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Comprehensive SAP based solution Drug formulation process of Active Pharmaceutical Ingredients Manufacturing

Ashish Kumar Mondal PMP® (B. Tech)

Certified in SAP SCM- Mfg. & Planning, SAP-Product Life cycle Management & Plant Maintenance, ISO 9001, six Sigma - Green Belt, CSCP, Scrum Master.

Abstract - Chemical formulation in the manufacturing of Active Pharmaceutical Ingredients (APIs) is an inherently complex and precision-critical process. Even minor deviations in formulation parameters can significantly alter product efficacy and safety, potentially transforming a life-saving drug into one that causes serious risks to patient health or compromises diagnostic outcomes. While modern enterprise resource planning (ERP) systems offer some capabilities to model chemical formulation using active ingredient management and proportional units of measure. ERP capabilities for end-to-end formulation control remains limited. Despite this criticality, formulation calculations in many pharmaceutical environments continue to rely on manual methods due to lack of comprehensive systematic ERP solution.

In practice, pharmaceutical manufacturers often perform formulation calculations externally verifying individual potency of available batches and manually input the results into ERP systems solely for execution, which increases the likelihood of errors and inconsistencies. Overall, the lack of a robust, system-driven formulation solution presents both operational and compliance risks, while also imposing significant financial and environmental burdens on the industry.

This white paper presents a comprehensive SAP-based solution framework designed to enable an end-to-end, systematic digital process for API formulation. The proposed approach integrates formulation calculations, material traceability, warehouse reservation creation with potency-based quantities of the available batches, and controlled execution workflows using SAP Manufacturing Execution, Quality Management, and Inventory Management modules, thereby enhancing accuracy, ensuring consistency, and reducing operational and compliance risks.

This is solution frame is not limited pharmaceutical industry specific, but this could be used for any chemical industry as well.

Keywords: API (Active Pharmaceutical Ingredient), Proportional Unit of Measure, BOM (Bill of Materials, Recipe, Base UoM, Active Unit of measure, Potency, process order, Chemical formulation.

1. INTRODUCTION:

All active ingredients vary in potency from batch to batch, meaning that a fixed volume (e.g., one liter) or weight (e.g., one gram) of a chemical does not contain the same amount of active ingredient each time. Therefore, formulation calculations should not be limited to the physical quantity of the chemical required for the desired manufacturing output. Instead, calculations must account for the specific potency of each available batch and determine the precise quantity needed accordingly. Current SAP capabilities for managing chemical formulation—such as proportional units of measure and limited material quantity calculation within master recipes is insufficient to support the complexity and precision required in Active Pharmaceutical Ingredient (API) manufacturing. These functionalities are relatively basic and do not provide a comprehensive, end-to-end solution for formulation control.

As a result, the pharmaceutical industry continues to rely on manual calculations and external tools, introducing significant risks related to accuracy, consistency, and data integrity. The absence of an integrated formulation framework increases the likelihood of composition errors, which can compromise product quality and patient safety. Moreover, additional time is required for preparation, and full-time resources are needed to validate formulation variations. Any error in formulation leads to the wastage of high-value pharmaceutical ingredients, thereby increasing the cost of goods manufactured (COGM). From an environmental perspective, improper or erroneous formulations necessitate the disposal of chemical materials, further amplifying regulatory and sustainability concerns.

2. SAP BASED SOLUTION METHODOLOGY

Required Master Data Setup:

1. **Material Master:**
   - **Base Unit of Measure :** Base UoM must be set the most discrete physical unit of measure**.**

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- **Alt Unit of Measure:** Maintain Conversion factor of all applicable unit of measure.
- **Proportional Unit of Measure :** Define proportional UoM based on requirement of measuring potency of the chemical, such as Unit/Liter, mg/dL,% of solid. Molar density etc..

2. **Bill Of Material:** Master data object which keep required component list required for manufacturing the product.
   - Maintain all chemical components (active ingredients) with potency (Proportional UoM, also some time called batch specific unit of measure.
   - Maintain a base quality either in physical unit or with Active units for which all component quantities are maintained in the bill of material.
   - Maintained formulae key in "SortSting" field for each component. These key points all calculation dependencies and calculation of requirement quantity.
3. **Maintain Master recipe:** The master recipe defines the sequence of operation steps and phases required for process manufacturing. It also maintains a structured list of component materials, specifying when they are to be consumed during the manufacturing process.
4. **Define order type :** Order type is a configuration object in SAP to define process order related controls. Make sure configuration to mandate batch assignment of the components for order release Note: Keep details formula in a custom table.

