



**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC SIX HEAD LIQUID  
FILLING AND SEALING MACHINE**

|                                |                                 |
|--------------------------------|---------------------------------|
| <b>EQUIPMENT ID No.</b>        |                                 |
| <b>LOCATION</b>                | <b>Filling and Sealing Room</b> |
| <b>DATE OF QUALIFICATION</b>   |                                 |
| <b>SUPERSEDES PROTOCOL No.</b> | <b>NIL</b>                      |



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**1.0 REPORT PRE- APPROVAL:**

**PREPARED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|------------------------------------------|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|------------------------------------------|------|-----------|------|
| OPERATING MANAGER<br>(QUALITY ASSURANCE) |      |           |      |
| HEAD<br>(ENGINEERING)                    |      |           |      |

**APPROVED BY:**

| DESIGNATION          | NAME | SIGNATURE | DATE |
|----------------------|------|-----------|------|
| HEAD<br>(PRODUCTION) |      |           |      |



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**2.0 OBJECTIVE:**

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

**3.0 SCOPE:**

- The Protocol covers all aspects of Performance Qualification for the Automatic Six Head Liquid Filling and Sealing machine.
- This Protocol will define the methods and documentation used to qualify the Automatic Six Head Liquid Filling and Sealing machine for PQ.



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**4.0 RESPONSIBILITY:**

The Qualification team, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

| DEPARTMENTS       | RESPONSIBILITIES                                                                                                                                                                                                                                                                                                            |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality Assurance | <ul style="list-style-type: none"><li>• Preparation, Review, Authorization and Compilation of the Performance Qualification Protocol.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li></ul> |
| Production        | <ul style="list-style-type: none"><li>• Review &amp; Approval of Protocol.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>                                                                                                                                                               |
| Engineering       | <ul style="list-style-type: none"><li>• Reviewing of qualification Protocol for correctness, completeness and technical excellence.</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li></ul>                                |
| Quality Control   | <ul style="list-style-type: none"><li>• Review &amp; analytical Support of Performance Qualification report.</li><li>• Approval of report post approval.</li></ul>                                                                                                                                                          |

**5.0 EQUIPMENT DETAILS:**

|                          |                                                       |
|--------------------------|-------------------------------------------------------|
| Equipment Name           | Automatic Six Head Liquid Filling and Sealing machine |
| Equipment ID.            |                                                       |
| Manufacturer's Name      |                                                       |
| Supplier's Name          |                                                       |
| Location of Installation | Filling and Sealing room                              |



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**6.0 SYSTEM DESCRIPTION:**

The Automatic Six Head Filling and Sealing machine is Divide into two Parts.

**Filling Process:**

The Six Head Automatic Filling machine Shall be Used to Filling by six head also work on Volumetric filling Principal, Whom fills with the help of vacuum and maintain the level of liquid in bottles on specified size and shape of bottles.

It is Comprises of Main Electric Panel with VFD, Relay, Operating panel, emergency switch & Push buttons, Nozzles Drive Assembly, Mechanical Stoppering System & Mechanical operation with motor gear box, cam, gears etc.

**Sealing Process:**

The Equipment shall be used to sealing with die by six head on specified size & shape of Bottle. Machines are equipped with cap feeder system for Continuous trouble free cap feeding.

It Comprises of Conveyer unit , Worm Assy, Star plate set sealing head Assy, Vibrator Bowl, Control Panel.



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**7.0 PRE-QUALIFICATION REQUIREMENTS:**

**7.1 SYSTEM PRE-REQUISITES:**

Verify that the DQ / IQ / OQ of the Automatic Six Head Liquid Filling and Sealing machine have been executed and approved.

Verify that the SOP for Operating, Cleaning and Preventive Maintenance of the Automatic Six Head Liquid Filling and Sealing machine has been prepared.

| S.No. | DESCRIPTION OF PRE-REQUISITE                                                             | COMPLETED (YES / NO) | CHECKED BY ENGINEERING SIGN / DATE | VERIFIED BY QA SIGN / DATE |
|-------|------------------------------------------------------------------------------------------|----------------------|------------------------------------|----------------------------|
| 1.    | DQ Protocol Document No.:                                                                |                      |                                    |                            |
| 2.    | IQ Protocol Document No.:                                                                |                      |                                    |                            |
| 3.    | OQ Protocol Document No.:                                                                |                      |                                    |                            |
| 4.    | SOP of "Operation and Cleaning of Automatic Six Head Liquid Filling and Sealing machine" |                      |                                    |                            |

