Nexa Pharmaceuticals Ltd.

Solid Dosage Manufacturing Facility — Building 3, Gazipur Industrial Estate

BATCH MANUFACTURING RECORD

Master Formula Ref. No. MF-VNT-250-03 | BMR Issue Date: 04 Jan 2026

Product Name	Vantrel® 250 mg Film-Coated Tablets	**Batch No.**	VNT-2026-0417
Product Code	FPD-VNT-250	**Dosage Form**	Film-coated tablet
Active Ingredient	Vantrelamide USP, 250 mg per tablet	**Batch Size (Theoretical)**	120.0 kg granulation → 250,000 tablets
Manufacturing Date	17 Mar 2026	**Manufacturing Licence No.**	DGDA/MFG/2019/0088
Expiry Date	16 Mar 2028	**Shelf Life**	24 months
Storage Condition	Store below 30°C, protect from moisture	**Pack Size**	10 × 10 blister strips per carton

This Batch Manufacturing Record (BMR) is a controlled GMP document issued in pre-numbered, sequentially paginated form per [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2000, World Health Organization, 2014]. No page may be removed, substituted, or photocopied for use. Every entry must be made in indelible ink, in real time, and signed with initials traceable to the signature log. Corrections follow single-line-strike-through-initial-date; no correction fluid or overwriting is permitted, consistent with [U.S. Food and Drug Administration, 2023, European Commission, 2022].

Master Formula Summary

#	Ingredient	Function	Qty / Unit	Qty / Batch
1	Vantrelamide USP	Active ingredient	250.0 mg	62.500 kg
2	Microcrystalline Cellulose PH-101	Diluent / filler	90.0 mg	22.500 kg
3	Lactose Monohydrate (spray-dried)	Diluent / filler	60.0 mg	15.000 kg
4	Povidone K-30	Binder (granulating fluid)	12.0 mg	3.000 kg
5	Croscarmellose Sodium	Disintegrant	14.0 mg	3.500 kg
6	Magnesium Stearate	Lubricant	4.0 mg	1.000 kg
7	Colloidal Silicon Dioxide	Glidant	2.0 mg	0.500 kg
8	Opadry® II White Y-22	Film-coating agent	8.0 mg	2.000 kg
9	Purified Water USP	Granulating / coating vehicle	q.s.	q.s. (removed in process)
	Total core tablet weight		**480.0 mg**	**120.000 kg**

Reference Documents: SOP-MFG-014 (Wet Granulation), SOP-MFG-021 (Compression), SOP-MFG-027 (Film Coating), SOP-QC-009 (In-Process Testing), SOP-QA-003 (Batch Review & Release).

1 Material Dispensing & Line Clearance

⚠ **Line Clearance Required.** Dispensing booth DB-02 must be cleared of all materials, labels and documents from the previous batch before staging begins. Line clearance is confirmed independently by the dispensing operator and a second qualified person before any container is opened.

Line Clearance Confirmed ☑ Yes ☐ No

Cleared By R. Talukder Date/Time: 17-Mar 06:12

Verified By (QA) N. Ferdous Date/Time: 17-Mar 06:20

Raw Material Dispensing Log — all quantities dispensed on calibrated balance BAL-07 (last calibration 02 Jan 2026, tag CAL-0219).

#	Material	Lot No.	Qty Dispensed	Check	Disp. By	Chk. By
1	Vantrelamide USP	VTA-25601	62.512 kg	☑	R.T.	A.K.
2	MCC PH-101	MCC-11087	22.498 kg	☑	R.T.	A.K.
3	Lactose Monohydrate	LAC-30945	15.004 kg	☑	R.T.	A.K.
4	Povidone K-30	PVP-05512	3.001 kg	☑	R.T.	A.K.
5	Croscarmellose Sodium	CCS-02278	3.498 kg	☑	S.H.	A.K.
6	Magnesium Stearate	MGS-09931	1.002 kg	☑	S.H.	A.K.
7	Colloidal Silicon Dioxide	CSD-01167	0.501 kg	☑	S.H.	A.K.
8	Opadry II White Y-22	OPD-44120	2.006 kg	☑	S.H.	A.K.
9	Purified Water USP	PW-batch-daily	38.4 L (approx.)	☑	R.T.	A.K.

