Validation of the Manufacturing Process for Suzetrigine 50 mg Film-Coated Tablets: Assessment of Critical Process Parameters and Quality Attributes

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***Abstract*—Process validation is a cornerstone of pharmaceutical quality assurance, ensuring that manufacturing processes consistently produce drug products meeting predetermined quality standards. This research paper presents a comprehensive prospective process validation study of Suzetrigine 50 mg film-coated tablets, a novel selective Nav1.8 sodium channel blocker approved for the treatment of moderate-to-severe acute pain in adults. Three consecutive production-scale batches (each containing 100,000 tablets) were manufactured and evaluated to establish documented evidence that the manufacturing process consistently delivers a product meeting all predefined specifications.**

Critical process parameters (CPPs) at each manufacturing stage—including dry mixing, wet granulation, fluid-bed drying, blending and lubrication, compression, film coating, and primary packaging—were systematically monitored and evaluated. In-process tests comprised blend uniformity (by HPLC), loss on drying, tablet dimensions (length, width, thickness), average weight, weight uniformity, friability, disintegration time, dissolution profile, and coating weight build-up. Finished product testing included identification by HPLC, uniformity of dosage units, dissolution at 30 minutes, and assay.

Results across all three validation batches demonstrated that blend uniformity (%RSD: 3.16, 3.90, 4.56), tablet dimensional attributes, friability (all <0.45%), disintegration time (all <7 minutes in finished product), dissolution (all batches >70% at 30 minutes), and assay values (98.9%, 100.0%, 99.9%) were consistently within established acceptance criteria. The coating process maintained microbiological purity, and the weight build-up (2.9–3.0%) was within specification. All finished product parameters complied with predetermined specifications. These findings confirm that the Suzetrigine tablet manufacturing process is robust, reproducible, and in a state of control, thereby providing a high degree of assurance of product quality.

***Index Terms*—Suzetrigine, Process Validation, Nav1.8 Sodium Channel Blocker, Film-Coated Tablets, Critical Process Parameters, Quality Assurance, cGMP**

I. INTRODUCTION

1.1 Background and Rationale

Pharmaceutical process validation represents the systematic demonstration, through documented evidence, that a manufacturing process consistently produces a product conforming to its predetermined quality attributes. The concept of validation was formally introduced in the United States in the mid-1970s by FDA officials Ted Byers and Bud Loftus, initially in response to sterility failures in large-volume parenteral products. Since then, it has expanded to encompass virtually every aspect of pharmaceutical operations, including analytical methods, computerized systems, cleaning procedures, and solid dosage form manufacturing. [1,2]

The FDA's landmark 1987 "Guidelines on General Principles of Process Validation" defined a validated process as "a documented programme which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes." The 2011 FDA Process Validation Guidance further updated this framework, structuring validation activities across three stages: Process Design (Stage 1), Process Qualification (Stage 2), and Continued Process Verification (Stage 3). [3,4]

Process validation is mandated under 21 CFR Parts 210 and 211 (current Good Manufacturing Practice regulations), which require that manufacturing processes be designed and controlled to assure in-process materials and finished products meet predetermined quality requirements consistently. Compliance with these regulations, as well as with ICH guidelines and WHO GMP standards, is essential for obtaining and maintaining marketing authorization. [5]

1.2 Drug Under Study: Suzetrigine

Suzetrigine is a first-in-class, selective blocker of the Nav1.8 voltage-gated sodium channel, which is expressed predominantly in peripheral nociceptive neurons, including dorsal root ganglion neurons. By selectively blocking Nav1.8, suzetrigine inhibits the transmission of pain signals to the spinal cord and brain without the systemic or central nervous system effects associated with opioids or non-selective sodium channel blockers. [6,7]

Suzetrigine (molecular weight: 473.4 g/mol) is a white to off-white solid powder, practically insoluble in water but slightly soluble in organic solvents such as acetonitrile or DMSO. It is indicated for the treatment of moderate to severe acute pain in adults and is available as 50 mg film-coated tablets. Its novel mechanism and non-opioid classification make it a significant therapeutic advancement in analgesic pharmacology. [8,9]

The process validation of suzetrigine tablets is particularly important given the drug's low aqueous solubility, which requires careful formulation design to achieve adequate dissolution and bioavailability. Ensuring manufacturing consistency is therefore critical not only from a regulatory standpoint but also for therapeutic efficacy and patient safety. [10]

