


| | | |
|-------------------------------|----|-------------------------------------------------------------------------------------------------------------------------------------------|
| PRODUCT QUALITY REVIEW REPORT | | <div>CONNEXO</div> <div>SMARTER DATA</div> <div></div> |
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General Information

| | |
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| PRODUCT CODE | |
| REVIEW PERIOD | |
| MFG. LIC. No. | |

Manufacturing Site Address

| | | |
|--------------|---------|---------|
| Product Name | SFGCode | FG Code |
|--------------|---------|---------|

Manufacturing Site Address Summary :-

Manufacturing Site Address 2

| | | | |
|--------------|------------|---------|---------|
| Product Name | Batch Code | SFGCode | remarks |
|--------------|------------|---------|---------|

Manufacturing Site Address 2 Summary:-

Warehouse Review

Review of Rejected Raw Materials and Packaging Materials

Raw Materials Rejection Grid

| | | | | | |
|-------|---------------|---------------|--------------|----------------------|-------------|
| SI No | Material Code | Material Name | Lot No/AR No | Reason For Rejection | Description |
|-------|---------------|---------------|--------------|----------------------|-------------|

Raw Materials Rejection Summary :-

Packing Materials Rejection Grid

| | | | | | |
|-------|---------------|---------------|--------------|----------------------|-------------|
| SI No | Material Code | Material Name | Lot No/AR No | Reason For Rejection | Description |
|-------|---------------|---------------|--------------|----------------------|-------------|


Packaging Materials Rejection Summary :-

Review of Expired Raw Materials and Packaging Materials

Expired Raw Materials Details

| | | | | |
|-------|---------------|---------------|--------------|-------------|
| SI No | Material Code | Material Name | Lot No/AR No | Expiry Date |
|-------|---------------|---------------|--------------|-------------|

Expired Raw Materials Summary :-

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Expired Packaging Materials Details

| SI No | Material Code | Material Name | Lot No/AR No | Expiry Date |
|-------|---------------|---------------|--------------|-------------|
|-------|---------------|---------------|--------------|-------------|

Expired Packaging Materials Summary :-

Review of Approved Supplier List:

| SI No | Material Code | Material Name | Manufacturer / Supplier / Vendor | Facility |
|-------|---------------|---------------|----------------------------------|----------|
|-------|---------------|---------------|----------------------------------|----------|

Summary of Review of Approved Supplier List :-

Vendor Qualification Details of Raw Material Excipients

| Material Name | Material Code | Manufacturer Name | Qualification Status | remarks |
|---------------|---------------|-------------------|----------------------|---------|
|---------------|---------------|-------------------|----------------------|---------|

Summary of Vendor Qualification Details of Raw Material Excipients :-

Vendor Qualification Details of Primary Packing Materials

| Material Name | Material Code | Manufacturer Name | Qualification Status |
|---------------|---------------|-------------------|----------------------|
|---------------|---------------|-------------------|----------------------|

Summary of Vendor Qualification Details of Primary Packing Materials :-

Vendor Qualification Details of Process Gases

| Gas Name | Gas Code | Manufacturer Name | Qualification Status |
|----------|----------|-------------------|----------------------|
|----------|----------|-------------------|----------------------|


Summary of Vendor Qualification Details of Process Gases :-

Manufacturing Review

| | |
|---------------------|--|
| PRODUCT DESCRIPTION | |
| Process Flow | |

Review of all Batches Manufactured

| | |
|--------------------------------------------------------------------|---|
| TOTAL NO. OF BATCHES MANUFACTURED DURING THE CURRENT REVIEW PERIOD | 0 |
| TOTAL NO. OF BATCHES APPROVED & RELEASED | |

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| | |
|-----------------------------------------|--|
| TOTAL NO. OF PROCESS VALIDATION BATCHES | |
| TOTAL NO. OF REPROCESSED BATCHES | |

Process Validation Batches Details:-

Reprocessing Details :-

Microbial Excursion Details :-

Code to code transfer details

| SL NO | BATCH NUMBER | EXISTING CODE | EXISTING MARKET | PROPOSED CODE | PROPOSED MARKET | TRANSFTER QUANTITY | REF NO |
|-------|--------------|---------------|-----------------|---------------|-----------------|--------------------|--------|
|-------|--------------|---------------|-----------------|---------------|-----------------|--------------------|--------|

