

SWISS PHARMA PVT. LTD.
3709, G.I.D.C. Phase IV, Vatva, Ahmedabad –382445,
India.



SUMMARY REPORT OF ANNUAL PRODUCT QUALITY REVIEW

Product Name	:		Mfg. by	:	Swiss Pharma Pvt. Ltd.
Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included	:	10

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Product Name	:		Mfg. by : Swiss Pharma Pvt. Ltd.
Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included : 10

1.0 APQR Number: APQR/SWGS1529/38

2.0 Review Period: September – October 2022

3.0 Product Name: Sparfloxacin Tablets 200 mg

4.0 Composition:

Each Film Coated tablet contains:

Sparfloxacin200 mg

Excipients.....Q.S.

Colour: Tartrazine & Titanium Dioxide BP

5.0 License Number and Validity:

License No: G/25/849

Valid Upto: 31.12.2026

6.0 Standard Batch Size:

7.0 Shelf Life: 3 Years

8.0 Batch details:

Sr. No.	Particulars	Observation
01	Number of Batches manufactured	10 Batches
02	Number of batches considered for APQR	10 Batches
03	No of batches released	10 Batches
04	Number of batches rejected in calendar year	Nil

9.0 A review of Technical agreement: Reviewed and found within validity

10.0 A review of Raw Materials (API) used in the product.

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10.1 Name of Raw Material:

Sr. No.	Ingrdients	Specifi- cation	Label claim (in kg)	Quantity/ Tablet (in mg)	Quantity/ Batch (in kg) require for 7.50 Lac Tablet	Reason for Inclusion
1.	Sparfloxacin	IHs	20.00	200.00	20.00	Active
2.	Microcrystalline cellulose	BP		300.00	30.00	Diluent
3.	PVP K-30	BP		13.000	1.300	Binder
4.	Maize Starch	BP		30.000	3.000	Diluent
5.	Colloidal silicon dioxide	BP		3.000	0.300	Glidant
6.	Magnesium stearate	BP		7.000	0.700	Lubricant
7.	Sodium Starch Glycolate	BP		3.500	0.350	Disintegrant
8.	Microcrystalline Cellulose	BP		110.0	11.00	Diluent
9.	Purified talc	BP		35.00	0.350	
Film - Coating						
10.	Insta moist shield Tartrazine	IHs		67.00	0.670	Film Former
11.	Isopropyl Alcohol	BP		QS	4.760	Solvent
12.	Methylene Dichloride	BP		QS	6.800	Solvent
13.	Instacoat aqua yellow (A03R00248)	His		13.30	1.303	Colouring agent
14.	Purified water	BP		66.50	6.650	Solvent
	Total/Avg. wt./ Tab			690 mg	69 Kg	

Note: Average Weight of Uncoated Tablet 680.000mg.

QS: Quantity sufficient

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Product Name	:		Mfg. by : Swiss Pharma Pvt. Ltd.
Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included : 10

11.0 A review of Primary Packaging materials used in the product.

11.1 Printed Aluminium Foil

Sr. No.	Test	Limit
1.	Description	Natural colour foil
2.	Printed Text	Should be sharp, readable and satisfactory
3.	Width	270 mm ± 2 mm
4.	Thickness	0.025 mm ± 0.005 mm
5.	Grammage	NLT 40 gm/m ²

11.2 Plain Aluminium Foil

Sr. No.	Test	Limit
1.	Description	Plain Aluminium Foil
2.	Dimension: Width	270.0 mm ± 2 mm
3.	Thickness	0.20 mm ± 0.05 mm
4.	Grammage	NLT 40 gm/m ²

11.3 Printed Craton

Sr. No.	Test	Limit
1.	Description	3 colour offset printing carton
2.	Length	130 mm ± 2 mm
3.	Width	14 mm ± 2 mm
4.	Height	70 mm ± 2 mm
5.	Thickness	0.15 mm ± 0.05 mm
6.	Grammage	NLT 350 gm/m ²

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12.0 A review of critical process parameters.