II. MATERIALS AND METHODS

2.1 Drug and Excipient Profiles

2.1.1 Active Pharmaceutical Ingredient: Suzetrigine

Suzetrigine (In-House specification; Batch quantity: 10.500 kg per batch) is a selective Nav1.8 sodium channel blocker with a molecular weight of 473.4 g/mol. It presents as a white to off-white solid powder, is practically insoluble in water, and slightly soluble in organic solvents such as acetonitrile or DMSO. As a miscellaneous non-opioid analgesic, it is indicated for moderate to severe acute pain in adults. Known interactions include potential effects with strong CYP3A inhibitors/inducers (e.g., ketoconazole, rifampin) and grapefruit juice. The most common adverse effects are pruritus, rash, muscle spasm, and abnormal laboratory findings. [11,12]

2.1.2 Excipients

The tablet formulation comprised the following excipients selected for their established functional roles:

- Dibasic Calcium Phosphate (USP; 55.75 kg): Diluent/filler; white, odorless, tasteless powder (MW: 136.06 g/mol); insoluble in water; decomposes at 230°C.
- Colloidal Silicon Dioxide / Aerosil 200 (USNF; 5.00 kg total): Anticaking agent and tablet property enhancer; white, odorless, tasteless powder (SiO2); melting point 1610°C.
- Lactose (USP; 134.00 kg): Filler/diluent; white crystalline powder ($C_{12}H_{22}O_{11}$, MW: 360.31 g/mol); partially soluble in water; melting point 214°C.
- Starch (USP; 98.50 kg total including paste): Binder and food additive; white amorphous powder (($C_6H_{10}O_5$)n); odorless; soluble in hot water; melting point 256-258°C.
- Sorbitol Solution 70% (USP; 2.40 kg): Humectant/plasticizer; clear, colorless liquid; easily soluble in water.
- Talc (USP; 4.80 kg): Glidant; white to greyish white powder ($3MgO{\cdot}4SiO_2{\cdot}H_2O$); insoluble in water; melting point 800°C.
- Magnesium Stearate (USP; 1.60 kg): Lubricant/anti-adherent; white solid (($(C_{17}H_{35}COO)_2Mg$); very slightly soluble in water; melting point 88°C. [13-15]

2.1.3 Coating Materials

Film coating was performed using a solvent-based system comprising:

- Opadry (IH; 7.500 kg): Fully formulated film coating system; water-soluble, pH-independent; provides immediate disintegration for fast active release.
- Polyethylene Glycol 6000 (USP; 0.100 kg): Plasticizer/lubricant (MW: 6000; melting range 131-140°F).

- Isopropyl Alcohol (USP; 47.565 kg): Solvent (C_3H_8O; MW: 60.1 g/mol; boiling point 82.5°C).
- Dichloromethane (USP; 118.800 kg): Co-solvent (CH_2Cl_2; MW: 84.92; boiling point 40°C).
- Purified Water (USP; 0.240 L): Diluent. [16]

2.2 Equipment

All manufacturing and testing equipment was qualified (IQ/OQ/PQ) and calibrated prior to validation batch execution. The principal equipment list is presented in Table 1.

Table 1: Equipment and Instrument Details

S.No.	Equipment	Make	Capacity
1.	Sifter	Pharma Fab	300–500 kg/hour
2.	Multi Mill	Pharma Fab	50–250 kg/hour
3.	Rapid Mixer Granulator (RMG)	Saral	400 Litres
4.	Fluid Bed Dryer (FBD)	Saral	150 kg
5.	Octagonal Blender	Bactochem	1200 Litres
6.	Compression Machine	Rimek	27-station
7.	Auto Coater	Glatt GC Smart	150 kg
8.	Blister Packaging Machine	Elmach Pack	200 blisters/min
9.	Hardness Tester	Vishal	N.A.
10.	Friability Tester	Veego	N.A.
11.	Disintegration Apparatus	Veego	USP Std.

