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| --- | --- | --- | --- |
| Company Name & Address | | *QCS No.* |  |
| *Version* |  |
| *Effective Date* |  |
| *Page No.* |  |
| *Name of Product* |  | Category |  |
| Self-Life |  | Packing Size |  |

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| PART-1 [Composition Details] |
| As per Label Claim [It must not defer from the Product Approval] |

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| PART-2 [Testing & Specifications] | | | |
| *Sr. No.* | Name of Parameter | Specification | MOA Reference |
| *1* | Description |  |  |
| *1.1* | Color |  |
| *1.2* | Odor |  |
| *1.3* | Taste |  |
| *1.4* | Others [Specify] |  |
| *2* | Physico-Chemical Parameters |  |
| *2.1* | Category Specific |  |
| *2.2* | Category Specific |  |
| *2.3* | Category Specific |  |
| *3* | Microbial Content |  |
| *3.1* | Staphylococcus aureus/g |  |
| *3.2* | Salmonella sp./g |  |
| *3.3* | Pseudomonas aeruginosa/g |  |
| *3.4* | Escherichia coli |  |
| *3.5* | Total microbial plate count (TPC) |  |
| *3.6* | Total Yeast & Mould |  |

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|  | | PART-2 [Testing & Specifications] | | |
| *Sr. No.* | Name of Parameter | | Specification | MOA Reference |
| *4* | Heavy Metal | |  |  |
| *4.1* | Lead | |  |
| *4.2* | Arsenic | |  |
| *4.3* | Cadmium | |  |
| *4.4* | Mercury | |  |
| *5* | Identifications [If Require] | |  |
| *5.1* | TLC/HPTLC | |  |
| *5.2* | Others | |  |
| *6* | Any Other [if required] | |  |

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| PART-3 [Accelerated Stability study – Temperature 400 C ± 20 & Humidity 75% RH ± 5%] | | | | | | | | |
| Name of product: Batch No. : | | | | | | | | |
| Batch Size: | | | | | | | | |
| Packing Detail: | | | | | | | | |
| Study Start Date: Study End Date: Report Date: | | | | | | | | |
| *Sr. No.* | Name of Parameter | | Specification | Acceptance Range | Initial Result (0 month) | 3 month Result | 6 month Result | Result |
| Dt: | Dt: | Dt: |
| *1* | Description | |  |  |  |  |  |  |
| *1.1* | Color | |  |  |  |  |  |  |
| *1.2* | Odor | |  |  |  |  |  |  |
| *1.3* | Taste | |  |  |  |  |  |  |
| *1.4* | Others [Specify] | |  |  |  |  |  |  |
| *2* | Physico-Chemical Parameters | |  |  |  |  |  |  |
| *2.1* | Category Specific | |  |  |  |  |  |  |
| *2.2* | Category Specific | |  |  |  |  |  |  |
| *2.3* | Category Specific | |  |  |  |  |  |  |
| *3* | Microbial Content | |  |  |  |  |  |  |
| *3.1* | Staphylococcus aureus/g | |  |  |  |  |  |  |
| *3.2* | Salmonella sp./g | |  |  |  |  |  |  |
| *3.3* | Pseudomonas aeruginosa/g | |  |  |  |  |  |  |
| *3.4* | Escherichia coli | |  |  |  |  |  |  |
| *3.5* | Total microbial plate count (TPC) | |  |  |  |  |  |  |
| *3.6* | Total Yeast & Mould | |  |  |  |  |  |  |
|  | | Result: The product is found Stable up to 6 Months When Stored at 40°C + 2°C & 75%+ 5% RH. | | | | | | |

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| --- | --- | --- |
|  | *Checked By* | *Approved By* |
| Name |  |  |
| *Date* |  |  |
| *Sign* |  |  |

NOTE: If Company performing In-House Quality Control testing methods other than API than they must provide their method of analysis [MoA].

## **Undertaking**

1. I/we hereby declare that the details furnished above are true and correct to the best of my knowledge and belief and I undertake to inform you of any changes therein, immediately. In case any of the above information is found to be false or untrue or misleading or misrepresenting, I am aware that I may be held liable for it.
2. I/we hereby declare that this detail is submitted online by using my user id and password so I am not signing this document but I am responsible for all documents submitted online. I/we am/are aware that I/we may be held liable for it.

Name

Designation

Signature with Stamp