Summary of Code to Code Transfer Details :-

Review of Manufacturing Process, Packing Process and relevant Validation Status :-

Review of Reprocessing/Repacking/Reworking along with CAPA and Effectiveness Check Verification (if any)

Batch reprocessing/reworking process Details :-

Batch Repacking Details :-

Review of Reprocessing/Repacking/Reworking Grid

| SL NO | PACKING BATCH NUMBER | MANUFACTURIN BATCH NUMBER | REPACKING ISSUED NUMBER | REPACKING FOR | QMS | REASON FOR REPACKING |
|-------|----------------------|---------------------------|-------------------------|---------------|-----|----------------------|
|-------|----------------------|---------------------------|-------------------------|---------------|-----|----------------------|


Review of Reprocessing/Repacking/Reworking Summary :-

Capa Details

| AR NO | CAPATYPE | DESCRIPTION OF ISSUE | ROOT CAUSE | CAPA VERIFICATION | FILE ATTACHMENT | REMARKS |
|-------|----------|----------------------|------------|-------------------|-----------------|---------|
|-------|----------|----------------------|------------|-------------------|-----------------|---------|

Summary of CAPA Details :-

Deviation Details

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| AR NO | DEVIATION RELATED TO | DESCRIPTION | ROOT CAUSE | DEVIATION OVSRVED ON | DEVIATION OVSRVED BY | CLASSIFICATION OF DEVIATION | FILE ATTACHMENT | REMARKS | STATUS |
|-------|----------------------|-------------|------------|----------------------|----------------------|-----------------------------|-----------------|---------|--------|
|-------|----------------------|-------------|------------|----------------------|----------------------|-----------------------------|-----------------|---------|--------|

Summary of Deviation Details :-

Review of all Batch Failures/Rejections along with CAPA and Effectiveness Check Verification (if any):

Batch Failures/Rejections Details :-

OOS Details

| AR NO | TEST NAME OF OOS | RESULTS OBTAINED | SPECIFICATION LIMIT | DETAILS OF OBVIOUS ERROR | FILE ATTACHMENT |
|-------|------------------|------------------|---------------------|--------------------------|-----------------|
|-------|------------------|------------------|---------------------|--------------------------|-----------------|

Summary of OOS Details :-

OOT Results

| AR NO | TEST NAME OF OOT | RESULTS OBTAINED | INITIAL INTERVAL DETAILS | PREVIOUS INTERVAL DETAILS | % DIFFERENCE OF DETAILS | TREND ALERT |
|-------|------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|
|-------|------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|

Summary of OOT Details :-

OOA Results

| AR NO | TEST NAME OF ALERT | RESULTS OBTAINED | INITIAL INTERVAL DETAILS | PREVIOUS INTERVAL DETAILS | % DIFFERENCE OF DETAILS | TREND ALERT |
|-------|--------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|
|-------|--------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|

Summary of OOA Details :-


OOL Results

| AR NO | TEST NAME OF OOL | RESULTS OBTAINED | INITIAL INTERVAL DETAILS | PREVIOUS INTERVAL DETAILS | % DIFFERENCE OF DETAILS | TREND ALERT |
|-------|------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|
|-------|------------------|------------------|--------------------------|---------------------------|-------------------------|-------------|

Summary of OOL Details :-

Review of Product Quality (Critical Process Parameters)

Unit Operation 1

| | | |
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| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 2

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 3

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 4

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 5

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 6

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 7

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 8

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |


Unit Operation 9

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Unit Operation 10

| CRITICAL PROCESS PARAMETER | CODES | ACCEPTANCE CRITERIA | RESULTS | | COMPLIES / DOES NOT COMPLIES |
|-------------------------------|-------|------------------------|---------|---------|---------------------------------|
| | | | Minimum | Maximum | |

Critical Process Parameters Review Summary :-

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Laboratory Review

Review of Drug Substance Test Results

pH Of Paracetamol Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Assay Of Paracetamol Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Impurity Of Paracetamol Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Dissolution Of Paracetamol Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Disintegration Of Paracetamol Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

pH Of Terbinafine Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Assay Of Terbinafine Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Impurity Of Terbinafine Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Dissolution Of Terbinafine Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|