**Checked By**  
**Production**  
**Sign / Date:** \_\_\_\_\_

**Verified By**  
**Quality Assurance**  
**Sign / Date:** \_\_\_\_\_

**Inference:**.....  
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**Reviewed By**  
**Manager QA**  
**Sign / Date:** \_\_\_\_\_



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**8.0 TESTS & CHECKS:**

**8.1 Performance Evaluation For Machine Speed Optimization:**

**Trial No.: 01**

|                                     |                           |                              |                            |
|-------------------------------------|---------------------------|------------------------------|----------------------------|
| <b>Date of Test</b>                 |                           | <b>Equipment ID</b>          |                            |
| <b>Total Bottles taken for test</b> |                           | <b>Bottle Size</b>           |                            |
| <b>Parameter</b>                    | <b>Low Speed (      )</b> | <b>Optimum Speed(      )</b> | <b>High Speed (      )</b> |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Total rejection</b>              |                           |                              |                            |

**Checked By**  
**Production**  
**Sign/Date: .....**

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**PROTOCOL No.:**

**Trial No.: 02**

|                                     |                           |                              |                            |
|-------------------------------------|---------------------------|------------------------------|----------------------------|
| <b>Date of Test</b>                 |                           | <b>Equipment ID</b>          |                            |
| <b>Total Bottles taken for test</b> |                           | <b>Bottle Size</b>           |                            |
| <b>Parameter</b>                    | <b>Low Speed (      )</b> | <b>Optimum Speed(      )</b> | <b>High Speed (      )</b> |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Total rejection</b>              |                           |                              |                            |

**Checked By**  
**Production**  
**Sign/Date: .....**

**Verified By**  
**Quality Assurance**  
**Sign/Date:.....**

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**PROTOCOL No.:**

**Trial No.: 03**

|                                     |                           |                              |                            |
|-------------------------------------|---------------------------|------------------------------|----------------------------|
| <b>Date of Test</b>                 |                           | <b>Equipment ID</b>          |                            |
| <b>Total Bottles taken for test</b> |                           | <b>Bottle Size</b>           |                            |
| <b>Parameter</b>                    | <b>Low Speed (      )</b> | <b>Optimum Speed(      )</b> | <b>High Speed (      )</b> |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Sample after .....( min)</b>     |                           |                              |                            |
| <b>Machine jam</b>                  |                           |                              |                            |
| <b>Bottle Breakage</b>              |                           |                              |                            |
| <b>Rejection</b>                    |                           |                              |                            |
| <b>Total rejection</b>              |                           |                              |                            |

**Checked By**  
**Production**  
**Sign/Date: .....**

**Verified By**  
**Quality Assurance**  
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**Inference:**

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| Nozzle No.     | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|----------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|                |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
| Max. fill vol. |            |                                |        |       |                                      |        |       |                                   |        |       |
| Avg. vol.      |            |                                |        |       |                                      |        |       |                                   |        |       |

**Checked By**  
**Production**  
**Sign/Date:** .....

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**Quality Assurance**  
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**PROTOCOL No.:**

**8.2.2 Fill Volume Variation: Trail-02**

|                                                                    |  |
|--------------------------------------------------------------------|--|
| <b>Date of test</b>                                                |  |
| <b>Product Name</b>                                                |  |
| <b>Batch No.</b>                                                   |  |
| <b>Fill vol. - .....(Limit: ± ..... % of Target Filled volume)</b> |  |
| <b>Measuring Cylinder ID</b>                                       |  |

| Nozzle No. | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|            |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
| 01         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 02         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 03         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |



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| Nozzle No.            | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|-----------------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|                       |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 04                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 05                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 06                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| <b>Min fill vol.</b>  |            |                                |        |       |                                      |        |       |                                   |        |       |
| <b>Max. fill vol.</b> |            |                                |        |       |                                      |        |       |                                   |        |       |



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| Nozzle No. | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|            |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
| Avg. vol.  |            |                                |        |       |                                      |        |       |                                   |        |       |

**Checked By**  
**Production**  
**Sign/Date: .....**

**Verified By**  
**Quality Assurance**  
**Sign/Date.....**

**Inference:**

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**Reviewed By**  
**Manager QA)**  
**Sign/Date: .....**





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**8.2.3 Fill Volume Variation: Trail-03**

|                                                                    |  |
|--------------------------------------------------------------------|--|
| <b>Date of test</b>                                                |  |
| <b>Product Name</b>                                                |  |
| <b>Batch No.</b>                                                   |  |
| <b>Fill vol. - .....(Limit: ± ..... % of Target Filled volume)</b> |  |
| <b>Measuring Cylinder ID</b>                                       |  |

| Nozzle No. | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|            |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
| 01         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 02         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 03         | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|            | 2          |                                |        |       |                                      |        |       |                                   |        |       |