5. **Formulation order creation Enhancement:** Develop an enhancement program to trigger all calculation logic to determine the actual required quantities of each chemical based on the potency of available batches while meeting all other chemical formulation constraints. As per program flow illustrated in Figure 1 & 1.

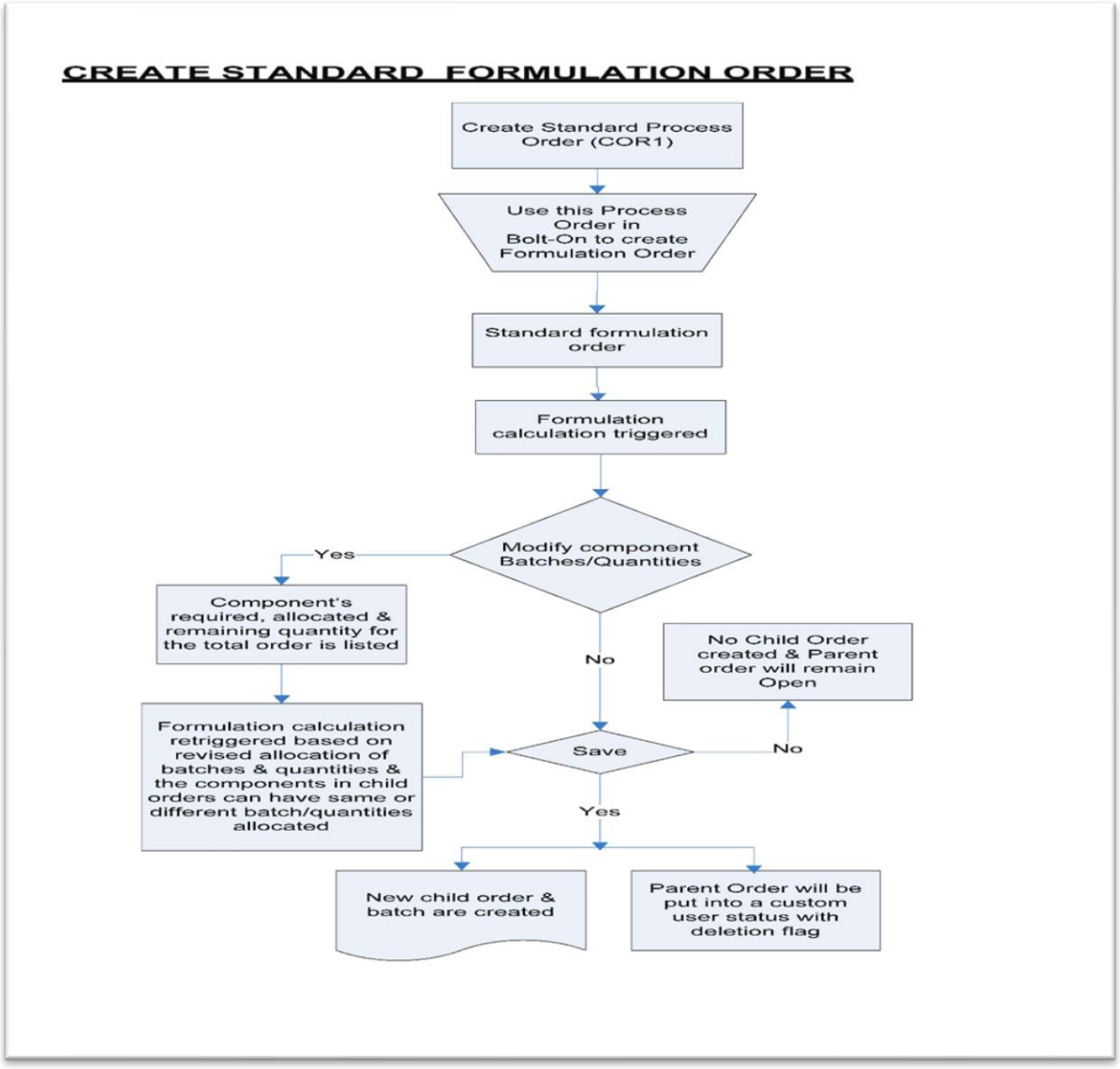

Figure 1 -Formulation Order Creation Flow

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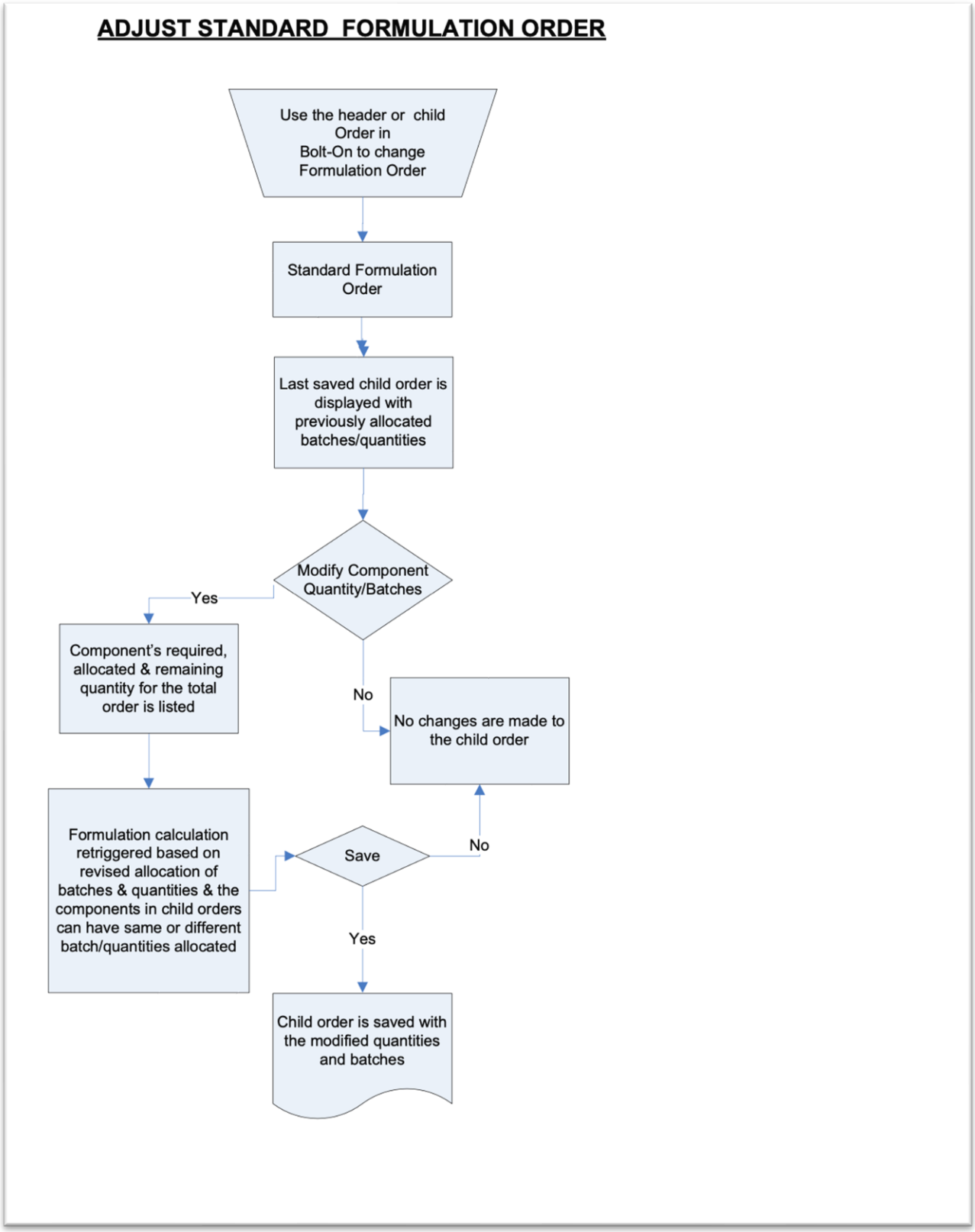

