 <b>Al Andalous</b> Pharmaceutical Ind.	<b>Process validation report</b>	Page 1 of 9
Product name: Constipride 1 mg Film Coated Tablets		
Reference protocol number: PVP098	Reference Protocol version:0	
Report number: PVR098/58kg	Report Version: 1	

---

Constipride 1 mg Film Coated Tablets

PROCESS VALIDATION REPORT

---

Validated Batches (190262, 190263, 190264,240238)



Product name: Constipride 1 mg Film Coated Tablets


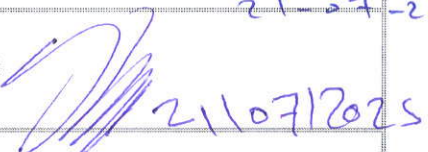

Reference protocol number: PVP098


Reference Protocol version:0

Report number: PVR098/58kg

Report Version:1


**VALIDATION REPORT APPROVAL**

	Name/Title	Sign/Date
Prepared by	Dr. Amr Magdy Validation senior specialist	Sign/Date  21-07-2025
Reviewed by	Dr. Shehab Dawood Validation Section Head	Sign/Date  21/07/2025
Approved by:	Dr. Mohamed Mustafa QA Manager	Sign/Date  P.P. Mustafa 21-7-2025

 <b>AI Andalous</b> Pharmaceutical Ind.	<b>Process validation report</b>	Page 3 of 9
Product name: Constipride 1 mg Film Coated Tablets		
Reference protocol number: PVP098	Reference Protocol version:0	
Report number: PVR098/58kg	Report Version:1	

**Table of contents:**

Item	Page number
OBJECTIVES	4
SCOPE	4
LIST OF MACHINE & EQUIPMENT AND ITS QUALIFICATION/CALIBRATION STATUS	5
MATERIALS SUPPLIERS LIST	5
CRITICAL PROCESS PARAMETERS	5
CRITICAL QUALITY ATTRIBUTES	6
STATISTICAL & CHARTS.	7
CRITICAL PERFORMANCE ATTRIBUTES	7
REFERENCE DOCUMENTS	7
STABILITY RESULTS	7
OBSERVATIONS	7
RECOMMENDATIONS	7
DEVIATIONS HAPPENED & ROOT CAUSE	7
ACTION REQUIRED	7
CONCLUSION	7
RECOMMENDED ONGOING PROCESS VERIFICATION FOR VALIDATION STUDY STAGE III	8
FINAL CONCLUSION	8
HISTORY OF CHANGES	9

 <b>Al Andalous</b> <u>Pharmaceutical Ind.</u>	<b>Process validation report</b>	Page 4 of 9
Product name: Constipride 1 mg Film Coated Tablets		
Reference protocol number: PVP098		Reference Protocol version:0
Report number: PVR098/58kg		Report Version:1

## 1. OBJECTIVES:

To provide documented evidence that the predetermined process of Constipride 1 mg Film Coated Tablets is capable of reliably and repeatedly reproduct product of the required quality after comparison of dissolution results of bio batch and validation batches.

## 2. SCOPE:

**Product Name:** Constipride 1 mg film coated tablets

**Bulk Code:** 10101128,

**Semi-Finish Code:** 201011280110

**Finished product code:** 301011280110

**Shelf life:** 24 months.


**Type of validation:** prospective

**Manufacturing Line:** Solid

**Required batch size which corresponds to the recent commercial scale:** 58.837 Kg = 287000 Tablets = 41000 Blisters

**Status of product:** Valid

**Production steps to be valid:** dissolution result only

 <b>AI Andalous</b> <small>Pharmaceutical Ind.</small>	<b>Process validation report</b>		Page 5 of 9
	Product name: Constipride 1 mg Film Coated Tablets		
	Reference protocol number: PVP098	Reference Protocol version:0	
Report number: PVR098/58kg	Report Version:1		

S.N.	Batch no	Manufacturing date	Expiry date	Batch size (Kg)
1.	190262	05/2019	05/2021	58.83kg
2.	190263	05/2019	05/2021	
3.	190264	05/2019	05/2021	
4.	240238	04/2024	04/2026	117.670 kg

### **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

 <b>Al Andalous</b> Pharmaceutical Ind.	<b>Process validation report</b>	Page 6 of 9
Product name: Constipride 1 mg Film Coated Tablets		
Reference protocol number: PVP098		Reference Protocol version:0
Report number: PVR098/58kg		Report Version:1

## 6. CRITICAL QUALITY ATTRIBUTES:

### 6.1. CQA results

Manufacturing step	Testing required	Position of samples	Sample size	Test responsibilities	Acceptance criteria	Batch No. 190262	Batch No. 190263	Batch No. 190264
<b>Finish Product</b>	Finish product specs MOA	80 tablets Collective Start, Middle, and End	Finish samples	Sampled by IPC to be analyzed by QC	<b><u>Dissolution for:</u></b> Prucalopride NLT 75 % after 30 min	Mean:100.10%	Mean:102.09%	Mean:102.33%

 <b>Al Andalous</b> Pharmaceutical Inc.	<b>Process validation report</b>	Page 7 of 9
Product name: Constipride 1 mg Film Coated Tablets		
Reference protocol number: PVP098		Reference Protocol version:0
Report number: PVR098/58kg		Report Version:1

**6.2. IPC results:**

NA

**7. STATISTICAL & CHARTS.**

**7.1. Charts:**

NA

**8. CRITICAL PERFORMANCE ATTRIBUTES**

NA

**9. REFERENCE DOCUMENTS**

MOA119/1-01-01  
 MOA119 V0,  
 PVP098  
 BMR098 V0

**10. STABILITY RESULTS:**

NA

**11. OBSERVATIONS**

NA

**12. RECOMMENDATIONS**

NA

**13. DEVIATIONS HAPPENED & ROOT CAUSE:**

NA

**14. ACTION REQUIRED:**

NA

**15. CONCLUSION:**

- Product: Constipride 1 mg film-coated tablets
- Batch record doc #: BMR098.
- Batch number: 190262, 190263 , 190264 &240238.
- 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

- Based on the obtained results and process parameters monitoring during the process in accordance with BMR098, the manufacturing process of Constipride 1 mg film-coated tablets 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	05/2019	First 3 Batches
1	07/2025	comparison of dissolution results of bio batch and validation batches