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| **PRODUCT DEVELOPMENT** | |
| Product: SOLRIAMFETOL HYDROCHLORIDE | |
| Market: Customer-Novartis Healthcare for US market. | **Strength:** |
| Source: Glenmark | Reference: IN-HOUSE |
| **Shelf-life:** |  |

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| Test | Specification | Reference |
| Description | White to off-white powder | USP |
| Solubility | Freely soluble in methanol and water; practically insoluble in acetone and ethyl acetate | USP |
| Identification |  |  |
| By IR | The Infrared absorption spectrum of the test sample should exhibit below vibration modes, C=O stretching 1702 ±10cm-1 C-O stretching 1129 ±10cm-1 C-N vibration 1076 ±10cm-1 | USP < 197K > |
| By HPLC | In the test for assay, the retention time of principal peak from the sample should match with that from Solriamfetol hydrochloride in-house reference/ Working standard | Inhouse |
| By HPLC | In the test for Content of S-isomer, the retention time of principal peak from the sample should match with that from Solriamfetol hydrochloride in-house reference standard from reference solution (f) | Inhouse |
| Loss on drying (Sample qty. 1.0 g at 105°C for 3hrs under vacuum in an oven) | Not more than 0.50% w/w | USP <731> |
| Residue on ignition (Sample qty. about 1.0g) | Not more than 0.10 % w/w | USP <281> |
| Related substances (by HPLC) |  | Inhouse |
| Impurity A i.e. (2R)-2-amino-3- phenylpropan-1-ol: | Not more than 0.15% |  |
| Impurity B i.e. (2R)-2- (carbamoylamino)-3-phenylpropyl carbamate: | Not more than 0.15% |  |
| Impurity C i.e. (2R)-2-{[(2R)-2- amino-3-phenylpropanoyl]amino}- 3-phenylpropyl carbamate: | Not more than 0.15% |  |
| Impurity D i.e. (2S,3S)-2,3- bis[(phenylcarbonyl)oxy]butanedioic acid: | Not more than 0.15% |  |
| Impurity E i.e. (S)-4-Benzyl-2- oxazolidinone: | Not more than 0.15% |  |
| Impurity F i.e. 1-[(2R)-1-hydroxy- 3-phenylpropan-2-yl]urea: Any other individual impurity: Total impurities: | Not more than 0.15% Not more than 0.10% Not more than 1.0% |  |
| Assay (by HPLC) (on dried basis) | Not less than 98.0 % w/w and Not more than 102.0 % w/w | Inhouse |
| Content of S-isomer (by HPLC) | Not more than 0.15% | Inhouse |
| Content of Acetic acid (by HPLC) | Not more than 5000 ppm | Inhouse |
| Content of Hydrochloride (by Potentiometry) (on dried basis) | Between 15.0% w/w and 16.6%w/w | Inhouse |
| Residual solvents (by GC) |  | Inhouse |
| Ethanol | Not more than 5000 ppm |  |
| Ethyl acetate | Not more than 5000 ppm |  |
| Isopropyl alcohol | Not more than 5000 ppm |  |
| Methanol | Not more than 3000 ppm |  |
| Methyl acetate | Not more than 5000 ppm |  |
| Methylene chloride Toluene | Not more than 600 ppm |  |
|  | Not more than 890 ppm |  |
| Polymorphic Identification (by XRD) | (A) The X-Ray diffractogram of substance being examined should exhibit characteristic 2θ values at 6.6°, 15.7°, 19.3°,20.2° and 24.7°±0.2°. | Inhouse |
| Microbiological limit test Total aerobic microbial count Total yeasts and moulds count | Not more than 1000 CFU/g Not more than 100 CFU/g | USP <61>, <62> |
| Specified micro-organisms |  |  |
| Escherichia coli Salmonella Pseudomonas aeruginosa Staphylococcus aureus | Should be absent/1g Should be absent/10g Should be absent/1g Should be absent/1g |  |
| Particle size (by Malvern) D(50) | Between 30 um-70 um | Inhouse |

**Storage Conditions:**

Store in a tightly closed container at a temperature not exceeding 25°C.

**Packaging details:**

The material is packed in transparent EVOH bag using vacuum sealing. This bag is enclosed in transparent EVOH bag with silica gel packets, which is further enclosed in black LDPE bag along with silica gel packets, which in turn is kept in triple laminated aluminum pouches sealed at three sides along with silica gel packets. The fourth side of the pouch is then sealed and kept in HDPE container.

**Revision History**

Changes in the current version and high-level summary of changes of all listed previous versions are maintained below.

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| --- | --- | --- |
| **Version**  **Effective Date** | **Reason for change** | **Summary of changes** |
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**Author**

The content Owner and Subject Matter Expert is Jonnala Uday Kiran Reddy, Principal Scientist

**Document Type**

This document is designed to be used as a template.

(NOTE: Templates are designed to be amendable and forms are not, i.e. content of forms must not be changed when used, but populated with data/information only).

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| **Version**  **Effective Date** | **Reason for Change** | **Summary of Changes** |
| --- | --- | --- |
| 1.0 | New From created | Content Change(s):  Not Applicable |

**Documents replaced**

Not Applicable

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