A R Shiny App for Mixing Drug Substance to Make Final Formulated Bulk

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Background

- **Relevant Manufacture Process:**
  - To manufacture Formulated Final Bulk (FFB) for the product of interest, bags of drug substance (DS) need to be mixed with certain volume of stabilizer to attain target potency with acceptable pH range and FFB volume
  - When target potency is met by calculation, it does not warrant that pH and FFB volume meet the criteria
  - Currently to obtain combinations of DS and stabilizer with target potency and acceptable pH and final volume, manual trial & error method is being used

- **What is Shinny:**
  - Framework for building interactive web applications using open source R language
  - Shiny Apps can be hosted online on a server, and be shared. Thus, our clients can run an unique analysis in R without touching an R console

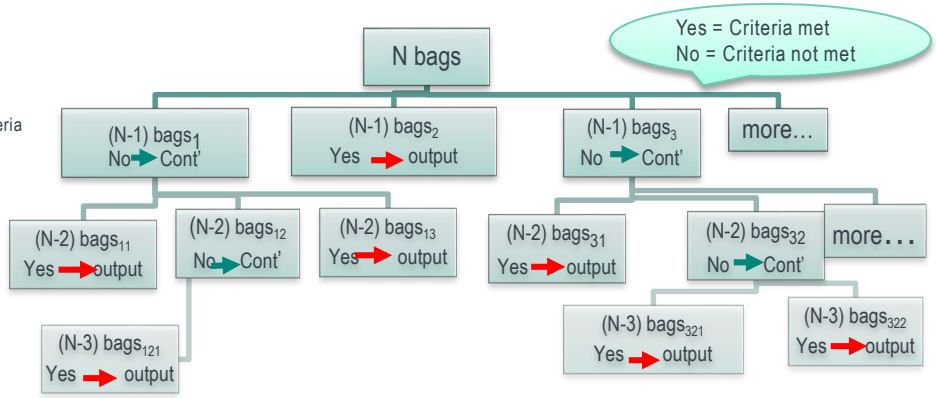
Problem Statement

- Currently the Excel worksheet with built-in calculations can tell whether the manually selected bags meet the acceptance criteria
- Successful combination can only be generated by tedious trial and error method
- Very difficult to find optimal combinations
- It is necessary to develop tool that allows users the flexibility to select bags and generate optimal combinations to maximize product yield and increase efficiency
- A tool easy to use from the manufacture floor

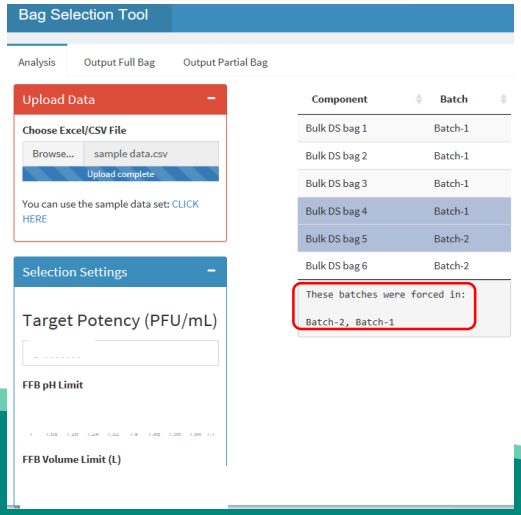
Objective

- **Acceptance criteria (AC) for FFB:**
  - Target potency)
  - pH:
  - FFB volume:
- **Challenges:**
  - Number of bags for final selection is unknown
  - Meeting one criterion does not guarantee meeting other 2 criteria
  - Optimal choice can only be generated by trying out all permutations
  - Trial and Error method is tedious and time consuming
  - Selection of full DS bags is highly preferred
  - Use of partial content from DS bags is an open option
- **Solutions:**
  - Recursive function starting from combinations with all bags to fewer bags
  - Separate functions for selection of full bags and partial bags
  - Each node stops when at least one branch meets the AC
  - Allow customized features
    a. Selection of certain bags
    b. Customized pH range
    c. Customized FFB volume

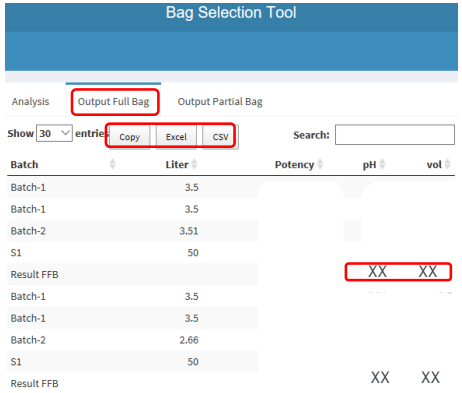
Recursive Function for search



Results/Resolution - input



Results/Resolution - Output



Business Results

- The tool is easy to use
- The search is nearly exhaustive, efficient, and flexible
- Ability to minimize DS waste
- Allow control on FFB batch size
- Allow older DS bags over recently manufactured DS to be selected before expiry

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