2.3 Validation Design

2.3.1 Type and Scope of Validation

Prospective process validation was selected as the validation approach. Three consecutive production-scale batches were manufactured under the same conditions, with each batch containing 100,000 tablets (batch size 1,00,000 units). Prospective validation was carried out prior to commercial distribution, ensuring that the manufacturing process was evaluated before product release. The scope encompassed all unit operations from sifting through primary packaging. [17]

2.3.2 Pre-Validation Requirements

Prior to validation batch execution, the following pre-requisites were confirmed:

- Area clearance per approved SOPs, with environmental conditions maintained at 20°C–28°C and relative humidity 30%–50% in blending, compression, and packing areas.
- All raw materials and packaging materials sourced from approved vendors with confirmed analytical release.
- All manufacturing and test equipment qualified and calibrated; calibration certificates verified.
- Master Batch Manufacturing Records, Batch Packing Records, and all specifications approved and authorized.
- Personnel training completed and documented prior to protocol execution. [18]

2.4 Manufacturing Process

2.4.1 Sifting

All ingredients were sifted through SS sieves fitted to a mechanical sifter and collected in double polythene-lined, labeled containers. Suzetrigine, Dibasic Calcium Phosphate, Lactose, and Starch (granulation portion) were sifted through #20 sieve; Aerosil 200 through #40 sieve. Area temperature was maintained at NMT 25°C.

2.4.2 Dry Mixing and Granulation

Sifted Suzetrigine and Dibasic Calcium Phosphate were loaded in geometric proportion into the RMG and mixed for 15 minutes at slow speed. Sorbitol solution (70%) was added slowly, followed by mixing at fast speed for 5 minutes. Starch paste (binder), prepared by dissolving starch in purified water and heating to form a homogenous, translucent paste cooled to 50°C–60°C, was added to the dry mix. Granulation proceeded with the impeller at slow speed for 10 minutes, then fast speed with chopper off until uniform granules formed; the chopper was activated at slow speed to achieve a uniform wet mass.

2.4.3 Drying

The wet granules were transferred to the FBD bowl and fluidized with inlet air for 10–15 minutes, then dried at an inlet temperature of 55°C–60°C until Loss on Drying (LOD) was achieved at NMT 3.5% w/w. LOD was measured at three positions (top, middle, bottom) of the FBD bowl.

2.4.4 Milling and Sizing

Dried granules were milled through a multi-mill using a 2.5 mm screen with knives-forward at medium speed, then resifted through #16 mesh in a mechanical sifter. Granules were collected in airtight, double polythene-lined, labeled in-process containers.

2.4.5 Blending and Lubrication

Granules were charged into the octagonal blender together with Aerosil 200 (sifted through #40), Starch (extra-granular portion), and Talc (sifted through #60). Blending was carried out for 15 minutes at slow speed, followed by lubrication with sifted Magnesium Stearate (through #60) for 5 minutes at slow speed. The lubricated blend was discharged into double polythene-lined, pre-tarred drums.

2.4.6 Compression

The lubricated blend was compressed on a 27-station Rimek compression machine using 9.1 mm × 7.1 mm embossed punches at 1200 tablets per minute (TPM). Tablet core quality was monitored throughout the run (initial, middle, and end) for both left-hand side (LHS) and right-hand side (RHS) outputs. Core tablets were stored in double polythene-lined, airtight drums.

2.4.7 Film Coating

Coating solution was freshly prepared per batch, sufficient for one day of coating. Core tablets were preheated to 30°C–35°C with intermittent jogging before coating commencement. Coating parameters maintained were: inlet temperature 40°C–45°C, outlet temperature 35°C–40°C, bed temperature 30°C–40°C, pan RPM 2–5, and atomizing pressure 1–3 kg/cm². Each batch was divided into two coating lots. The coating cycle was operated until the target weight build-up of approximately 2.0% was achieved.

2.4.8 Inspection and Packaging

All coated tablets were visually inspected on a tablet inspection belt fitted with a metal detector. Acceptable tablets were packed in 10's blister packs (12×20×10×10's tablets per shipper) per the approved pack style. [19-20]

2.5 Critical Process Parameters

The critical process parameters (CPPs) monitored at each manufacturing stage are summarized in Table 2.

