VLUERP

Enterprise resource planning · Industry edition

Pharmaceutical manufacturing

Four sums between a product and a recall

Potency correction, content uniformity as a statistic, cleaning limits and a shelf life capped by its inputs — on top of formulae, lot genealogy, QC release and recalls.

USP <905>
Acceptance value, not a range

Salt × purity
Two corrections that multiply

Shelf life capped
By the API lot's own expiry

Formulae, lots and recalls — plus four sums

Formulae, lot genealogy, QC release, expiry and recalls run on the same engines as the Chemicals and Food add-ons. Pharma adds four sums that decide whether a batch is legal.

1. **API lot** — Assay, water, solvent
2. **Quarantine** — Received and held
3. **Charge** — Salt factor × purity
4. **Batch** — Units made and reconciled
5. **Uniformity** — Acceptance value per USP
6. **Release** — Faults block release
7. **Market** — Expiry capped by inputs

Potency corrected

The salt factor and the effective purity multiply, so every unit is charged with enough powder to hold its label claim.

Uniformity as a statistic

Content uniformity is judged on the acceptance value, not on whether each result sits between 95 and 105.

Cleaning limits computed

Dose, 10 ppm and visually clean are all computed; whichever is lowest governs, and swab recovery tightens it.

A shelf life that can't lie

A batch cannot outlive the materials it was made from — the earliest expiry caps the date on the pack.

71.2%	7.0185	3	10%
of claim, uncorrected	mg powder per 5 mg tablet	cleaning criteria computed	process overage ceiling

The right dose — in every unit

The active is rarely the molecule on the label, and never 100% pure. VLUERP corrects the charge, then judges the batch the way USP <905> does.

Potency correction

- Salt factor: amlodipine besylate ÷ amlodipine = **1.386892**.
- Effective purity = assay × (1 – water) × (1 – solvent); an as-is assay is not corrected for water twice.
- Both multiply: a 5 mg amlodipine tablet takes **7.0185 mg** of powder.
- A process overage is kept separate from potency correction, and refused above 10%.

Content uniformity

- Acceptance value AV = $|M - \bar{X}| + k \cdot s$, with M pinned to 98.5-101.5 and k = 2.4 at n = 10, 2.0 at n = 30.
- The pass region is a tent, not a box — the batch screen draws it over the 95-105 box people assume.
- A batch with a mean of exactly 100% can fail on spread, while a tighter one at 98.8% passes.
- Faults block release; warnings are shown but do not stop the batch.

Dispensed at a fixed 5 mg, a tablet holds 71.2%

In a worked example, a 5 mg amlodipine tablet needs **7.0185 mg** of powder. Weigh 5 mg and it holds **71.2%** of its claim; correcting for purity alone gives 5.0606 mg — still only **72.1%**. The page prints both figures, because they differ.

Materials in quarantine

API lots received with assay, water and expiry, and held until released.

A seeded failing batch

Mean 100.000%, s 6.430, AV 15.432 — it fails, as blender segregation really looks.

Reconciliation

The figure that matters is the unexplained part, not the yield.

A clean line, an honest date — both computed

Cleaning limits worked out on three criteria, and an expiry that can never run past the drum the active came from.

Cleaning validation

- Dose criterion TDD × MBS ÷ (SF × MDD), plus 10 ppm and visually clean at 4 µg/cm².
- A potent previous product makes dose bite; a small next batch, ppm; a small machine, visual.
- Swab recovery makes the limit smaller, not larger — the other way round, a dirty machine passes.

Shelf life and expiry

- Stability supports a shelf life; the API lot's own expiry can cap it — and the screen shows by what.
- A retest date is not an expiry: it is reported, never applied as a cap.
- Life left on every material lot is shown before it is charged.

Seeded faults caught — in testing

Case	What happened	Figure
Potency correction	5 mg weighed where 7.0185 mg was required	**71.2% of claim**
Content uniformity	Batch B00006: mean 100.000%, s 6.430	**AV 15.432 — fails**
Tight batch	Batch B00013 at 98.8% with a tight spread	**Passes**
Cleaning, blister line	940 µg found after warfarin; visually clean governs	**Limit 85 µg**
Shelf life	Batch B00011: 24 months of stability	**9 months granted**
Cause of the cap	The paracetamol drum expires February 2027	**Capped by the API lot**

Under-potency and overage are different numbers: weighing 5 mg instead of 7.0185 mg is 40.37% less than required, yet the tablet is 28.8% under claim.

Every screen in the module — and what is on it

Read off the running application — the panels, columns and figures actually there. The batch page draws the uniformity tent.

4 screens

36 functions

01 Plant

- Potency correction value
- Reconciliations off limits
- Rejected or quarantined
- Shelf life capped
- Mean acceptance value
- Deviations open
- Stability supports
- Actually expires
- Capped by

02 Products

- Form
- Label strength
- Salt factor
- API lot
- Effective purity
- Charge per unit
- Correction
- % of unit
- Shelf life

03 Materials

- Receive a lot
- Assay
- Water
- Effective purity
- Expiry
- Life left
- On hand
- Value
- Quarantine

04 Batches

- Plan a batch
- Made
- Product
- API lot
- Units
- Acceptance value
- Uniformity
- Expires
- State

Not a separate program — a complete business system

The trade module sits on top of a complete ERP: everything it does lands directly in the accounts, the stores and the reports — no double entry.

Accounting

Editable chart of accounts, automatic entries from every transaction, VAT and financial statements.

Financial dimensions

Cost centres, departments, business lines and sites — with statements per factory.

Inventory

Warehouses and bins, batches and serials, moving average, FIFO or standard cost.

Purchasing & sales

RFQs, purchase orders and receipts, quotations, invoices and ageing.

Maintenance & assets

Equipment register, preventive maintenance, work orders and depreciation.

Access & language

Roles and rights per module, audit trail, full Arabic and English interface.

Standards and criteria applied

USP <905>	Dose criterion	10 ppm	4 µg/cm²
Uniformity of dosage units	Carry-over from the therapeutic dose	Carry-over into the next product	Visually clean surface limit

The lowest of the three cleaning limits governs, after swab recovery. Formulae, genealogy, expiry and recalls use the Chemicals and Food engines.

Bring one product and its API

Book a session and we'll set up the demo with one of your own products and API lots — then correct its potency, judge a batch and check its expiry.

Request a demo

Website	**www.vluerp.com**
Demo request	**www.vluerp.com/#demo**
Email	**hello@vluerp.com**

1. **Products:** salt factor, effective purity and the powder charged per unit.
2. **A batch:** the acceptance value drawn as a tent over the 95-105 box.
3. **Plant screen:** what potency correction is worth, reconciliations off limits and open deviations.
4. **Expiry:** a shelf life capped by the API lot, and why.

Switched on from Add-ons with a free seven-day trial, and it runs on the same general ledger.