Steps	Critical Process Parameter		Control Variable	Response Parameters
Dry Mixing	Sequence of Excipients addition	Fixed order of addition	Mixing time	Mixing uniformity
	Load Mixing vessel	Fixed batch size		
	Mixing Speed	Fixed RPM		
Granulation	Amount of binder solution	Fixed quantity of binder	Granulation time	Type of granulation and Tapped density
	Speed of RMG	Fixed Speeds	Additional qty. of water	
Drying	Temperature	Fixed Temperature range	Drying Time	Drying capability
	LOD	As per specified		
Milling	Screen Size	Fixed screen size	-----	Uniform particle size
	Number of blades	Number of blades fixed		
	Speed of machine	Fixed speed		
Lubrication	Sequence of Lubricants addition	Fixed order addition	Blending time	Blend uniformity
	Load of blending vessel	Fixed batch size		
	Blending speed	Fixed RPM		
Compression	Compression speed	Fixed machine speed	Desired Speed & Force to be set.	To comply In-process test specification of uncoated Tablet
	Compression force	Fixed compression force		
Coating	Coating Speed	Fixed machine speed	Desired temp & speed to be set.	To comply In-process test specification of coated Tablet
	Temperature	Fixed Temp. range		
Alu-Alu Blister Packing	Temperature	Fixed	Desired temp & speed to be set.	Leakage control
	Machine Speed	Fixed		

Note: Setting and conditions as mentioned in the batch manufacturing record to be followed.

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Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included : 10

13.0 A review of critical in-process controls and finished product results.

Batch No.	Batch Size (Tablets)	Mfg. Date	Exp. Date
AR38101	7.50 Lac. Tablets	10/2021	09/2024
AR38102	7.50 Lac. Tablets	10/2021	09/2024
AR38103	7.50 Lac. Tablets	10/2021	09/2024
AR38104	7.50 Lac. Tablets	10/2021	09/2024
AR38105	7.50 Lac. Tablets	10/2021	09/2024
AR38106	7.50 Lac. Tablets	11/2021	10/2024
AR38107	7.50 Lac. Tablets	11/2021	10/2024
AR38108	7.50 Lac. Tablets	11/2021	10/2024
AR38109	7.50 Lac. Tablets	11/2021	10/2024
AR38110	7.50 Lac. Tablets	11/2021	10/2024

14.0 A review of Out of specifications and their investigation

Sr. No.	OOS Number	Details of OOS	Status
NA	NA	NA	NA

Total Number of OOS: -- Nil

There was no any OOS observed during review period.

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Product Name	:		Mfg. by : Swiss Pharma Pvt. Ltd.
Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included : 10

15.0 A review of deviations and CAPA has taken against each deviation, the effectiveness of resultant corrective and preventive actions taken.

Sr. No.	Deviation Number	Details of Deviation	CAPA	Effectiveness of CAPA taken.
NA	NA	NA	NA	NA

Total Number of Deviations: Nil
During the review period, no any Deviation was initiated

16.0 A review of changes proposed, approved and implemented that are directly or indirectly related

Sr. No.	Change control Number	Details of Change control	Status
NA	NA	NA	NA

Total Number of Change Controls: Nil
There was no any Change Control observed during review period.

17.0 A review of marketing authorization variations submitted granted or refused, including those for third country (export only) dossier : NA

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Product Name	:		Mfg. by	: Swiss Pharma Pvt. Ltd.
Generic Name	:	Sparfloxacin Tablets 200 mg	Batch No. Included	: 10

18.0 A review of the results of stability monitoring program and any adverse trends.

Sr. No.	Batch Number	Mfg. Date	Expiry Date	Stability condition	Intervals	Remark (Any Adverse trend)
1	AR38101	10/2021	09/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
2	AR38102	10/2021	09/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
3	AR38103	10/2021	09/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory

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4	AR38104	10/2021	09/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
5	AR38105	10/2021	09/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
6	AR38106	11/2021	10/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
				40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory

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7	AR38107	11/2021	10/2024	30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
8	AR38108	11/2021	10/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
9	AR38109	11/2021	10/2024	40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory
				30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
				40°C ± 2°C. 75% ±, 5% RH	Initial 01 Month 03 Months 06 Months	Satisfactory

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10	AR38110	11/2021	10/2024	30°C ± 2°C. Relative Humidity 75% ±, 5% RH	Initial 03 Months 06 Months 09 Months 12 Months 18 Months 24 Months 36 Months	Satisfactory
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19.0 A review of all quality related returned Goods.