Remarks: Minor over-dispense on Item 1 (+0.012 kg, within the ±0.5% tolerance of SOP-MFG-014 §4.2) — no deviation raised. All dispensed containers labelled with batch number VNT-2026-0417 and staged in bin cart BC-14 per [U.S. Food and Drug Administration, 2023].

2 Manufacturing Process & In-Process Controls

2.1 Wet Granulation

Equipment: High-Shear Granulator HSG-200 (Equip. ID GRN-04) **SOP:** SOP-MFG-014

Parameter	Set Point	Actual	Check	Verified By
Impeller speed (dry mix)	250 rpm / 3 min	250 rpm / 3 min	☑	M.C.
Binder solution addition rate	1.2 L/min	1.1 L/min	☑	M.C.
Chopper speed (wet massing)	1500 rpm / 5 min	1500 rpm / 5 min	☑	M.C.
Wet granule endpoint (power, amps)	8–10 A	9.2 A	☑	M.C.
Fluid-bed dryer inlet temp.	60 °C ±5	58 °C	☑	J.P.
Dried granule LOD (loss on drying)	1.5–2.5 %	2.1 %	☑	J.P.
Milling screen (oscillating mill)	1.0 mm	1.0 mm	☑	J.P.

2.2 Blending & Lubrication

Equipment: Octagonal Blender OB-150 (Equip. ID BLD-03) **SOP:** SOP-MFG-014 §6

Parameter	Set Point	Actual	Check	Verified By
Extragranular blending (CCS, CSD)	10 rpm / 10 min	10 rpm / 10 min	☑	J.P.
Lubrication blending (Mg stearate)	10 rpm / 3 min	10 rpm / 3 min	☑	J.P.
Blend uniformity (10 spots, RSD)	≤ 5.0 %	3.2 %	☑	F.N.

2.3 Compression

Equipment: Rotary Tablet Press RTP-35D (Equip. ID CMP-02), 35 stations **SOP:** SOP-MFG-021

IPC Parameter (checked every 30 min)	Limit	1st Reading	Check	Verified By
Average tablet weight	480 mg ±5 %	481.4 mg	☑	F.N.
Individual weight variation	±7.5 %	within limit	☑	F.N.
Hardness	6–9 kp	7.6 kp	☑	F.N.
Thickness	5.4–5.8 mm	5.6 mm	☑	F.N.
Friability	≤ 0.8 %	0.31 %	☑	F.N.
Disintegration time	≤ 15 min	8 min 40 s	☑	F.N.

IPC readings taken and logged every 30 minutes throughout the compression run (14 sets total, 06:40–13:10); full raw data retained on IPC log sheet IPC-CMP-VNT-0417, cross-referenced here. All 14 sets met acceptance criteria; no OOS observed.

2.4 Film Coating

Equipment: Perforated Coating Pan PCP-60 (Equip. ID COT-01) **SOP:** SOP-MFG-027

Parameter	Set Point	Actual	Check	Verified By
Inlet air temperature	55–65 °C	61 °C	☑	J.P.
Pan speed	8 rpm	8 rpm	☑	J.P.
Spray rate	45 g/min	44 g/min	☑	J.P.
Weight gain (target 3 % w/w)	2.8–3.2 %	3.0 %	☑	J.P.
Coated tablet appearance	Uniform, no picking/mottling	Conforms	☑	F.N.

All in-process controls in this section fall within the limits established by the Master Formula and are consistent with the current annexed process validation, per the in-process testing expectations of [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2000, World Health Organization, 2014]. Complete raw IPC data sheets are appended to this BMR as Annex A.

3 Packaging & Yield Reconciliation

3.1 Packaging Line Clearance & Operations

Line: Blister Line BL-03 (Equip. ID PKG-05) **SOP:** SOP-MFG-033

Step	Check	Verified By
Line cleared of prior product/labels	☑	A.K.
Correct printed cartons/leaflets staged (rev. VNT-L-06)	☑	A.K.
Blister foil batch coding legible & correct (VNT-2026-0417 / Exp 03-2028)	☑	A.K.
Reconciliation of printed packaging materials issued vs. used vs. destroyed	☑	N.F.

