                |             |  |  |
| Section                   | 8.0 completed b   | py:   |                                |             |  |  |
|                           | Name  | Position  | Signature                      | Date        |  |  |
|                           |   |   |                                |             |  |  |
| 9.0 CO                    | NCLUSION  |   |                                |             |  |  |
| 9.1                       | 9.1 The raw material evaluation study indicated that the proposed material is comparable / not comparable (choose either one) to the existing material and is deemed suitable / not suitable for use at the site for the drug products listed in Section 1 of this raw material evaluation. |   |                                |             |  |  |
| Comment:                  |   |   |                                |             |  |  |
| Section 9.0 completed by: |   |   |                                |             |  |  |
|                           | Name Position Signature Date  |   |                                |             |  |  |
|                           |   |   |                                |             |  |  |