Disintegration Of Terbinafine Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

pH Of Pentoprazole Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Assay Of Pentoprazole Test Result

| PRODUCT QUALITY REVIEW REPORT | | <div><div>CONNEXO</div><div>SMARTER DATA</div></div> |
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| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Impurity Of Pentoprazole Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Dissolution Of Pentoprazole Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Disintegration Of Pentoprazole Test Result

| BATCH NO | TESTS PARAMETER | LSL | USL | LCL | UCL | OBSERVED VALUE | COMPLIES / DOES NOT COMPLIES |
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|
|----------|-----------------|-----|-----|-----|-----|----------------|------------------------------|

Summary of Review of Drug Substance Test Results :-

Review of Raw Material Excipient Test Results

| SL. NO | MATERIAL | TEST PARAMETER | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|----------|----------------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Summary of Review of Raw Material Excipient Test Results:-

Review of Packing Material Test Results

| SL. NO | PRIMARY PACKING MATERIAL | TEST PARAMETER | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|--------------------------|----------------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Summary of Review of Packing Material Test Results :-

Dilution Buffer 1 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |


Dilution Buffer 2 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 3 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 4 - Test Results

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| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 5 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 6 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 7 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 8 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 9 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Dilution Buffer 10 - Test Results

| SL. NO | TESTS PARAMETER | STAGE | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|-------|---------------------|----------------|---------|------------------------------|
| | | | | Minimum | Maximum | |

Summary of Review of Drug Product – In process Test Results :-


Review of Drug Product –Finished Product Test Results

| SL. NO | TESTS PARAMETER | SPECIFICATION LIMIT | OBTAINED VALUE | | COMPLIES / DOES NOT COMPLIES |
|--------|-----------------|---------------------|----------------|---------|------------------------------|
| | | | Minimum | Maximum | |

Summary of Review of Drug Product –Finished Product Test Results :-

Summary of Ongoing Stability Studies

| SL. NO | BATCH NO. | TYPE | STORAGE CONDITION | TESTING INTERVALS MONTHS COMPLETED | STABILITY PROTOCOL NO. |
|--------|-----------|------|-------------------|------------------------------------|------------------------|
|--------|-----------|------|-------------------|------------------------------------|------------------------|

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Summary of Ongoing Stability Studies :-

Stability Study Related OOS/OOT

| SL. NO | BATCH NO. | TESTING INTERVALS MONTHS | OOS NUMBER |
|--------|-----------|--------------------------|------------|
|--------|-----------|--------------------------|------------|

Summary of Stability Study Related OOS/OOT:-

Review of Visual Inspection – Reserve Samples

| COLUMN 1 | COLUMN 2 | COLUMN 3 | COLUMN 4 | COLUMN 5 | COLUMN 6 | COLUMN 7 | COLUMN 8 |
|----------|----------|----------|----------|----------|----------|----------|----------|
|----------|----------|----------|----------|----------|----------|----------|----------|

Summary of Review of Visual Inspection – Reserve Samples:-

Summary of Review of Analytical Method Validations:-

Summary of Review of Contract Testing Laboratories:-

Summary of Review of Environmental Monitoring Trend and water trends Reports :-

Laboratory Review Summary :-

Engineering And Maintenance Review

Preventive Maintenance Details

Summary of Review of Preventive Maintenance Details :-

Summary of Qualification details :-


Summary of Calibration Details :-

HVAC Qualification Status

| SL. NO | TEST DESCRIPTION | FREQUENCY | STATUS |
|--------|------------------|-----------|--------|
|--------|------------------|-----------|--------|

Summary of HVAC Qualification Status :-

Sanitization and Sterilization Details of Utilities

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| SL. NO | EQUIPMENT NAME | FREQUENCY | STATUS |
|--------|----------------|-----------|--------|
|--------|----------------|-----------|--------|

Summary of Sanitization and Sterilization Details of Utilities :-

Compressed Gases

| SL. NO | COMPRESSED GAS | TEST | FREQUENCY | STATUS |
|--------|----------------|------|-----------|--------|
|--------|----------------|------|-----------|--------|

Engineering Summary

Summary of Engineering :-

Quality System Review

Review of Deviations

Review of Current Period Deviations

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Previous Review Period Deviations

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Summary of Review of period Deviations :-

Review of OOS (Microbiological)

Current Review Period OOS

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Previous Review Period OOS


| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

OOS Summary

Summary of OOS :-

Review of OOAC (Microbiological)