Figure 2 Formulation Order Adjustment Process Flow

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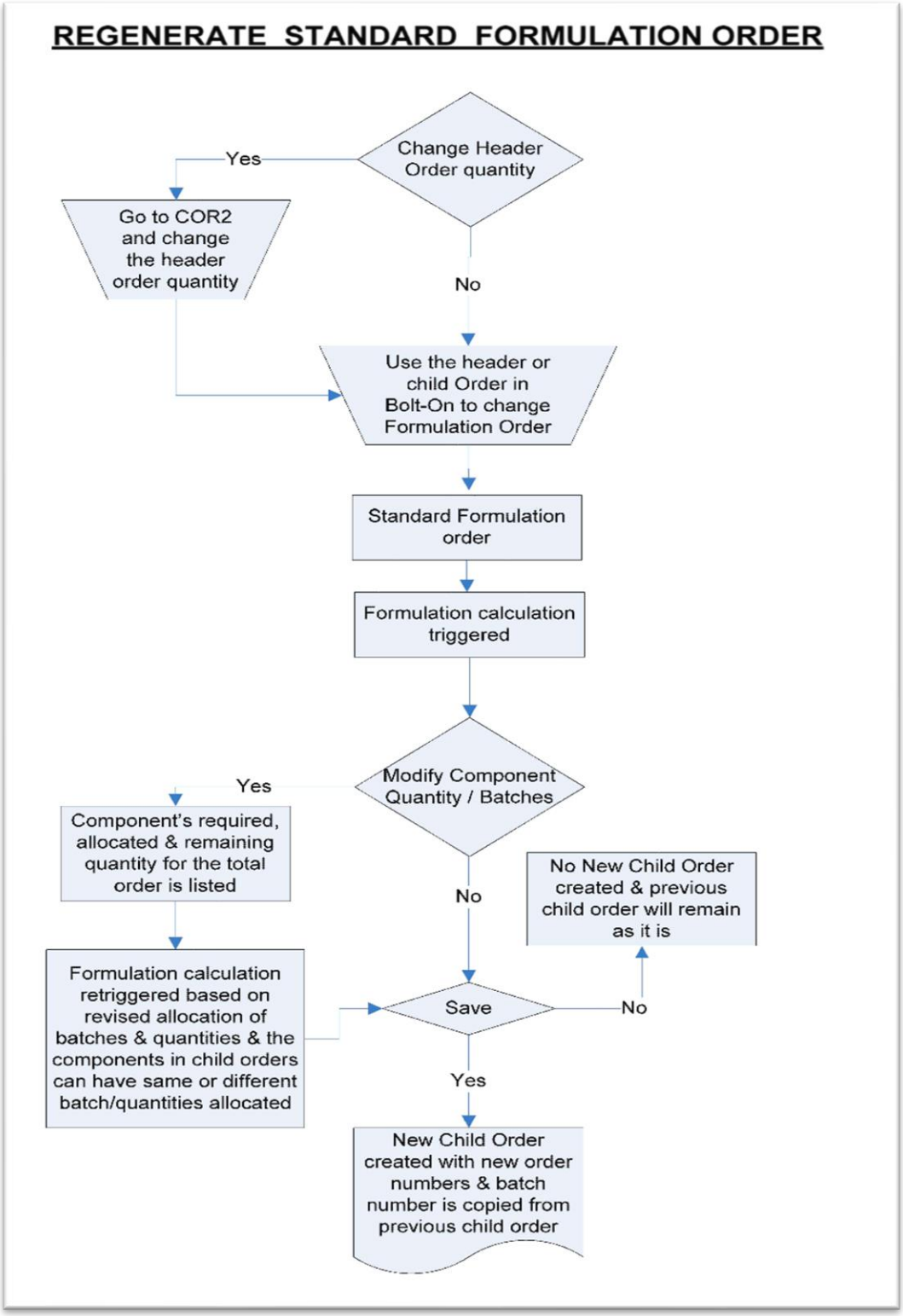

Figure 3 Regeneration of Formulation order in case of error

Few typical examples of formula and constraints

FR#01: Ability to create standard formulation order: After the standard process is finalized for its scheduled dates and ordered quantity, the formulation event will be triggered manually by the user with the aid of a custom transaction giving the user the ability to convert the process order into one of the following:

1. Standard Formulation Order
2. Twin Order

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3. Pump Over order
4. Blend Order
5. Regenerate Formulation Order.