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| Nozzle No.            | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|-----------------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|                       |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 04                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 05                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| 06                    | 1          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 2          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 3          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 4          |                                |        |       |                                      |        |       |                                   |        |       |
|                       | 5          |                                |        |       |                                      |        |       |                                   |        |       |
| <b>Min fill vol.</b>  |            |                                |        |       |                                      |        |       |                                   |        |       |
| <b>Max. fill vol.</b> |            |                                |        |       |                                      |        |       |                                   |        |       |



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**PROTOCOL No.:**

| Nozzle No. | Bottle No. | Low Speed (.....Bottles/ min ) |        |       | Optimum Speed (..... Bottles / min ) |        |       | High Speed (..... Bottles/Minute) |        |       |
|------------|------------|--------------------------------|--------|-------|--------------------------------------|--------|-------|-----------------------------------|--------|-------|
|            |            | Initial                        | Middle | Final | Initial                              | Middle | Final | Initial                           | Middle | Final |
| Avg. vol.  |            |                                |        |       |                                      |        |       |                                   |        |       |

**Checked By**  
**Production**  
**Sign/Date: .....**

**Verified By**  
**Quality Assurance**  
**Sign/Date.....**

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date: .....**



**PERFORMANCE QUALIFICATION  
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FOR  
AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**8.3 PHYSICAL TEST:**

**TRIAL NO.: 01**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of test</b> |  | <b>Pack Size</b>    |  |
| <b>Product Name</b> |  | <b>Equipment ID</b> |  |
| <b>Batch No.</b>    |  | <b>Speed</b>        |  |

| <b>Nozzle No.</b> | <b>Bottle No.</b> | <b>Physical appearance</b> | <b>Foreign particle</b> | <b>Remarks</b> |
|-------------------|-------------------|----------------------------|-------------------------|----------------|
| <b>01</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |
| <b>02</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |
| <b>03</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |
| <b>04</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |
| <b>05</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |
| <b>06</b>         | <b>1</b>          |                            |                         |                |
|                   | <b>2</b>          |                            |                         |                |

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**Production**  
**Sign/Date:** .....

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**Quality Assurance**  
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**PERFORMANCE QUALIFICATION  
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FOR  
AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**TRIAL NO.:02**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of test</b> |  | <b>Pack Size</b>    |  |
| <b>Product Name</b> |  | <b>Equipment ID</b> |  |
| <b>Batch No.</b>    |  | <b>Speed</b>        |  |

| <b>Nozzle No.</b> | <b>Bottle No.</b> | <b>Physical appearance</b> | <b>Leakage</b> | <b>Foreign particle</b> | <b>Remarks</b> |
|-------------------|-------------------|----------------------------|----------------|-------------------------|----------------|
| <b>01</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>02</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>03</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>04</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>05</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>06</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |

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**PERFORMANCE QUALIFICATION  
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MACHINE**

**PROTOCOL No.:**

**TRIAL NO.:03**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of test</b> |  | <b>Pack Size</b>    |  |
| <b>Product Name</b> |  | <b>Equipment ID</b> |  |
| <b>Batch No.</b>    |  | <b>Speed</b>        |  |

| <b>Nozzle No.</b> | <b>Bottle No.</b> | <b>Physical appearance</b> | <b>Leakage</b> | <b>Foreign particle</b> | <b>Remarks</b> |
|-------------------|-------------------|----------------------------|----------------|-------------------------|----------------|
| <b>01</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>02</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>03</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>04</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>05</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |
| <b>06</b>         | <b>1</b>          |                            |                |                         |                |
|                   | <b>2</b>          |                            |                |                         |                |

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Sign/Date: .....**

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Sign/Date.....**

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Manager QA  
Sign/Date:.....**



**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**8.4 Sealing Quality: Trial-01: At minimum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

| Observation |                             |                 |                 |              |               |         |
|-------------|-----------------------------|-----------------|-----------------|--------------|---------------|---------|
| Bottle No.  | Proper Sealing ( Leak Test) | Proper Teething | Breakage of Cap | Cut on Seals | Seal Rotation | Remarks |
| 1.          |                             |                 |                 |              |               |         |
| 2.          |                             |                 |                 |              |               |         |
| 3.          |                             |                 |                 |              |               |         |
| 4.          |                             |                 |                 |              |               |         |
| 5.          |                             |                 |                 |              |               |         |
| 6.          |                             |                 |                 |              |               |         |
| 7.          |                             |                 |                 |              |               |         |
| 8.          |                             |                 |                 |              |               |         |
| 9.          |                             |                 |                 |              |               |         |
| 10.         |                             |                 |                 |              |               |         |
| 11.         |                             |                 |                 |              |               |         |
| 12.         |                             |                 |                 |              |               |         |

