



201000220 205



### CERTIFICATE OF ANALYSIS

|                                            |                                       |  |
|--------------------------------------------|---------------------------------------|--|
| Product Name : FLAVOXATE HYDROCHLORIDE USP |                                       |  |
| Batch Number : 20127FVH(M)                 | Analytical Report No. : AR/SRV/270/20 |  |
| Dispatch Quantity : 250.00 Kg              | Manufacturing date : September' 2020  |  |
| Date of Analysis : 29.09.2020              | Expiry date : August' 2025            |  |
| Dispatch To : Laboratorio Chile S.A.       |                                       |  |

| S.No. | Test                                       | Specification                                                                                                                                                                                               | Result                                                                                                                                                                                                      |
|-------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01    | Description                                | White or almost white, crystalline powder                                                                                                                                                                   | White crystalline powder                                                                                                                                                                                    |
| 02    | Solubility                                 | Slightly soluble in alcohol, in water, and in methylene chloride.                                                                                                                                           | Slightly soluble in alcohol, in water, and in methylene chloride.                                                                                                                                           |
| 03    | Identification                             |                                                                                                                                                                                                             |                                                                                                                                                                                                             |
|       | A. Infrared absorption                     | The Infrared absorption spectrum of a potassium bromide dispersion of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of Flavoxate Hydrochloride working standard. | The Infrared absorption spectrum of a potassium bromide dispersion of the sample exhibits maxima only at the same wavelengths as that of a similar preparation of Flavoxate Hydrochloride working standard. |
|       | B. HPLC                                    | The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.                                                                         | The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.                                                                         |
|       | C. Test for Chlorides                      | It responds to the test for chlorides                                                                                                                                                                       | Responds to the test for chlorides                                                                                                                                                                          |
| 04    | Related substance by HPLC (%w/w)           |                                                                                                                                                                                                             |                                                                                                                                                                                                             |
|       | Flavoxate related compound A               | Not more than 0.3                                                                                                                                                                                           | 0.003                                                                                                                                                                                                       |
|       | Flavoxate related compound B               | Not more than 0.1                                                                                                                                                                                           | 0.04                                                                                                                                                                                                        |
|       | Flavoxate related compound C               | Not more than 0.1                                                                                                                                                                                           | Not detected                                                                                                                                                                                                |
|       | Any single unspecified degradation product | Not more than 0.1                                                                                                                                                                                           | 0.01                                                                                                                                                                                                        |
|       | Total impurities                           | Not more than 1.0                                                                                                                                                                                           | 0.09                                                                                                                                                                                                        |

|                                                                                                                  |                                                                                                                  |                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Compiled by<br>(Executive-QA)                                                                                    | Checked by<br>(Dy. Manager-QC)                                                                                   | Approved by<br>(Sr. Manager-QA)                                                                                    |
| <br>29/09/2020<br>Sign / Date | <br>29/09/2020<br>Sign / Date | <br>29/09/2020<br>Sign / Date |

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| S.No.            | Test                                 | Specification                              | Result                      |
|------------------|--------------------------------------|--------------------------------------------|-----------------------------|
| 05               | Loss on drying (%w/w)                | Not more than 0.5                          | 0.09                        |
| 06               | Residue on Ignition (%w/w)           | Not more than 0.1                          | 0.07                        |
| 07               | Assay on dried basis (%w/w)          | Not less than 98.0 and not more than 102.0 | 100.4                       |
| 08               | Residual solvents by HS-GC (ppm)     |                                            |                             |
|                  | Methanol                             | Not more than 3000                         | <15 (Below detection limit) |
|                  | Isopropyl Alcohol                    | Not more than 5000                         | 151                         |
|                  | Toluene                              | Not more than 890                          | 106                         |
|                  | Benzene                              | Not more than 2                            | Not detected                |
| Additional Tests |                                      |                                            |                             |
| 09               | Bulk density (g/mL)                  |                                            |                             |
|                  | Untapped density                     | 0.20 to 0.30                               | 0.26                        |
|                  | Tapped density                       | 0.30 to 0.45                               | 0.43                        |
| 10               | Particle Size Distribution( $\mu$ m) | d(0.9)                                     | 9.740                       |

**Result:** The above material is complies as per USP 40 and In-house specifications.

**Doc. Ref. No.:** SRIAM/QC/FP/FVH-002 (Version No.:06)

| Compiled by<br>(Executive-QA)                                                                                    | Checked by<br>(Dy. Manager-QC)                                                                                   | Approved by<br>(Sr. Manager-QA)                                                                                    |
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