

# PRODUCT SPECIFICATION

| DOCUMENT No.        | : | HA/EXT/SPC/LS/ 001 |  |  |
|---------------------|---|--------------------|--|--|
| ISSUE DATE          | : | 31.01.2020         |  |  |
| REVISION No. & DATE | : | 00                 |  |  |
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## TITLE: LAGERSTROEMIA SPECIOSA EXTRACT (≥ 2% COROSOLIC ACID)

| Product name          | : | Lagerstroemia speciosa extract (≥2% Corosolic acid) |                     |   |                                  |
|-----------------------|---|---|---------------------|---|----------------------------------|
| Common name           | : | Banaba / Crepe-myrtle                               | Final extract ratio | : | 15:1                             |
| <b>Botanical name</b> | : | Lagerstroemia speciosa (L.) Pers.                   | Solvent             | : | Methanol, Water                  |
| Family                | : | Lythraceae  | Excipient/s         | : | Nil                              |
| Country of origin     | : | India   | Re-test date        | : | 3 years from date of manufacture |
| Part used             | : | Leaves  | Fresh / Dry         | : | Dry                              |

| S. No. | Tests                                   | Limits  | Method used                                 |  |
|--------|---|---|---|--|
| 1.     | Description                             | Green to brown powder with characteristic odor and taste                          |   |  |
| 2.     | Identification tests                    | TLC - Chromatographic profile to match with that of Botanical Reference Standard. | As per in-house method                      |  |
| 3.     | Phytochemical analysis                  |   |   |  |
|        | Corosolic acid (%w/w)                   | Not less than 2.0   | By HPLC; in-house method                    |  |
| 4.     | Physico-chemical analysis               |   |   |  |
|        | Moisture (%w/w)                         | Not more than 8.0   | As per USP <921> Method III                 |  |
|        | pH (1% w/v solution)                    | Between 3.0 – 5.0   | As per USP <791>                            |  |
| 5.     | Particle size                           |   |   |  |
|        | Bulk Density (g/cc)                     | Between 0.30 – 0.80   | As per USP <616>                            |  |
|        | Tapped bulk density (g/cc)              | Between 0.30 – 1.00   | Method – I                                  |  |
|        | Material passing through 80 mesh (%w/w) | Not less than 99.0  | As per USP <786> Particle size distribution |  |
| 6.     | Heavy metals (ppm)                      |   |   |  |
|        | Lead (Pb)                               | Not more than 3.0   |   |  |
|        | Cadmium (Cd)                            | Not more than 2.0   | As per USP <233>                            |  |
|        | Arsenic (As)                            | Not more than 1.0   | -   |  |
|        | Mercury (Hg)                            | Not more than 0.1   |   |  |
| 7.     | Pesticides (ppm)                        |   |   |  |
|        | Organochlorine Pesticides               | TD 1 1/4  | As per AOAC / USP                           |  |
|        | Organophosphorus Pesticides             | To comply with  |   |  |
|        | Synthetic pyrethroids                   | USP <565>   |   |  |
| 8.     | Residual solvent analysis (ppm)         |   |   |  |

| Prepared by:            | Checked by:      | Issued by:         |
|-------------------------|------------------|--------------------|
| Adar                    | 5                | GPIP               |
| Research Executive - QC | Sr. Officer - QC | Sr. Executive – QA |
| Date: 31.01.2020        | Date: 31.01.2020 | Date: 31.01.2020   |



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|    | Methanol                                     | Not more than 3000   | As per USP <467>  |
|----|--|----------------------|-------------------|
| 9. | Microbiological analysis                     |                      |                   |
|    | Total aerobic microbial count (cfu/g)        | Not more than 10,000 | As per USP <2021> |
|    | Yeast and mold (cfu/g)                       | Not more than 100    | As per USP <2021> |
|    | Bile tolerant gram-negative bacteria (org/g) | Not more than 100    | As per USP <2021> |
|    | Escherichia coli (org/1g)                    | Negative             | As per USP <2022> |
|    | Salmonella sp. (org/10g)                     | Negative             | As per USP <2022> |
|    | S.aureus (org/1g)                            | Negative             | As per USP <2022> |

**Recommended storage** – Store in well-closed containers, protected from light and moisture at room temperature.

Non-GMO, non-irradiated, non ETO treated, BSE / TSE free, allergen free.

**Packaging** – 25 kg drums

#### **Certifications & Accreditations**

For manufacturing facilities:

For testing facilities:







### **Revision History:**

| <b>Revision No.</b> | Date       | Change       |
|---------------------|------------|--------------|
| 00                  | 31.01.2020 | New Document |
|                     |            |              |

| Prepared by:            | Checked by:      | Issued by:         |
|-------------------------|------------------|--------------------|
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| Research Executive - QC | Sr. Officer - QC | Sr. Executive – QA |
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