Search option will be provided to look up the order based on the material number. During conversion of original process order into child / formulation order, system must not consider assembly scrap %age defined in master data or original process order for header qty calculation of child / formulation order. Child / formulation header total qty must be equal to original order total qty.

FR#02: Ability to perform batch determination for the components: Once the user selects the standard formulation order batches, quantities for the components are automatically determined. For automatic batch determination, FIFO and FEFO rules apply with FEFO taking precedence over FIFO.

Before batch determination the original parent deletion flag must be so that the components reserved against the initial order are made available during batch determination. If the child orders are not saved, then the deletion flag set to the original order has to be removed. If the auto batch determination picks up the batch with missing activity value or AIM, then the corresponding component line must be displayed with a yellow traffic light and pick qty must be displayed as zero.

FR#03: Components must not expire before the due date of the order: The expiry date of the batch selected must be more than or equal to the due date of the order. Manual batch determination overrides FIFO and FEFO rules; status and expiry rules still apply.

FR#04: Ability to allocate multiple batches against a component: In case of any scenarios where a single batch is not enough to meet the requirement, then multiple batches will be selected. All batches selected need to meet the above criteria. For materials that cannot have split batches, this functionality of multiple batches will not be allowed.

FR#05: Material with a "restricted" status must not be automatically allocated to an order: Restricted batches (MCH1-ZUSTD) can only be manually selected as part of the formulation work order.

FR#06: Allocate pre-solutions to order prior to the manufacturing of the pre-solutions: In cases where a component is a pre-solution, this solution must be shown as available in inventory even though its status is planned (released process order).The system must allow allocation of this component's batches even though activity may not be assigned but the component line must be displayed with a yellow traffic light and pick qty must be displayed as zero. Orders that contain pre-solutions batches without activity must not be released until that batches are available in inventory with an assigned activity level.

Pre-solutions order quantity equals CAUFV-GAMNG (Total order quantity) where (CAUFV- OBJNR) equals Object Number (OBJNR) in JEST. (Object Status) From the data thus fetched, select only the orders which have a status of Released (I0002) and not Delivered (I0012), and/or Technically Completed (I0045).

FR#07: Quantities proposed by the system must be in line with calculation rules defined: Formulation orders use a set of pre-defined calculation types to arrive at the component quantities. These calculation type values are stored in the "Sort String" (STPO-SORTF) field inside the Material BOM as a numerical field. There are 7 calculation types that are defined:

- Calculation Type 1: Constant.
- Calculation Type 2: Percent Solids.
- Calculation Type 4: Fill to
- Calculation Type 5: Enzyme
- Calculation Type 6: Reverse Fill to
- Calculation Type 7: Flush
- Calculation Type 8: Antibody

Net, Pick and Accumulated quantities are calculated as part of the formulation logic. Net Quantity is the actual solid quantity (the percent solid). The total net quantity calculated as per formulation logic will not be changed. The quantity may be divided into one or multiple batches but the total net quantity will not be changed by the user.

Net quantities are to be displayed in their stock keeping unit of measure Pick Quantity is the stock keeping quantity. Pick quantities are to be displayed in their Base UOM

Pick quantity must be displayed in Stock keeping UoM. Incase BOM component UoM and material master base UoM are not same then program must apply respective conversion factor to maintain the consistency in quantity and UoM. Accumulated quantity is the sum of pick quantities and the preceding components. Accumulated quantities are to be displayed in grams for reagent Manufacturing

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Calculation types 1 : Component quantity is added to the solution as a constant in relation to the base quantity i.e., component quantities are proportional to the product quantity. This is the standard SAP functionality of any component being issued to the order based on the proportion to the base quantity in the BOM.

Net Quantity = Pick Quantity = (BOM Quantity *Order Size) / BOM Base Qty

Calculation type 2 : Component quantity is added to the solution as a wet amount but calculated as the constant dry amount divided by the lower limit of the aim activity to achieve the resultant wet amount in grams.

