

Deccan Nutraceuticals Pvt. Ltd., Pune

# General Information

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- Fully owned subsidiary of Alkaloids Corporation, Kolkata (India).
- Factory located on a plot admeasuring 22,000 sq m
- Started manufacturing in 2003.
- Manufacture Herbal Extracts, Intermediates and APIs. All products are completely processed from start-to-finish in this plant.
- The premises has 4 (four) independent manufacturing blocks, in addition to a separate Warehouse, Quality Unit, Water Purification plant (potable/USP grade), Effluent Treatment Plant etc.

# General information (continued)

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- Manufacturing Block I is used for the initial stage extraction of botanical parts and manufacture of intermediates up to crude stage.
- Manufacturing Blocks II & IV are used for the final purification and packaging / labeling of finished products. These blocks are designed to meet Class 100,000 clean room requirements.
- Manufacturing Block III is used for pilot plant trials of fermentation based products.
- QC has three sections – Instrumentation Lab, Wet Lab and Microbiology Lab.

# List of products

Sr. No.	API's	Regulatory Filings	Mfging Block
1	Digoxin USP/Ph. Eur./BP/IP/JP	1) COS No. RO-CEP 2010-298 2) USDMF No. 28628	Blocks I & IV
2	Artemether Int. Ph. / IP	-	Block II
3	Artesunate Int. Ph. / IP	-	Block II
Sr. No.	Intermediates	Regulatory Filings	Mfging Block
1	10-Deacetylbaaccatin III (10-DAB III)	USDMF No. 25226	Blocks I & IV
2	Lysergol	-	Block I & II
3	Dihydroartemisinin	-	Block I
Sr. No.	Herbal Extracts	Regulatory Filings	Mfging Block
1	<i>Coleus forskohlii</i> extract	-	Blocks I & II
2	Horsechestnut extract	-	Blocks I & II

# International regulatory inspections

Sr. No.	Dates	Agency	Name of auditor(s)	Outcome
1	27-30 Jan 2014	USFDA	Sandra A. Huges Ralph H. Vocque	Inspection closed; EIR dated 24-Apr-2014.
2	22-26 Feb 2016	USFDA	Andrew J. Idzior	Inspection closed; EIR dated 17-May-2016.
3	22-24 June 2016	EDQM	Dr Thomas HECKER Ms Andrea SPRICK	Initial report date 3-Aug-2016; 'the company operates in general compliance with EUGMP'; CAPA submitted.
4	26-30 Sept 2016	USFDA	Dr Ademola Daramola	Inspection closed; EIR dated 21-Jan-2017.