Sr. No.	Batch number	Reason	CAPA	Effectiveness of CAPA taken.
NA	NA	NA	NA	NA

20.0 A review of all complaints.

Sr. No.	Market Complaint Number	Details of Market Complaint	CAPA	Effectiveness of CAPA taken.
NA	NA	NA	NA	NA

21.0 A review of Recall.

Sr. No.	Batch number	Reason	CAPA	Effectiveness of CAPA taken.
NA	NA	NA	NA	NA

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Product Name	:		Mfg. by : Swiss Pharma Pvt. Ltd.
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22.0 A review of adequacy of any other previous corrective actions on Product process or Equipments.

Sr. No.	Description of CAPA	Effectiveness of Implementation	Remark
NA	NA	NA	NA

Conclusion: A review of adequacy of any other previous Corrective actions on Product process or Equipments has been done and there was no any Corrective action on Product process or Equipments.

23.0 For new marketing authorization and variations to the marketing authorizations, a review of post marketing commitments: NA

24.0 A review of the qualification status of relevant equipments and utilities.

Sr. No.	Equipments/Area	SOP No.
1.	Granulation Area	PG/002
2.	Balance Cleaning	PT/001
3.	Shifter	PT/005
4.	Rapid Mixer Granulator	PT/006
5.	Paste kettle	PT/004
6.	Multi mill	PT/007
7.	Fluidized Bed Dryer	PT/011
8.	Blender	PT/008

Tablet Compression Machine details:

Compression Machine			
Sr. No.	Equipments/ Area	SOP No.	Equipment Code No.
1.	Area	PG/002	NA
2.	Compression M/C 31 station – D. B. Tooling D. R.	PT/015	T-18
3.	Compression M/C 45 station – D. B. Tooling D. R.	PT/017	T-33

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Check following parameters at given frequencies:

Parameter	Specifications	Frequency
Upper Punches	Elongated with break line	-----
Lower Punches	Elongated without break line	-----
Punch size	17.9 x 7.9 mm Dia	-----
Die Bore size	17.9 x 7.9mm Dia	-----
Appearance	Uncoated yellow colour elongated Tablets , having breakline on one side and other side is plain	Every 30 min.
Wt. of 20 Tabs.	13.400 gm. \pm 2.5 %	Every 30 min.
Individual Weight of Tabs	670 mg. \pm 5 %	Every 1 hours
Thickness	5.50 mm \pm 2 mm	Every 1 hours
Hardness	4 Kg./ Cm ² \pm 2 Kg./Cm ²	Every 1 hours
Disintegration Time	NMT 15 min.	Every 1 hours
Friability	NMT 1%	Every 1 hours
Room Temp.	25 ⁰ C \pm 3 ⁰ C	Every 2 hours
% RH	45% \pm 5%	Every 2 hours

25.0 A review of process validation.

Sr. No.	Product Name	Batch Number	Reason	Remark.
NA	NA	NA	NA	NA

26.0 A review of all contractual agreements.

Sr. No.	Name of Contractor	Validity of Agreement
NA	NA	NA

27.0 A review of Monitoring of Water and Environment Monitoring.

The trend analysis with graphical presentation has been performed for the water and Environment Monitoring sampling points analyzed during calendar year.

Bacterial colonies were found within limit and fungus was not observed.

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28.0 A review of all External inspections carried out.

Sr. No.	Name of External Inspection	Date of External inspection	Status
NA	NA	NA	NA

29.0 A review of control samples:

During review period control sample was reviewed and found satisfactory.

30.0 A review of previous APQR responses:

No Recommendation was observed from Previous APQR under review period.

31.0 Conclusion:

All the batches manufactured during the review period along with related quality data has been reviewed. The review of data showed that all the critical process parameters, System and Procedures are in well within Specification limits which ensure consistent process performance and product quality.

32.0 Recommendation if any: NA



Analyzed by
 Mr. Gaurav Darji
 Date: 10/09/2022



Checked by
 Mr. Kalpesh Prajapati
 Date: 10/09/2022




Approved by
 Mr. Navin Kapadiya
 Date: 10/09/2022