3.2 Yield Reconciliation

Stage	Theoretical Qty	Actual Qty	% Yield	Limit
Granulation (dried, milled granule)	120.000 kg	119.340 kg	99.45 %	98.0–101.0 %
Compression (core tablets)	250,000 tabs	248,910 tabs	99.56 %	97.0–101.0 %
Coating (coated tablets)	248,910 tabs	248,370 tabs	99.78 %	98.5–100.5 %
Packaging (blister strips, saleable)	24,837 strips	24,790 strips	99.81 %	98.0–100.5 %
Overall batch yield	250,000 tabs	248,370 tabs	**99.35 %**	**97.0–101.0 %**

Reconciliation statement. Losses at each stage were accounted for by in-process sampling (QC retains: 420 tablets), IPC destructive testing (hardness, friability, disintegration: 180 tablets), line-start/line-clearance rejects (350 tablets), and normal processing loss (dust extraction, transfer adherence). No unexplained loss exceeding the 3.0 % action limit of SOP-QA-003 §8 was observed; overall yield of 99.35 % is within the approved range.

Reconciled By: N. Ferdous **Date:** 20-Mar-2026

QA Verified By: Dr. S. Aktar **Date:** 21-Mar-2026

4 QA Review & Batch Release

4.1 Deviation & Exception Summary

Dev. No.	Description	CAPA / Impact	Closed
DEV-2026-0091	Fluid-bed dryer inlet temp. read 58 °C vs. set 60 °C (within ±5 °C range)	Logged as observation only; no CAPA required, LOD result conforms	☑
DEV-2026-0092	Raw material over-dispense, Vantrelamide +0.012 kg (+0.019 %)	Within SOP-MFG-014 tolerance; QA impact assessment: no effect on potency	☑

4.2 QA Release Checklist

Item	Check
All BMR pages present, sequentially numbered, no missing entries	☑
All in-process control results within specification (Section 2, Annex A)	☑
Yield reconciliation reviewed and within approved limits (Section 3)	☑
All deviations closed with documented impact assessment	☑
QC finished-product test results received and conforming (COA-VNT-0417)	☑
Packaging reconciliation complete, no printed-material discrepancy	☑
Batch-specific label/carton proof matches approved artwork	☑

Hold Statement. This batch remains on quarantine hold and may not be transferred to saleable stock until every checklist item above is marked complete and the QA Release signature below is signed and dated. A single unresolved OOS or open deviation is sufficient grounds for rejection under [U.S. Food and Drug Administration, 2023, European Commission, 2022].

4.3 Batch Disposition

☑ **RELEASED for distribution** ☐ Rejected ☐ Reworked (ref. deviation no. _____)

Prepared By (Production)	Reviewed By (QC)	Released By (QA)
Name: M. Chowdhury	Name: Dr. F. Nasrin	Name: Dr. S. Aktar
Title: Production Supervisor	Title: QC Manager	Title: Head of Quality Assurance
Signature: _____	Signature: _____	Signature: _____
Date: 22-Mar-26	Date: 22-Mar-26	Date: 23-Mar-26

This is the final page of this pre-numbered Batch Manufacturing Record for Batch VNT-2026-0417. Retain per document retention schedule DOC-RET-002 (one year past expiry, per [World Health Organization, 2014]).

References

European Commission. Eudralex volume 4: Eu guidelines for good manufacturing practice for medicinal products for human and veterinary use. Guideline, European Commission, Health and Food Safety Directorate-General, 2022.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Ich q7: Good manufacturing practice guide for active pharmaceutical ingredients. Guideline Q7, ICH, 2000.

U.S. Food and Drug Administration. Title 21 cfr part 211: Current good manufacturing practice for finished pharmaceuticals. Code of Federal Regulations, 2023. 21 CFR 211.

World Health Organization. Who good manufacturing practices for pharmaceutical products: Main principles. WHO Technical Report Series 986, Annex 2, WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2014.