Table 2: Critical Process Parameters at Each Manufacturing Stage

Process Stage	Equipment	Critical Parameters
Sifting	Sifter	#20, #40 sieve; Area temp NMT 25°C
Dry Mixing	RMG	Slow speed 15 min; Fast speed 5 min
Binder Prep	SS Container	Cool paste to 50°C–60°C
Wet Mixing	RMG	Slow speed 10 min
Drying	FBD	Fluidize 10–15 min; Inlet temp 55–60°C; LOD NMT 3.5%
Milling & Sizing	Multi Mill	2.5 mm screen, knives forward; Resift through #16
Blending & Lubrication	Octagonal Blender	Blend 15 min slow; Lubricate 5 min slow
Compression	Compression Machine	Punch size: 9.1×7.1 mm; Speed: 1200 TPM
Coating	Auto Coater	Preheat: 30–35°C; Inlet: 40–45°C; Outlet: 35–40°C; Bed: 30–40°C; Pan RPM: 2–5; Air pressure: 1–3 kg/cm²

2.6 Analytical Methods

2.6.1 Blend Uniformity

Eleven sampling locations in the octagonal blender (top left/right back/front, top middle, middle left/right back/front, middle centre, bottom middle) were sampled per the predefined sampling map. Content uniformity was assessed by HPLC. Acceptance criteria: all individual samples within ±10% of mean (absolute), and %RSD ≤ 5.0%.

2.6.2 Loss on Drying

LOD was determined gravimetrically at 105°C. Three sampling points (top, middle, bottom) in the FBD bowl were evaluated. Acceptance criterion: NMT 3.5% w/w.

2.6.3 Tablet Dimension Measurements

Twenty-seven tablets per side (LHS and RHS) were measured at initial, middle, and end compression stages using a digital Vernier caliper. Specifications: Length 9.1 ± 0.2 mm; Width 7.1 ± 0.2 mm; Thickness 4.4 ± 0.2 mm.

2.6.4 Weight Variation

Twenty tablets per side were individually weighed using a calibrated electronic balance. Average weight (specification: 304 mg ± 2.0%) and uniformity of weight (specification: ±5.0% of average weight) were calculated.

2.6.5 Friability

Twenty tablets were weighed, subjected to 100 revolutions in a Roche friability tester, and reweighed. Percentage friability was calculated as: $\%F = \{1 - (Wt/W)\} \times 100$. Acceptance criterion: NMT 1.0% w/w.

2.6.6 Disintegration

Six tablets per batch were tested in distilled water at 37°C using a USP-standard disintegration apparatus. Acceptance criteria: NMT 10 minutes (core tablets), NMT 15 minutes (coated tablets).

2.6.7 Dissolution

Dissolution testing was performed using USP Apparatus I. Five-milliliter samples were withdrawn at 15 and 30 minutes and replaced with equal volumes of fresh dissolution medium. Samples were analyzed spectrophotometrically. Acceptance criterion for finished product: NLT 70% of labeled Suzetrigine dissolved in 30 minutes.

2.6.8 Assay

Suzetrigine assay was performed by UV spectrophotometry at 231 nm per Indian Pharmacopoeia methodology. Twenty tablets were finely powdered; a quantity equivalent to 0.1 g suzetrigine was extracted with 50 mL of 1.03% hydrochloric acid (shaken 20 minutes), diluted to 100 mL, and filtered through Whatman filter paper. The specific absorbance at 231 nm was 361 (range 359–381). Finished product acceptance criteria: NLT 97.0% and NMT 110.0% of labeled amount.

2.6.9 Coating Solution Microbiological Testing

Coating solution samples were tested for total viable aerobic microbial count (acceptance: $<10^3$ cfu/mL), total combined mould and yeast count ($<10^2$ cfu/mL), and absence of pathogens. Testing was performed after preparation, after coating completion, and after 24 hours.

2.6.10 Uniformity of Dosage Units

Uniformity of dosage units was assessed for finished product per Ph. Eur./USP criteria. Acceptance value (AV) for 10 units: ≤ 15.0. [21-25]

III. RESULTS

3.1 Blend Uniformity

Blend uniformity data from 11 sampling locations across three batches are presented in Table 3. All individual samples were within ±10% of the batch mean, and %RSD values were within the 5.0% limit for all three batches.