Current Review Period OOAC

| | | |
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|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Previous Review Period OOAC

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Summary of OOAC :-

Review of OOAL(Microbiological)

Current Review Period OOAL

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Previous Review Period OOAL

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Summary of OOAL :-

Review of OOS (Analytical)

Current review period OOS

Previous review period OOS

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Summary of OOSA :-

Review of OOT (Analytical)


Current Review Period OOT

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|

Previous Review Period OOS

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
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Summary of OOT :-

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Review of Change Controls

Current Review Period Change Controls

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |

Previous Review Period Change Controls

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |

Summary of Change Control :-

Review of Lab Incident

Current Review Lab Incident

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |

Previous Review Lab Incident

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |

Summary of Lab Incident :-

Review of Market Complaints

Current Review Period Complaints

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |


Previous Review Period Complaints

| S. NO | DATE OF INITIATION | RECORD NO | SITE/DIVISION | DEPARTMENT | INITIATOR | SHORT DESCRIPTION | BATCH NO | DUE DATE | CURRENT STATUS |
|-------|--------------------|-----------|---------------|------------|-----------|-------------------|----------|----------|----------------|
| | | | | | | | | | |

Summary of Market Complaints :-

Quality Related Notification

Current Review Period Quality Related Notification

| PRODUCT QUALITY REVIEW REPORT | | <div> <div>CONNEXO</div> <div>SMARTER DATA</div> <div>  </div> </div> |
|-------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| PQR NO. | 18 | |
| PRODUCT NAME | | |
| GENERIC NAME | | |
| PRODUCT CODE | | |

| SL. NO. | BATCH NO. | QUALITY RELATED NOTIFICATION | | | | CAPA | | |
|---------|-----------|------------------------------|-------------|--------|--------|-----------------|--------|----|
| | | No. | Description | Impact | Status | Description No. | Status | EC |

Summary of previous Review Period Quality Related Notification :-

Summary of Review of Product Recalls :-

Summary of Review of Returned Products :-

Summary of Review of Salvaged Drugs :-

Summary of Review of previous PQR recommendations :-

Summary of Review of Quality Agreements :-

Summary of Review of Manufacturing Authorizations :-

Summary of Review of Open Validations :-

Regulatory Review

Dossier variation details

| SL. NO | AGENCY | NOTIFICATION NO | NOTIFICATION TYPE | DESCRIPTION |
|--------|--------|-----------------|-------------------|-------------|
|--------|--------|-----------------|-------------------|-------------|

Summary of Dossier variation details :-

New marketing authorisation


| SL. NO | COUNTRY NAME | DESCRIPTION OF PACKING | DATE OF APPLICATION | STATUS OF APPLICATION | DATE OF AUTHORIZATION | REMARKS |
|--------|--------------|------------------------|---------------------|-----------------------|-----------------------|---------|
|--------|--------------|------------------------|---------------------|-----------------------|-----------------------|---------|

Summary of New marketing authorisation:-

Recommendations

Recommendations Summary

Summary of Recommendations :-

| PRODUCT QUALITY REVIEW REPORT | | <div> <div>CONNEXO</div> <div>SMARTER DATA</div> </div> <div>  </div> |
|-------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| PQR NO. | 18 | |
| PRODUCT NAME | | |
| GENERIC NAME | | |
| PRODUCT CODE | | |

Discussion, Evaluation And Conclusion

Discussion Evaluation and Conclusion

Summary of Discussion, Evaluation And Conclusion :-

List Of Annexures/Attachments

Annexure 1 :-

Annexure 2 :-

Annexure 3 :-

Annexure 4 :-

Annexure 5 :-

Annexure 6 :-

Annexure 7 :-

Annexure 8 :-

Annexure 9 :-

Annexure 10 :-


Annexure 11 :-

Annexure 12 :-

Annexure 13 :-

Annexure 14 :-

Annexure 15 :-

| PRODUCT QUALITY REVIEW REPORT | | <div> <div>CONNEXO</div> <div>SMARTER DATA</div> </div> <div>  </div> |
|-------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| PQR NO. | 18 | |
| PRODUCT NAME | | |
| GENERIC NAME | | |
| PRODUCT CODE | | |

Annexure 16 :-

Annexure 17 :-

Annexure 18 :-

Annexure 19 :-

Annexure 20 :-