The component quantities are not proportional to the product quantity and different active ingredient concentrations of batches must be taken into account in arriving at the component quantity. The component quantity is calculated as dry amounts, but the inventory is maintained in wet units. The BOM quantities for these are maintained in wet units. A planned activity level range is maintained in the material master of the component. The selected batches AIM is compared to the planned AIM value (maintained in the material master) and the requirement is calculated based on the following formula:

Net Quantity = (BOM Quantity*Order Qty) /BOM Base Qty
Pick Quantity = (BOM Quantity*Order Qty/BOM Base Qty) * 100 / (Batch Characteristic value maintained against "Z_PERCENT_SOLID")

Note: BOM with components of calculation type 2 always have another component of either calculation type 4 or 6 for the additive solution liquid (like water or acetone.)

Calculation type 4 : Component quantity for these is dependent on the other component quantities inside the work order. This is the quantity of the water/filler liquid to be added to the mix to arrive at the specified quantity maintained in the BOM. Component quantity is calculated by subtracting the total quantity for all the preceding components as per the quantity specified in the BOM . Calculation type 4 is always designated below calculation types 2, 5 or 8 in the BOM structure which are always done before calculation type 4.

Net Quantity = Pick Quantity =
((Order Quantity * BOM Quantity) / BOM Base Qty)) – (Sum of all preceding pick quantities)

There is a possibility for multiple times Calculation type '4' component shall repeats, When such a situation, there should have the additional assignment of Water/filler liquid. This water/filler liquid quantity calculation to be obtain each time by subtracting the sum of the all preceding components from the extended BOM quantity. The rule to

be applied for type '4's, regardless of how many appear on the BOM is that must achieve the TOTAL at each type '4'.

An audit for calculation type '4' should insure the deviation between accumulated qty and order qty with in 1% tolerance.

Calculation type 5 : The components are maintained in "KU" in the BOM. The component quantities are calculated by dividing the BOM quantity to the AIM of the batch.

Calculation type 6 : Component with calculation type 6 is always the first line item in the BOM component list. The default quantity for this is equal to the base quantity of the BOM. The calculations for calculation type 2, 5 and 8 are done before this calculation is done. Component quantity is calculated by subtracting the total quantity for all the components as per the order quantity

Pick Quantity = Net Quantity = Order Quantity – (Sum of all other pick quantities) Calculation type 6 – With Type 7

Calculation type 6 is always the first line item in the BOM component list. The default quantity for this is equal to the base quantity of the BOM. The calculations for calculation type 2, 5 and 8 are done before this calculation is done. Component quantity is calculated by subtracting the total quantity for all the components as per the order quantity

Pick Quantity = Net Quantity = Order Quantity – (Sum of all other pick quantities that are not Type 7) – (BOM qty for type 7)

Calculation type 7 : This calculation type is only valid when the order quantity is greater than 19.1 kgs and a component exists with calculation type 6. The purpose of this calculation type is to reserve a fixed amount of the first addition for flushing the vessel.

The calculation type 7 is used for flushing of the formulation vessels for which a fixed amount of flushing fluid needs to be kept aside. The calculation type seven component quantity needs to be fixed as per the quantity maintained in the BOM for all the orders which hare greater than 19.1kgs. The BOM component quantity needs to be retained in all the child orders irrespective of the number of vessels.

Net Quantity = Pick Quantity = BOM Quantity

There is a possibility for multiple times Calculation type '7' component shall repeats at when order quantity is greater than 19.1kgs, When such a situation, there should have the deduction of calculation type '7' component from calculation type '6' component at each time so that it matches the total accumulation quantity with order quantity. The rule to be applied for type '7's, regardless of how many appear on the BOM is that must achieve the TOTAL to the Order quantity.

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Calculation type 8: The components are maintained in "DU" per kg in the BOM. The component quantities are calculated by dividing the BOM quantity to the AIM of the batch.

