

|                                                                                   |                                                      |                 |                |        |
|-----------------------------------------------------------------------------------|------------------------------------------------------|-----------------|----------------|--------|
|  | RAW MATERIAL SPECIFICATION                           |                 | Page No.       | 1 of 3 |
|                                                                                   | Quality Control Department                           |                 |                |        |
| Name of Raw Material                                                              | Hydroxypropyl Methyl Cellulose 15 cps (Hypromellose) |                 |                |        |
| Specification No.                                                                 | RM/SPEC/HM/001-01                                    | Supersedes No.: | RM/SPEC/001-02 |        |
| Reference                                                                         | IP/BP/USP                                            | Effective Date  | 03/04/2025     |        |
| Ref. Annexure No.                                                                 | A/SOP/QC/030/02                                      | Review Month    | Mar'2030       |        |

## GENERAL INFORMATION

Pharmacopeial reference : IP/BP/USP

Special requirement of pack : Material should be packed in LDPE bag in HDPE/ Fiber drum.

Approved vendor : Please refer current approved vendor list.

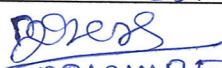
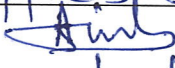
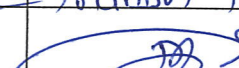
Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

|                 |                |
|-----------------|----------------|
| Analysis Sample | Control sample |
| 80 g            | 160 g          |

Retest Period : 12 Months

Storage : Store well closed container, Store protected from moisture and Preserve in well-closed containers. No storage requirements are specified.

|             | PREPARED BY                                                                                     | REVIEWED BY                                                                                     | APPROVED BY                                                                                       |
|-------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Name        | Manisha Dhese                                                                                   | Appa. S. Shinde                                                                                 | Manish Mahajan                                                                                    |
| Sign/Date   | <br>02/04/25 | <br>02/04/25 | <br>02/04/25 |
| Designation | Sr. Executive                                                                                   | Asst. Manager                                                                                   | Manager                                                                                           |
| Department  | Quality Control                                                                                 | Quality Control                                                                                 | Quality Assurance                                                                                 |



## RAW MATERIAL SPECIFICATION

Page No. 2 of 3

Quality Control Department

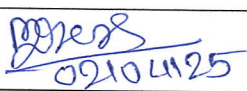
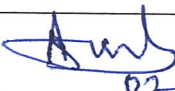
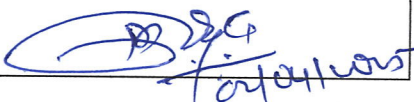
Name of Raw Material

Hydroxypropyl Methyl Cellulose 15 cps (Hypromellose)

Specification No.

RM/SPEC/HM/001-01

| SR. NO. | TEST                     | SPECIFICATIONS                                                                                                                               | REFERENCE |
|---------|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| 01.     | Description <sup>#</sup> | A White, yellowish white or Greyish-white, powder or granules; hygroscopic after drying.                                                     | IP/BP     |
|         |                          | A White to slightly off white, fibrous or granular powder                                                                                    | USP       |
| 02.     | Solubility               | It dissolves in cold water giving a colloidal solution. Practically insoluble in hot water, in acetone, in ethanol and in toluene.           | IP        |
|         |                          | Practically insoluble in hot water, in acetone, in anhydrous ethanol and in toluene. It dissolves in cold water giving a colloidal solution. | BP        |
|         |                          | Insoluble in dehydrate alcohol, in ether and in chloroform. Swells in water and produces a clear to opalescent viscous, colloidal mixture.   | USP       |
| 03.     | Identification Test      |                                                                                                                                              |           |
|         | Test A                   | The powdered material aggregates on the surface.                                                                                             | IP/BP/USP |
|         | Test B                   | A clear or slightly turbid solution occurs with its thickness dependent on the viscosity grade.                                              | IP/BP/USP |
|         | Test C                   | A red color develops at first and changes to purple within 100 minutes.                                                                      | IP/BP/USP |
|         | Test D                   | A coherent, clear film forms on the glass slide.                                                                                             | IP/BP/USP |
|         | Test E                   | The flocculation temperature is higher than 50° C.                                                                                           | IP/BP/USP |
| 04.     | Appearance of solution   | The solution should not more opalescent than opalescence standard OS3 and should not more intensely coloured than reference solution YS6.    | IP        |
|         |                          | Solution should not be more opalescent than reference solution III and should not more intensely coloured than reference solution Y6.        | BP        |
| 05.     | pH <sup>#</sup>          | 5.0 to 8.0                                                                                                                                   | IP/BP/USP |
| 06.     | Viscosity <sup>#</sup>   | 12 mPas – 18 mPas                                                                                                                            | IP/BP/USP |
| 07.     | Heavy Metals             | NMT 20 ppm                                                                                                                                   | IP        |

|           | PREPARED BY                                                                                     | REVIEWED BY                                                                                     | APPROVED BY                                                                                           |
|-----------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Sign/Date | <br>02/04/25 | <br>02/04/25 | <br>for all work |

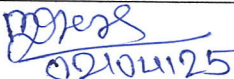
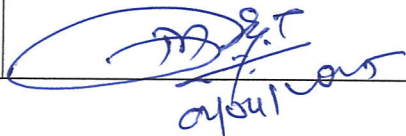
|                                                                                   |                                                      |          |        |
|-----------------------------------------------------------------------------------|------------------------------------------------------|----------|--------|
|  | RAW MATERIAL SPECIFICATION                           | Page No. | 3 of 3 |
|                                                                                   | Quality Control Department                           |          |        |
| Name of Raw Material                                                              | Hydroxypropyl Methyl Cellulose 15 cps (Hypromellose) |          |        |
| Specification No.                                                                 | RM/SPEC/HM/001-01                                    |          |        |

| SR. NO. | TEST                                                          | SPECIFICATIONS | REFERENCE |
|---------|---------------------------------------------------------------|----------------|-----------|
| 08.     | Sulphated Ash / Residue on Ignition                           | NMT 1.5 %      | IP/BP/USP |
| 09.     | Loss On Drying <sup>#</sup>                                   | NMT 5.0 %      | IP/BP/USP |
| 10.     | Assay <sup>#</sup> (On dried basis) (Substitution Type- 2910) |                | IP/BP/USP |
|         | Methoxy                                                       | 28.0% - 30.0%  |           |
|         | Hydroxypropoxy                                                | 7.0 % - 12.0 % |           |

# : Re-evaluation tests

## REVISION HISTORY FOR SPECIFICATION:

| Revision No. | Revision Description                                                                                                                                                                      | Effective Date |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| 01           | 1) Individual Pharmacopoeial grade new document prepared as per Approved Change control No. CC/QC/23/002<br>2) Only SPEC and ATR prepared as per approved change control No. CC/QC/25/008 | 03/04/2025     |

|           | PREPARED BY                                                                                     | REVIEWED BY                                                                                     | APPROVED BY                                                                                       |
|-----------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Sign/Date | <br>02/04/25 | <br>02/04/25 | <br>02/04/25 |