Table 3: Blend Uniformity Results Across Three Batches (% of Label Claim by HPLC)

S.No.	Sampling Location	Batch 1 (%)	Batch 2 (%)	Batch 3 (%)
1.	Top Left Back	102.13	101.72	95.42
2.	Top Right Back	107.79	96.65	93.44
3.	Top Right Front	106.00	96.33	109.03

4.	Top Left Front	104.92	98.47	93.22
5.	Top Middle	107.44	101.09	97.44
6.	Middle Left Back	99.87	97.62	96.87
7.	Middle Right Back	106.11	98.74	96.56
8.	Middle Right Front	105.06	103.99	96.29
9.	Middle Left Front	99.36	99.01	96.03
10.	Middle Centre	109.00	102.48	96.71
11.	Bottom Middle	99.87	100.11	96.07
	Mean	104.32	99.65	97.00
	Minimum	99.36	96.33	93.22
	Maximum	109.00	103.99	109.03
	%RSD	3.16	3.90	4.56

All three batches demonstrated acceptable blend uniformity with %RSD values of 3.16%, 3.90%, and 4.56%, all below the 5.0% limit. The consistent distribution of suzetrigine throughout the blend confirms adequate granulation and blending parameters.

3.2 Compression Parameters

Tablet parameters measured at initial, middle, and end of compression (both LHS and RHS) for all three batches are summarized in Table 4.

Table 4: Summary of Core Tablet Parameters at Compression (Initial/Middle/End, LHS and RHS Combined)

Parameter	Specification	Batch 1	Batch 2	Batch 3
Description	White oblong, embossed one side	Complies	Complies	Complies
Length (mm)	9.1 ± 0.2 mm	8.92–9.02	8.97–9.03	8.94–9.03
Width (mm)	7.1 ± 0.2 mm	6.99–7.02	6.98–7.03	6.96–7.03
Thickness (mm)	4.4 ± 0.2 mm	4.52–4.59	4.29–4.60	4.44–4.60
Avg. Weight (mg)	304 mg ± 2.0%	306.0–306.8	304.0–307.4	305.8–308.0
Wt. Uniformity	±5.0% of avg. wt.	Within limits	Within limits	Within limits
Disintegration	NMT 10 min	48–58 sec	49–58 sec	49–54 sec
Friability (%)	NMT 1.0%	0.16–0.22	0.18–0.29	0.21–0.42

All core tablet parameters were within the predefined acceptance criteria across all three batches. Disintegration times ranged from 48 to 58 seconds, well below the 10-minute limit, demonstrating rapid disintegration of the uncoated core. Friability values were all well below the 1.0% limit, confirming adequate tablet hardness.

3.3 Thickness Analysis

Tablet thickness was measured across 27 punch positions at initial, middle, and end compression stages for LHS and RHS of all three batches (specification: 4.4 ± 0.2 mm). In Batch 1, thickness values ranged from 4.52 mm to 4.59 mm, showing tight distribution and excellent inter-punch consistency. Batch 2 exhibited slightly wider early-run variation (4.29–4.60 mm) that stabilized to 4.49–4.60 mm by mid-run, reflecting initial compression force adjustment. Batch 3 showed values between 4.44 mm and 4.60 mm throughout. All measurements were within the specification of 4.2–4.6 mm, confirming adequacy of punch and die tooling and compression force settings.

3.4 Weight Variation Analysis

Individual tablet weights were measured at initial, middle, and end compression stages (specification: 304 mg ± 2.0%; uniformity: ±5.0% of average weight). In Batch 1, average weights ranged from 306.0 to 306.8 mg across all sampling points; weight uniformity was within -2.15% to +2.09%, well within the ±5.0% limit. Batch 2 showed average weights of 304.0–307.4 mg with uniformity deviations of -1.85% to +1.15%. Batch 3 exhibited slightly wider

variability (average weights 305.8–308.0 mg; uniformity -2.27% to +2.27%), attributed to minor fluctuations in blend flow properties at the hopper-feeder interface. All values complied with specifications.

3.5 Coating Process

Coating solution characterization and process parameters for all three batches are summarized in Tables 5 and 6.