# Taxus baccata – 10-DAB III



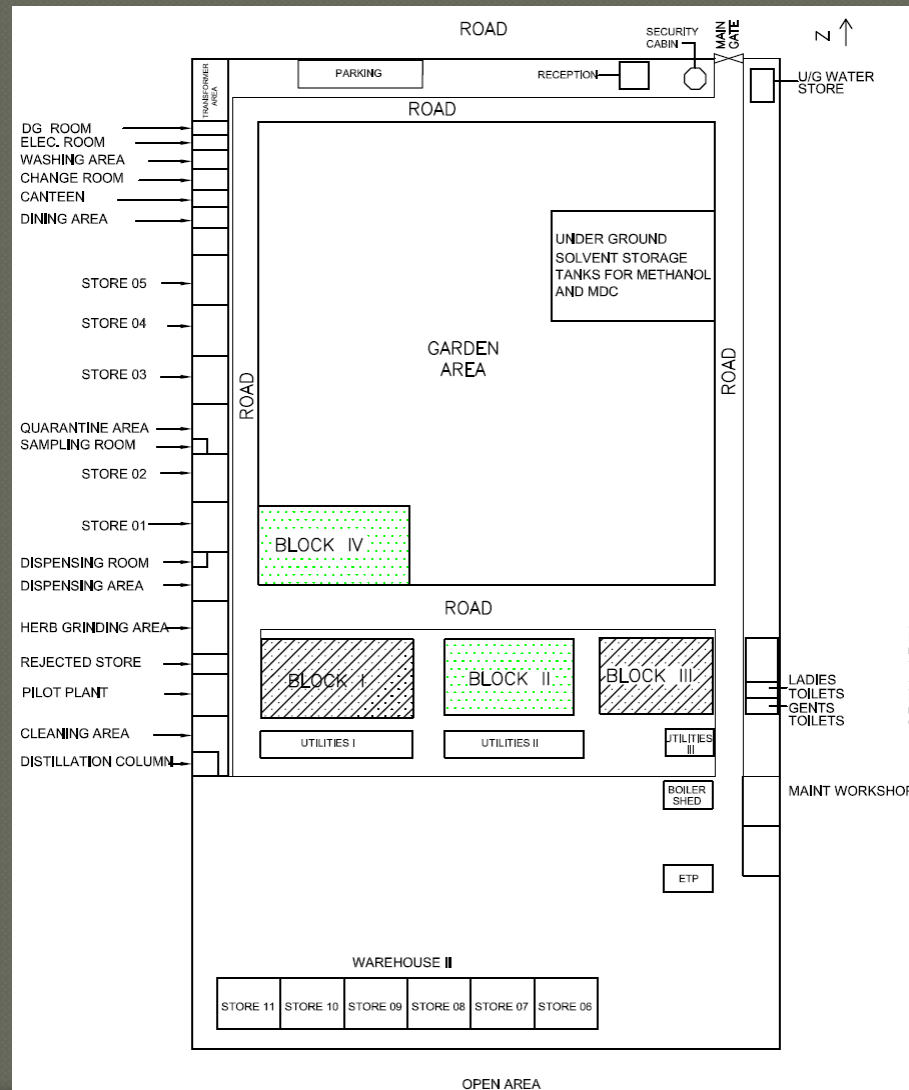
- Part of plant: leaves (needles)
- Sourced from Netherlands, EU
- Grown for Ornamental and Pharmaceutical use
- Slow growing plant
- Harvesting age: 3 years (min.)
- Harvesting season: June to Sept
- Yield: ~ 5 MT dried leaves/ha
- 10-DAB III ~ 0.15 %
- No pesticides used
- Harvesting as per GACP

# Digitalis lanata – Digoxin



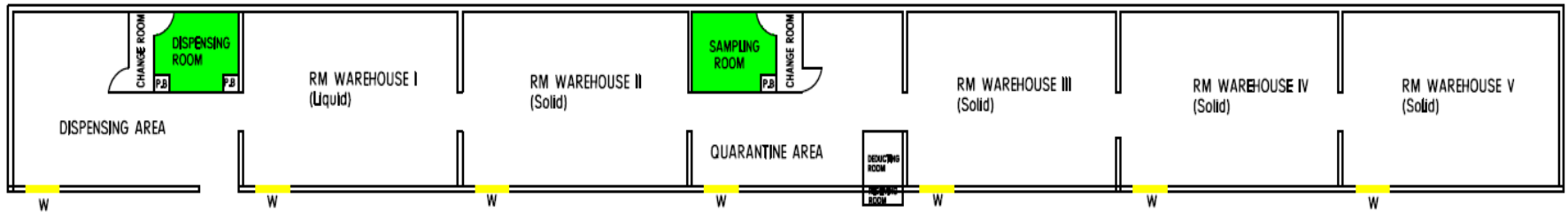
- Part of plant: leaves
- Sourced from Netherlands, EU
- Plants grown for Pharmaceutical use
- Sowing: March-April
- Harvesting season: Sept-Oct
- Yield: 5 MT dried leaves/ha
- Digoxin ~ 0.85 %
- No pesticides used
- Cultivation as per GACP
- 1 ha reserved for seeds generation

