

**Glenmark Life Sciences Ltd.**

Plot No. Z/103/I, SEZ Phase-II, Dahej, Taluka Vagra,

Dist. Bharuch, 392130, Gujarat, India.

Tel : 02641289801

**QUALITY ASSURANCE DEPARTMENT  
CERTIFICATE OF ANALYSIS**

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**Product** : SOLRIAMFETOL HYDROCHLORIDE**Specification No** : SPC-I232-001902/3.0**SAP Code** : SD46401**Batch. No.** : 82211216**Insp. Lot No.** : 890000103035**Reference** : IN-HOUSE**Date of Mfg.** : 28.06.2021**Retest Date** : 27.06.2023**Date of Report** : 30.06.2021

TEST	LIMIT	OBSERVATION
Description	White to off-white powder	White powder
<b>Solubility</b>		
In Methanol	Freely soluble	Freely soluble
In Water	Freely soluble	Freely soluble
In Acetone	Practically Insoluble	Practically Insoluble
in ethyl acetate	Practically Insoluble	Practically Insoluble
<b>Identification</b>		
By IR	The Infrared absorption spectrum of the test sample should exhibit below vibration modes, C=O stretching 1702 $\pm 10\text{cm}^{-1}$ C-O stretching 1129 $\pm 10\text{cm}^{-1}$ C-N vibration 1076 $\pm 10\text{cm}^{-1}$	The Infrared absorption spectrum of the test sample exhibits below vibration modes, C=O stretching 1701.84 $\text{cm}^{-1}$ , C-O stretching 1129.88 $\text{cm}^{-1}$ , C-N vibration 1076.67 $\text{cm}^{-1}$ .
By HPLC	In the test for assay, the retention time of principal peak from the sample should match with that from Solriamfetol hydrochloride inhouse reference /Working standard.	In the test for assay, the retention time of principal peak from the sample matches with that from Solriamfetol hydrochloride inhouse Working standard.
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)	In the test for Content of S-isomer, the retention time of principal peak from the sample matches with that from Solriamfetol hydrochloride in-house working standard from reference solution (f).
Loss on drying	Not more than 0.50%w/w	0.19 %w/w
Residue on ignition	Not more than 0.10%w/w	0.03 %w/w
<b>Related substances (By HPLC)</b>		
Impurity A i.e.	Not more than 0.15%	Below Quantification Limit

**Prepared By** : Anil Dixit**Designation** : Executive**Date** : 30.06.2021**Approved By** : Parag Nimkar**Designation** : Assistant Manager**Date** : 30.06.2021**Printed Date** : 30.06.2021**Copy No.** : 1

This is electronically signed document, hence need not to be signed.

Registered Office : Plot No 170-172, Chandramouli Industrial Estate, Mohol Bazarpet, Solapur-413213, India.

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TEST	LIMIT	OBSERVATION
(2R)-2-amino-3-phenylpropan-1-ol: Impurity B i.e. (2R)-2-(carbamoylamino)-3-phenylpropyl carbamate: Impurity C i.e. (2R)-2-[(2R)-2-amino-3- phenylpropanoyl]amino}-3-phenylpropyl carbamate: Impurity D i.e. (2S,3S)-2,3- bis[(phenylcarbonyl)oxy]butanedioic acid: Impurity E i.e. (S)-4-Benzyl-2-oxazolidinone: Impurity F i.e. 1-[(2R)-1-hydroxy-3-phenylpropan-2- yl]urea: Any other individual impurity: Total impurities: Assay (by HPLC) (On dried basis)  Content of S-isomer (by HPLC) Content of Acetic acid (by HPLC) Content of Hydrochloride (by Potentiometry) (on dried basis) <b>Residual Solvents (By GC)</b> Ethanol Ethyl acetate Isopropyl alcohol Methanol Methyl acetate Methylene chloride	 Not more than 0.15%  Not more than 0.15%  Not more than 0.15%  Not more than 0.15% Not more than 0.15%  Not more than 0.10% Not more than 1.0 % Not less than 98.0%w/w and Not more than 102.0%w/w  Not more than 0.15% Not more than 5000 ppm Between 15.0% w/w and 16.6% w/w  Not more than 5000 ppm Not more than 5000 ppm Not more than 5000 ppm Not more than 3000 ppm Not more than 5000 ppm Not more than 600ppm	 Below Quantification Limit  Not Detected  Below Quantification Limit  Not Detected Not Detected  Below Quantification Limit Below Quantification Limit 99.5 %w/w  Not Detected Not Detected 15.8 %w/w  Not Detected 141 ppm Not Detected 144 ppm Not Detected Not Detected

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TEST	LIMIT	OBSERVATION
Toluene	Not more than 890 ppm	Not Detected

LOD/LOQ values for Solriamfetol HCl -

Limit of Detection for Impurity A, Impurity F, Impurity B, Impurity D  
and Any other individual impurity is 0.01%Limit of Quantification for Impurity A, Impurity F, Impurity B,  
Impurity D and Any other individual impurity is 0.03%Limit of Detection for Impurity E is 0.005%, S-Isomer is 0.015% and  
Impurity C is 0.015%Limit of Quantification for Impurity E is 0.015%, S-Isomer is 0.03% and  
Impurity C is 0.03%

Limit of Detection for Acetic acid is 156 ppm

Limit of Quantification for Acetic acid is 518 ppm

Limit of Detection for Ethanol is 51 ppm, Ethyl acetate is 25 ppm,

Isopropyl alcohol is 50 ppm, Methanol is 15 ppm, Methyl acetate is 25  
ppm, Methylene chloride is 60 ppm, and Toluene is 9 ppm

Limit of Quantification for Ethanol is 152 ppm, Ethyl acetate is 75 ppm,

Isopropyl alcohol is 151 ppm, Methanol is 45 ppm, Methyl acetate is 75  
ppm, Methylene chloride is 181 ppm and Toluene is 26 ppm**Storage Condition :**

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

**Remark :** The product complies as per above specification**Prepared By :** Anil Dixit**Designation :** Executive**Date :** 30.06.2021**Approved By :** Parag Nimkar**Designation :** Assistant Manager**Date :** 30.06.2021**Printed Date :** 30.06.2021**Copy No. :** 1**This is electronically signed document, hence need not to be signed.****Registered Office :** Plot No 170-172, Chandramouli Industrial Estate, Mohol Bazarpeth, Solapur-413213, India.