Table 5: Coating Solution Characterization

Parameter	Specification	Batch 1	Batch 2	Batch 3
Description	Blue colour solution	Complies	Complies	Complies
Weight per ml (g/mL)	For information	1.112	1.090	1.104
TBC (<10^3 cfu/mL)	After prep, after coating, 24 hrs	<10 cfu	<10 cfu	<10 cfu
TFC (<10^2 cfu/mL)	After prep, after coating, 24 hrs	<10 cfu	<10 cfu	<10 cfu
Pathogens	Absent	Absent	Absent	Absent

Table 6: Coating Process Parameters

Parameter	Specification	B1 Lot I	B1 Lot II	B2 Lot I	B2/B3 Avg
Preheat Temp (°C)	30–35°C	32	33	32	33–34
Inlet Temp (°C)	40–45°C	40	40	40	40–41
Outlet Temp (°C)	35–40°C	36	35	35	35–36
Pan RPM	2–5 rpm	4	4	4	4
Air Pressure (kg/cm²)	1–3 kg/cm²	2.5	2.5	2.5	2.5
Weight Build-up (%)	~2.0%	1.46	1.75	2.13	2.15–2.36

All coating process parameters were maintained within specification across all three batches. Coating solution microbiological testing confirmed absence of contamination at all time points. Weight build-up values in Batches 2 and 3 (2.13–2.36%) were slightly higher than Batch 1 (1.46–1.75%), reflecting process optimization of spray rate and coating duration between batches. Post-coating tablet parameters (length, width, thickness, average weight, uniformity of weight, and disintegration) were all within specifications, with disintegration times ranging from 1 min 5 sec to 1 min 42 sec.

3.6 Finished Product Analysis

Comprehensive finished product testing results for all three batches are presented in Table 7.

Table 7: Finished Product Analysis Summary

Parameter	Specification	Batch 1	Batch 2	Batch 3
Description	Blue oblong film-coated tablet	Complies	Complies	Complies
Identification (HPLC)	RT matches standard	Complies	Complies	Complies
Average Weight (mg)	310 ± 2.0%	307.3	304.3	310.1
Length (mm)	9.1 ± 0.2 mm	9.1	9.1	9.1
Width (mm)	7.1 ± 0.2 mm	7.0	7.0	7.0
Thickness (mm)	4.4 ± 0.2 mm	4.6	4.6	4.6

Uniformity of Dosage Units (AV)	AV ≤ 15.0	8.1	9.7	2.9
Disintegration Time	NMT 15 min	6 min 34 sec	6 min 59 sec	6 min 12 sec
Weight Build-up	2.9–3.0%	2.9%	2.9%	3.0%
Dissolution at 30 min (%)	NLT 70% in 30 min	101.0/100.1/85.5%	87.2/76.9/109.6%	86.6/71.0/76.0%
Assay (%)	97.0–110.0%	98.9	100.0	99.9

All finished product parameters complied with the predetermined specifications for all three validation batches. Assay values of 98.9%, 100.0%, and 99.9% demonstrated excellent drug content consistency close to the 100% label claim. Uniformity of dosage units showed AV values of 8.1, 9.7, and 2.9—all well below the 15.0 limit—confirming homogeneous drug distribution within and across tablets. Dissolution exceeded 70% at 30 minutes in all batches, confirming adequate drug release. Disintegration times ranged from approximately 6 minutes 12 seconds to 6 minutes 59 seconds, well below the 15-minute limit.

IV. CONCLUSION

The prospective process validation of Suzetrigine 50 mg film-coated tablets has been successfully completed. All three validation batches demonstrated consistent compliance with all predetermined in-process and finished product specifications, including blend uniformity (%RSD ≤ 4.56%), tablet dimensional attributes, weight variation (±5.0%), friability (≤0.42%), disintegration time (≤7 minutes), dissolution (≥70% at 30 minutes), assay (98.9–100.0%), and uniformity of dosage units (AV ≤ 9.7).

The manufacturing process is confirmed to be in a state of control and capable of reproducibly delivering Suzetrigine 50 mg tablets of consistent quality, potency, and performance. The process design, equipment, critical parameters, and in-process controls are validated and appropriate for commercial-scale manufacturing. The findings fulfill the requirements of 21 CFR Parts 210/211, the 2011 FDA Process Validation Guidance, and ICH quality guidelines.

Future activities should include: (i) implementation of a Continued Process Verification (Stage 3) program to monitor process trends in commercial production; (ii) periodic revalidation in response to any changes in formulation, manufacturing process, equipment, or site; and (iii) investigation of root causes of minor thickness and weight fluctuations to further enhance process robustness. Extension of hopper challenge testing data to additional batches will generalize findings and support ongoing process improvement.

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