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**PERFORMANCE QUALIFICATION  
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MACHINE**

**PROTOCOL No.:**

**8.5 Sealing Quality: Trial-02: At minimum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

| Observation |                             |                 |                 |              |               |         |
|-------------|-----------------------------|-----------------|-----------------|--------------|---------------|---------|
| Bottle No.  | Proper Sealing ( Leak Test) | Proper Teething | Breakage of Cap | Cut on Seals | Seal Rotation | Remarks |
| 1.          |                             |                 |                 |              |               |         |
| 2.          |                             |                 |                 |              |               |         |
| 3.          |                             |                 |                 |              |               |         |
| 4.          |                             |                 |                 |              |               |         |
| 5.          |                             |                 |                 |              |               |         |
| 6.          |                             |                 |                 |              |               |         |
| 7.          |                             |                 |                 |              |               |         |
| 8.          |                             |                 |                 |              |               |         |
| 9.          |                             |                 |                 |              |               |         |
| 10.         |                             |                 |                 |              |               |         |
| 11.         |                             |                 |                 |              |               |         |
| 12.         |                             |                 |                 |              |               |         |

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**Production**  
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**PERFORMANCE QUALIFICATION  
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MACHINE**

**PROTOCOL No.:**

**8.6 Sealing Quality: Trial-03: At minimum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

**Observation**

| <b>Bottle No.</b> | <b>Proper Sealing ( Leak Test)</b> | <b>Proper Teething</b> | <b>Breakage of Cap</b> | <b>Cut on Seals</b> | <b>Seal Rotation</b> | <b>Remarks</b> |
|-------------------|------------------------------------|------------------------|------------------------|---------------------|----------------------|----------------|
| 1.                |                                    |                        |                        |                     |                      |                |
| 2.                |                                    |                        |                        |                     |                      |                |
| 3.                |                                    |                        |                        |                     |                      |                |
| 4.                |                                    |                        |                        |                     |                      |                |
| 5.                |                                    |                        |                        |                     |                      |                |
| 6.                |                                    |                        |                        |                     |                      |                |
| 7.                |                                    |                        |                        |                     |                      |                |
| 8.                |                                    |                        |                        |                     |                      |                |
| 9.                |                                    |                        |                        |                     |                      |                |
| 10.               |                                    |                        |                        |                     |                      |                |
| 11.               |                                    |                        |                        |                     |                      |                |
| 12.               |                                    |                        |                        |                     |                      |                |

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**PERFORMANCE QUALIFICATION  
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MACHINE**

**PROTOCOL No.:**

**8.7 Sealing Quality: Trial-01: At Maximum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

| Observation |                             |                 |                 |              |               |         |
|-------------|-----------------------------|-----------------|-----------------|--------------|---------------|---------|
| Bottle No.  | Proper Sealing ( Leak Test) | Proper Teething | Breakage of Cap | Cut on Seals | Seal Rotation | Remarks |
| 1.          |                             |                 |                 |              |               |         |
| 2.          |                             |                 |                 |              |               |         |
| 3.          |                             |                 |                 |              |               |         |
| 4.          |                             |                 |                 |              |               |         |
| 5.          |                             |                 |                 |              |               |         |
| 6.          |                             |                 |                 |              |               |         |
| 7.          |                             |                 |                 |              |               |         |
| 8.          |                             |                 |                 |              |               |         |
| 9.          |                             |                 |                 |              |               |         |
| 10.         |                             |                 |                 |              |               |         |
| 11.         |                             |                 |                 |              |               |         |
| 12.         |                             |                 |                 |              |               |         |

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**PERFORMANCE QUALIFICATION  
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AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**8.8 Sealing Quality: Trial-02: At Maximum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

| Observation |                             |                 |                 |              |               |         |
|-------------|-----------------------------|-----------------|-----------------|--------------|---------------|---------|
| Bottle No.  | Proper Sealing ( Leak Test) | Proper Teething | Breakage of Cap | Cut on Seals | Seal Rotation | Remarks |
| 1.          |                             |                 |                 |              |               |         |
| 2.          |                             |                 |                 |              |               |         |
| 3.          |                             |                 |                 |              |               |         |
| 4.          |                             |                 |                 |              |               |         |
| 5.          |                             |                 |                 |              |               |         |
| 6.          |                             |                 |                 |              |               |         |
| 7.          |                             |                 |                 |              |               |         |
| 8.          |                             |                 |                 |              |               |         |
| 9.          |                             |                 |                 |              |               |         |
| 10.         |                             |                 |                 |              |               |         |
| 11.         |                             |                 |                 |              |               |         |
| 12.         |                             |                 |                 |              |               |         |