# Site Layout-Bird's eye view

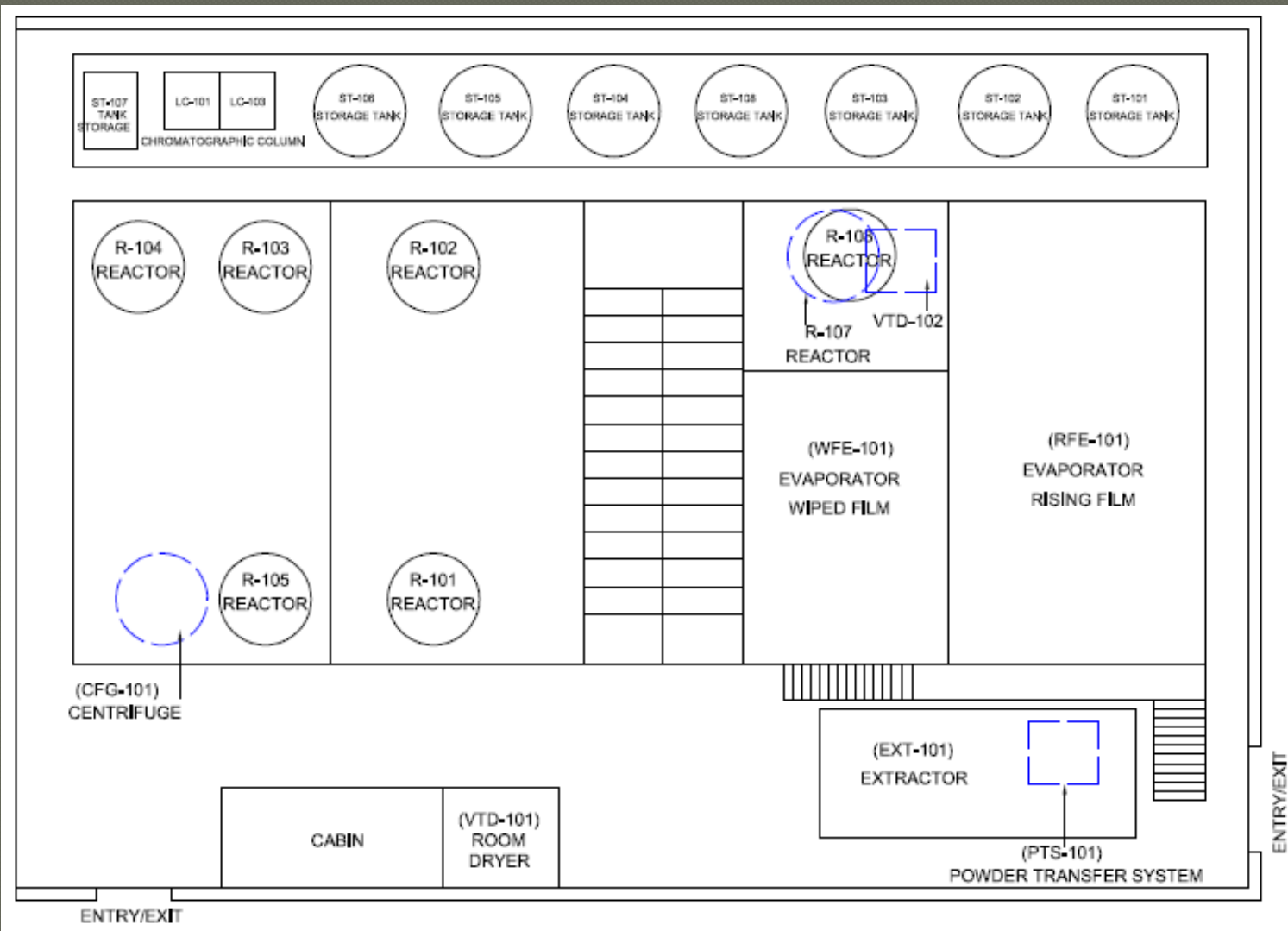




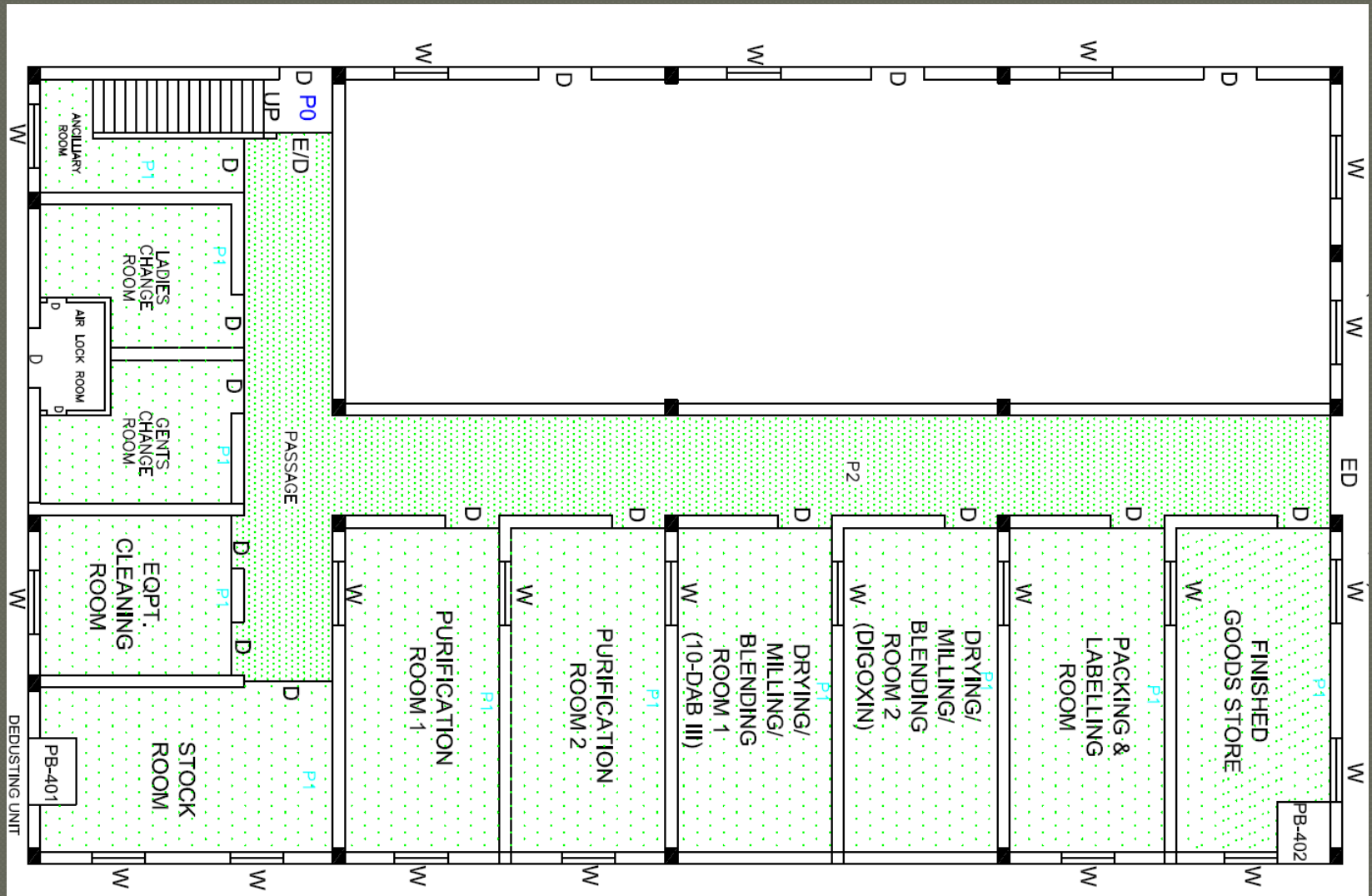
# Schematic Layout of Warehouse



# Schematic Layout of Block I



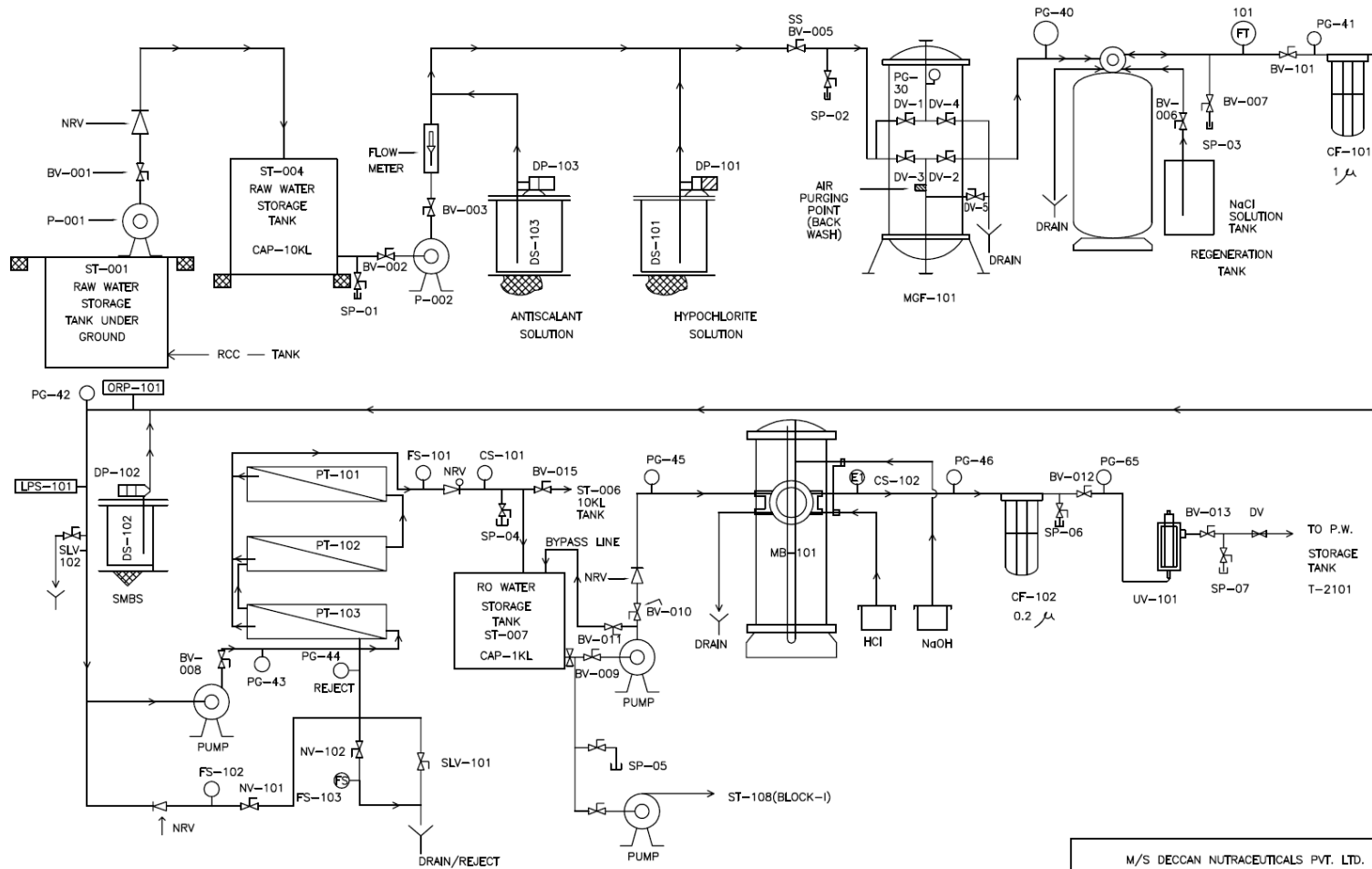
# Schematic Layout of Block IV



# QC Laboratory



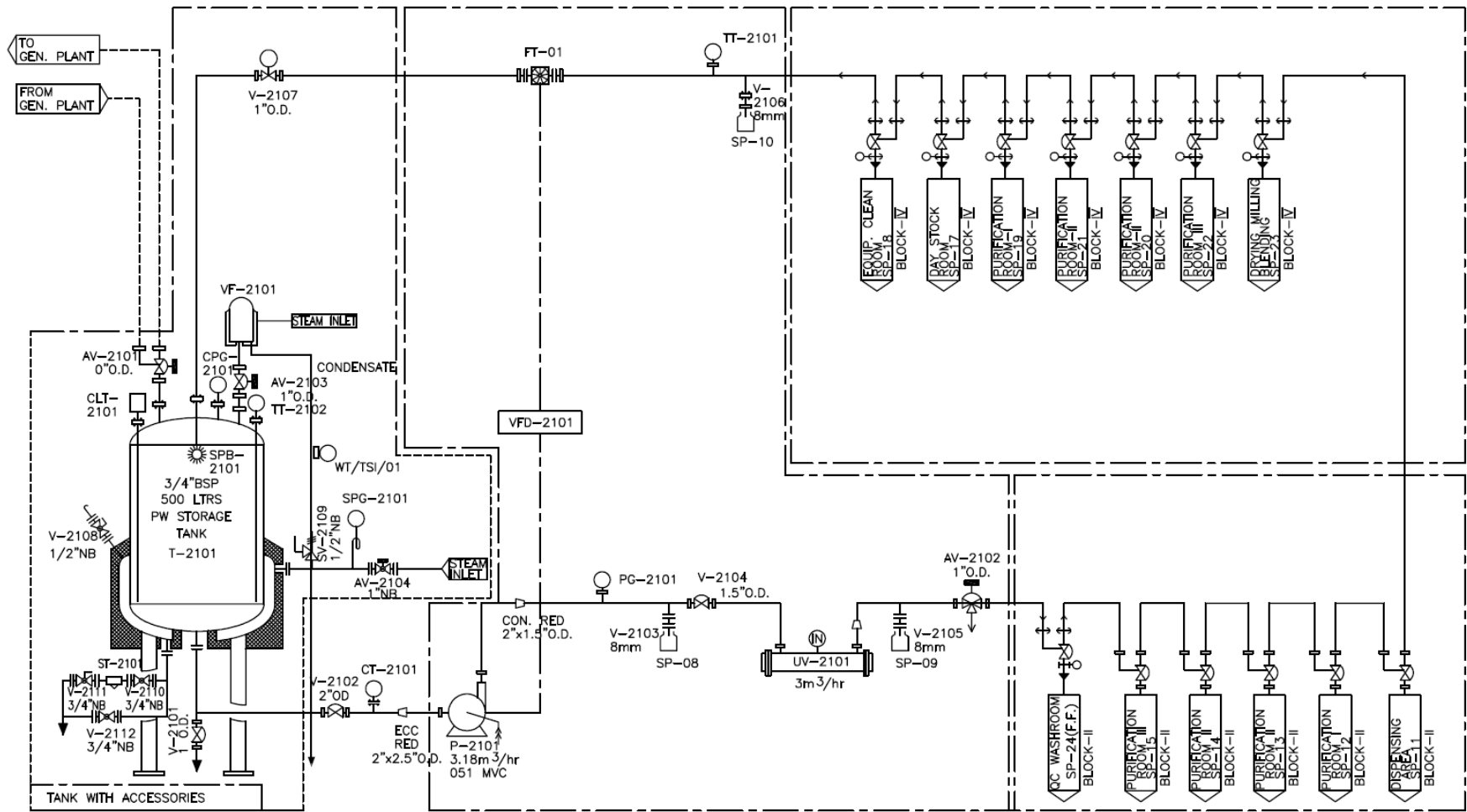
# Water Purification Plant



M/S DECCAN NUTRACEUTICALS PVT. LTD.

WATER GENERATION SYSTEM DIAGRAM

# Purified Water Storage & Distribution



# Quality Policy

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We, at Deccan Nutraceuticals Private Limited, are committed to produce, high quality phytochemicals, APIs as per our customer's requirement by following regulatory and government norms through integrated efforts.

# Salient features of QMS

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- GMP at DNPL flows from Top to bottom
- Management is involved in macro and micro development process of QMS
- Updated SOPs with training for enhanced knowledge and continual compliance
- Specific efforts taken to involve people for seamless integration of GMPs across the organization
- Speedy corrective and preventive action
- As a part of Continual improvement with risk based approach we strive to keep pace with the regulatory updates
- We promote proactive initiatives by the employees across the plant, the key aspect of our current state of compliance



# EXPANSION – BLOCK V (UNDER CONSTRUCTION)

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Thanks