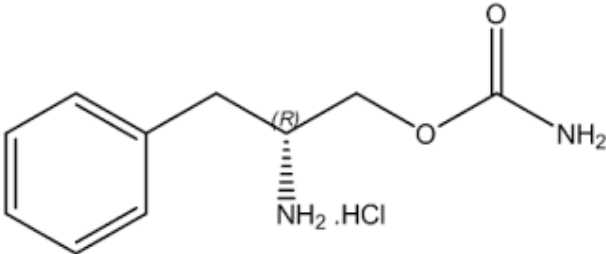

	<b>GLENMARK LIFE SCIENCES LIMITED, DAHEJ</b> <b>QUALITY ASSURANCE DEPARTMENT</b>		
<b>FINISHED PRODUCT SPECIFICATION</b>			<b>Page No: 1 of 6</b>
<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
<b>Specification No:</b>	SPC-I232-002406 / 1.0	<b>Reference:</b>	IN-HOUSE
<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

<b>Molecular Formula:</b> C <sub>10</sub> H <sub>15</sub> N <sub>2</sub> O <sub>2</sub> Cl		<b>Molecular Weight:</b> 230.69
<b>CAS No.</b>	: [178429-65-7]	
<b>Chemical Name</b>	: (R)-2-amino-3-phenylpropylcarbamate hydrochloride	
<b>Structural Formula :</b> <div style="text-align: center; margin-top: 20px;">  </div>		
<b>Sample Quantity</b>	: About 60g (20 g for Analysis, 40 g for Reserve sample)	
<b>Mode of Packing</b>	: 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.	
<b>Storage Condition</b>	: Store in a tightly closed container at a temperature not exceeding 25°C.	

<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
<b>Quality Assurance</b>	<b>Quality Control</b>	<b>Quality Assurance</b>
Tanmay Hirpara	Devanand Baraiya	DevendraPal Singh
24.02.2022	24.02.2022	24.02.2022
<b>Printed On :</b> 24.02.2022	<b>Printed By :</b> Tanmay Hirpara	<b>Copy No. :</b> Master Copy


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<b>FINISHED PRODUCT SPECIFICATION</b>			<b>Page No: 2 of 6</b>
<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
<b>Specification No:</b>	SPC-I232-002406 / 1.0	<b>Reference:</b>	IN-HOUSE
<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

Sr. No.	Test	Specification	Reference	MOA No.
1.	Description	White to off-white powder	USP	MOA-I232-000001
2.	Solubility	Freely soluble in methanol and water; practically insoluble in acetone and ethyl acetate	USP	MOA-I232-000002
3.	Identification			
	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 $1076 \pm 10\text{cm}^{-1}$	USP < 197K >	MOA-I232-000003
	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	MOA-I232-003121
	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	MOA-I232-003122
4.	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>	MOA-I232-000008

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<b>FINISHED PRODUCT SPECIFICATION</b>			<b>Page No: 3 of 6</b>
<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
<b>Specification No:</b>	SPC-I232-002406 / 1.0	<b>Reference:</b>	IN-HOUSE
<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

Sr. No.	Test	Specification	Reference	MOA No.
5.	Residue on ignition (Sample qty. about 1.0g)	Not more than 0.10 % w/w	USP <281>	MOA-I232-000009
6.	Related substances (by HPLC)		Inhouse	MOA-I232-003120
	<b>Impurity A</b> i.e. (2R)-2-amino-3-phenylpropan-1-ol:	Not more than 0.15%		
	<b>Impurity B</b> i.e. (2R)-2-(carbamoylamino)-3-phenylpropyl carbamate:	Not more than 0.15%		
	<b>Impurity C</b> i.e. (2R)-2-[(2R)-2-amino-3-phenylpropanoyl]amino}-3-phenylpropyl carbamate:	Not more than 0.15%		
	<b>Impurity D</b> i.e. (2S,3S)-2,3-bis[(phenylcarbonyl)oxy]butanedioic acid:	Not more than 0.15%		
	<b>Impurity E</b> i.e. (S)-4-Benzyl-2-oxazolidinone:	Not more than 0.15%		
	<b>Impurity F</b> 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%		
7.	Assay (by HPLC) (on dried basis)	Not less than 98.0 % w/w and Not more than 102.0 % w/w	Inhouse	MOA-I232-003121
8.	Content of S-isomer (by HPLC)	Not more than 0.15%	Inhouse	MOA-I232-003122

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<b>FINISHED PRODUCT SPECIFICATION</b>			<b>Page No: 4 of 6</b>
<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
<b>Specification No:</b>	SPC-I232-002406 / 1.0	<b>Reference:</b>	IN-HOUSE
<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

Sr. No.	Test	Specification	Reference	MOA No.
9.	Content of Acetic acid (by HPLC)	Not more than 5000 ppm	Inhouse	MOA-I232-003228
10.	Content of Hydrochloride (by Potentiometry) (on dried basis)	Between 15.0% w/w and 16.6%w/w	Inhouse	MOA-I232-003123
11.	Residual solvents (by GC) Ethanol Ethyl acetate Isopropyl alcohol Methanol Methyl acetate Methylene chloride Toluene	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 600 ppm Not more than 890 ppm	Inhouse	MOA-I232-003127
12	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	MOA-I232-003128
13	<b>Microbiological limit test</b> Total aerobic microbial count Total yeasts and moulds count  <b>Specified micro-organisms</b> Escherichia coli Salmonella Pseudomonas aeruginosa Staphylococcus aureus	Not more than 1000 CFU/g Not more than 100 CFU/g  Should be absent/1g Should be absent/10g Should be absent/1g Should be absent/1g	USP <61>, <62>	MOA-I232-000026

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**FINISHED PRODUCT SPECIFICATION**

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<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
<b>Specification No:</b>	SPC-I232-002406 / 1.0	<b>Reference:</b>	IN-HOUSE
<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

<b>Sr. No.</b>	<b>Test</b>	<b>Specification</b>	<b>Reference</b>	<b>MOA No.</b>
14	Particle size (by Malvern) D(50)	Between 30 um-70 um	Inhouse	MOA-I232- 003475

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**FINISHED PRODUCT SPECIFICATION**

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<b>Product :</b>	<b>SOLRIAMFETOL HYDROCHLORIDE</b>		
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<b>SAP Group No:</b>	TDF02406	<b>Supersedes:</b>	Nil
<b>SAP Code:</b>	FD46401, SD46401, MD46401, BD46401	<b>Reference SOP:</b>	QA034
<b>Specification Type :</b>	Finished Product Specification of Glenmark Life Sciences Limited, Dahej for, <b>Customer-Novartis Healthcare for US market.</b>		

**Revision History:**

<b>Revision No.</b>	<b>Effective date</b>	<b>Changes made</b>	<b>Reference Change control number</b>
1.0	Current effective date	- New Specification is prepared for <b>Customer-Novartis Healthcare</b>	CCI232220129

<b>Prepared By</b>	<b>Checked By</b>	<b>Approved By</b>
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