Net_Quantity = (BOM Quantity*Order Qty) /BOM Base Qty
Pick Quantity = (BOM Quantity*Order Qty) / (Batch Characteristic value maintained against "Z_ENZYME_ACTIVITY_ME or Z_ENZYME_ACTIVITY_GR ")

Note: If Base UOM of component is ME then use Z_ENZYME_ACTIVITY_ME. If Base UOM is GR then use Z_ENZYME_ACTIVITY_GR

Accumulated Quantity for each line item in the order is sum of pick quantities of itself and the preceding components.

CALCULATION TYPES AT FLUIDS MANUFACTURING

At a fluids facility, the calculation types are component specific. Each component, irrespective of the bill it goes to, has a specified calculation type assigned to it. These calculation type values will be stored in the "Sort String" (STPO- SORTF) field inside the Material BOM as alpha numerical fields.

Post inspection calculation types will not be brought into the formulation enhancement. Provision will be provided during confirmation to ensure these unplanned goods are issued based on the quality inspection results.

Pre- inspection, the endogenous, or in-process or batch specific concentrations of the components (e.g. TP, CHOL), have to be stored in the corresponding batch characteristics.

Note:- In case of FM special calculation type those are independent of BOM qty, batch determination should be done as per requirement quantity and incase one batch is not sufficient, then partial batch need to be assigned and remaining required quantity should be taken from the next batch.

REFERENCES (VANCOUVER STYLE)

[1] World Health Organization. *WHO good manufacturing practices for pharmaceutical products: main principles*. Geneva: WHO; 2014.
[2] U.S. Food and Drug Administration. *Code of Federal Regulations, Title 21, Part 210—Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs*. Silver Spring (MD): FDA; 2023.
[3] U.S. Food and Drug Administration. *Code of Federal Regulations, Title 21, Part 211—Current Good Manufacturing Practice for Finished Pharmaceuticals*. Silver Spring (MD): FDA; 2023.
[4] International Council for Harmonization (ICH). *ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*. Geneva: ICH; 2016.
[5] International Council for Harmonization (ICH). *ICH Q11: Development and Manufacture of Drug Substances*. Geneva: ICH; 2012.
[6] International Council for Harmonization (ICH). *ICH Q9: Quality Risk Management*. Geneva: ICH; 2023.
[7] International Council for Harmonization (ICH). *ICH Q10: Pharmaceutical Quality System*. Geneva: ICH; 2008.
[8] European Medicines Agency. *EudraLex Volume 4: EU Guidelines for Good Manufacturing Practice, Annex 16: Certification by a Qualified Person and Batch Release*. London: EMA; 2016.
[9] European Medicines Agency. *EudraLex Volume 4: Good Manufacturing Practice Guidelines*. London: EMA; 2015.
[10] Sandle T. Avoiding errors with the batch release process: best practice cGMPs. *J GXP Compliance*. 2022;26(3):12–20.
[11] Schniepp SJ. A look at batch record review. *Pharm Technol*. 2017;41(6):34–38.
[12] Xiong H, Yu LX, Qu H. Batch-to-batch quality consistency evaluation of pharmaceutical products. *AAPS J*. 2013;15(3):906–915.
[13] Iyer KR, et al. Data integrity in pharmaceutical manufacturing: ensuring ALCOA+ compliance. *J Pharm Innov*. 2020;15(4):567–575.
[14] Rathore AS, Winkle H. Quality by design for biopharmaceuticals. *Nat Biotechnol*. 2009;27(1):26–34.
[15] Leuenberger H. New trends in the production of pharmaceutical granules: batch versus continuous processing. *Eur J Pharm Biopharm*. 2001;52(3):289–296.
[16] FDA. *Guidance for Industry: Process Validation—General Principles and Practices*. Silver Spring (MD): FDA; 2011.
[17] PIC/S. *Guide to Good Manufacturing Practice for Medicinal Products*. Geneva: Pharmaceutical Inspection Co-operation Scheme; 2018.
[18] Sharma G, et al. pharmaceutical manufacturing process optimization and quality risk management. *Int J Pharm Sci Rev Res*. 2018;49(2):45–52.
[19] Garcia T, Cook D. Batch genealogy and traceability in pharmaceutical manufacturing systems. *Pharm Eng*. 2019;39(4):1–8.
[20] ISO. *ISO 9001: Quality Management Systems—Requirements*. Geneva: International Organization for Standardization; 2015.