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**PERFORMANCE QUALIFICATION  
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MACHINE**

**PROTOCOL No.:**

**8.9 Sealing Quality: Trial-03: At Maximum Speed**

|                     |  |                     |  |
|---------------------|--|---------------------|--|
| <b>Date of Test</b> |  | <b>Batch Number</b> |  |
| <b>Product Name</b> |  | <b>Bottle Size</b>  |  |
| <b>Equipment ID</b> |  | <b>Speed</b>        |  |

| Observation |                             |                 |                 |              |               |         |
|-------------|-----------------------------|-----------------|-----------------|--------------|---------------|---------|
| Bottle No.  | Proper Sealing ( Leak Test) | Proper Teething | Breakage of Cap | Cut on Seals | Seal Rotation | Remarks |
| 1.          |                             |                 |                 |              |               |         |
| 2.          |                             |                 |                 |              |               |         |
| 3.          |                             |                 |                 |              |               |         |
| 4.          |                             |                 |                 |              |               |         |
| 5.          |                             |                 |                 |              |               |         |
| 6.          |                             |                 |                 |              |               |         |
| 7.          |                             |                 |                 |              |               |         |
| 8.          |                             |                 |                 |              |               |         |
| 9.          |                             |                 |                 |              |               |         |
| 10.         |                             |                 |                 |              |               |         |
| 11.         |                             |                 |                 |              |               |         |
| 12.         |                             |                 |                 |              |               |         |

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**PROTOCOL No.:**

**9.0 CHECKLIST OF ALL TESTS & CHECKS:**

The following table lists the number of tests / samples to be carried out & comments on the sample record sheet.

| TESTS OR CHECKS            | EXECUTED [Y/N] | COMMENT |
|----------------------------|----------------|---------|
| Machine Speed Optimization |                |         |
| Fill Variation Test        |                |         |
| Physical Test              |                |         |
| Sealing Quality            |                |         |

**10.0 REFERENCES:**

- Validation Master Plan
- Schedule M: “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2: Good Manufacturing Practices and Inspection.

**11.0 DOCUMENTS TO BE ATTACHED:**

- Training Record.
- Any Other Relevant Documents

**12.0 NON COMPLIANCE:**

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**13.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

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PHARMA DEVILS

**PERFORMANCE QUALIFICATION  
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**PROTOCOL No.:**

**14.0 CHANGE CONTROL, IF ANY:**

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**15.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**16.0 CONCLUSION:**

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**17.0 RECOMMENDATION:**

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**PERFORMANCE QUALIFICATION  
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**PROTOCOL No.:**

**18.0 ABBREVIATIONS:**

|      |   |                                                       |
|------|---|-------------------------------------------------------|
| gm   | : | gram                                                  |
| BSS  | : | British Standard Sieve                                |
| BMR  | : | Batch Manufacturing Record                            |
| WHO  | : | World Health Organization                             |
| FDA  | : | Food and Drug Administration                          |
| CFR  | : | Code of Federal Regulations                           |
| GMP  | : | Good Manufacturing Practices                          |
| QA   | : | Quality Assurance                                     |
| CQA  | : | Corporate Quality Assurance                           |
| SOP  | : | Standard Operating Procedure                          |
| LFS  | : | Automatic Six Head Liquid Filling and Sealing machine |
| °C   | : | Degree Centigrade                                     |
| mm   | : | Millimeter                                            |
| Amp. | : | Amper                                                 |
| DQ   | : | Design Qualification                                  |
| IQ   | : | Installation Qualification                            |
| OQ   | : | Operational Qualification                             |
| PQ   | : | Performance Qualification                             |
| Pvt. | : | Private                                               |
| Ltd. | : | Limited                                               |



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**PROTOCOL No.:**

**19.0 REPORT POST APPROVAL:**

**PREPARED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|------------------------------------------|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|------------------------------------------|------|-----------|------|
| OPERATING MANAGER<br>(QUALITY ASSURANCE) |      |           |      |
| HEAD<br>(ENGINEERING)                    |      |           |      |

**APPROVED BY:**

| DESIGNATION          | NAME | SIGNATURE | DATE |
|----------------------|------|-----------|------|
| HEAD<br>(PRODUCTION) |      |           |      |