Sildocare 8 mg hard gelatin capsule

PROCESS VALIDATION REPORT

Validated Batches (170125, 180132, 180133,160028)

Al Andalous
Pharmaceutical Ind.

VALIDATION REPORT APPROVAL		
	Name/Title	**Sign/Date**
Prepared by	**Dr. Amr Magdy** **Validation Senior specialist**	**Sign/Date** 21-07-2
Reviewed by	**Dr. Shehab Dawood** **Validation Section Head**	**Sign/Date** 21/07/2025
Approved by:	**Dr. Mohamed Mustafa** **QA Manager**	**Sign/Date** P. Pan 21-7-2

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1. OBJECTIVES:

To provide documented evidence that the predetermined process of Sildocare 8 mg hard gelatin capsule is capable of reliably and repeatedly rende product of the required quality after comparison of dissolution results of bio batch and validation batches.

2. SCOPE:

Product Name: Sildocare 8 mg hard gelatin capsule

Bulk Code: 10101099,

Semi-Finish Code: 201010990110

Finished product code: 301010990121

Shelf life: 24 months.

Type of validation: prospective

Manufacturing Line: Solid

Required batch size which corresponds to the recent commercial scale: 122.500 Kg = 350000 cap = 35000 Blisters

Status of product: Valid

Production steps to be valid: dissolution result only

S.N.	Batch no	Manufacturing date	Expiry date	Batch size (Kg
1.	170125	03/2017	02/2019	122.5 kg
2.	180132	04/2018	04/2020	
3.	180133	04/2018	04/2020	
4.	160028	01/2016	01-2018	

3. LIST OF MACHINE & EQUIPMENT AND ITS QUALIFICATION/CALIBRATION STATUS:

NA

3.1. List of equipment used: (IPC/QC laboratories)

NA

4. MATERIALS SUPPLIERS LIST:

NA

5. CRITICAL PROCESS PARAMETERS:

NA

6. CRITICAL QUALITY ATTRIBUTES:

6.1. CQA results

Manufacturing step	Testing required	Position of samples	Sample size	Test responsibilities	Acceptance criteria	Batch No. 170125	Batch No. 180132	Batch No. 180133
Finish Product	Finish product specs MOA	80 tablets Collective Start, Mid-dle, and End	Finish samples	Sampled by IPC to be analyzed by QC	**Dissolution for**: Silodosin NLT 75% after 60 min	96.34%	99.55%	103.51%

6.2. IPC results:

NA

7. STATISTICAL & CHARTS.

7.1. Charts:

NA

8. CRITICAL PERFORMANCE ATTRIBUTES

NA

9. REFERENCE DOCUMENTS

MOA068
MOA119 V0,
PVP076 V1
BMR076

10. STABILITY RESULTS:

NA

11. OBSERVATIONS

NA

12. RECOMMENDATIONS

NA

13. DEVIATIONS HAPPENED & ROOT CAUSE:

NA

14. ACTION REQUIRED:

NA

15. CONCLUSION:

- Product Sildocare 8 mg hard gelatin capsule
- Batch record doc #: BMR098
- Batch number: 170125, 180132 , 180133 &160028.
- All Equipment, Facilities, and utilities which products of 3 consecutive batches and bio batch manufactured on are qualified as mentioned in the original validation study.
- All materials dispensed for 3 consecutive batches and bio batch are from the approved supplier list as mentioned in the original validation study.
- All parameters of manufacturing of 3 consecutive batches and bio batch are within critical process parameters
as mentioned in the original validation study.
- All results of Critical quality attributes of 3 consecutive batches and bio batch, which are critical to the finished product, are with all acceptance criteria after being added to the specifications of Sildocare 8 mg hard gelatin capsule finished product.
- All controls and procedures required are followed in 3 consecutive batches.

- Based on the obtained results and process parameters monitoring during the process in accordance with BMR098, the manufacturing process of Sildocare 8 mg hard gelatin capsule is valid.

16. RECOMMENDED ONGOING PROCESS VERIFICATION FOR VALIDATION STUDY STAGE III:

NA

17. FINAL CONCLUSION

- After the comparison of dissolution results of bio batch and validation batches the results within the acceptance limit

18.HISTORY OF CHANGES

Version number	Month/Year	Changes
0	05/2018	First 3 Batches
1	11/2021	After addition of supplier LEE due to change C039/12
2	01/2023	Addition organic impurity test and change dissolution on hetero supplier
3	10/2023	After adding LOD test
4	07/2025	comparison of dissolution results of bio batch and validation batches