Audit Report

External Quality Compliance

SITE AUDITED: VVF (India) Limited.
Plot No.141/143, Panchal Udyog Nagar,
Bhimpore, Nani Daman, Daman.

DATE: 14th & 15th September 2016.

AUDITOR(S): **1. Mr. Baldev Singh Thakur (Lead auditor).**
(CMO-Quality Coordinator India)
2. Mr. Dipen Raval (Support Auditor).
(Manager-Co-packs)

AUDITEES: **1. Mr. Dinesh Kabra –** GM- Operations.
2. Mr. Matish Thakkar – AGM-Quality.
3. Mr. P. M. Sharma – Production- Sr. Manager.
4. Mr. Mrudang Vachharajani – HR – Sr. Manager.

SCOPE:

1. RB Global Manufacturing Quality Manual (GMQM-Version-6).
2. Internal Policies and Procedures of the Company under Audit.

The Follow up audit on 14th – 15th September 2016 is perform to confirmed, that all the actions from the previous audit performed on 8th & 9th October 2015; is suitably addressed along with the review of current status of the site with respect to GMQM standard.

OVERALL CONCLUSION:

During the last audit performed on 8th & 9th October 2015; 07 major and 20 other observations were reported. The detail of the compliances of the observation as on date is define in brief in the later part of the report. Due to the open observations from the previous audit and the new observations observed during follow up audit; 05 major and 06 others observations are reported in the follow up audit report.

The audited site has been given the following rating: **YELLOW** which equates to the facility being: **MEDIUM RISK.**

SUMMARY:

Background and Site Overview –

The Vegetable Vitamin Foods (VVF) Co. was founded in 1939, in India, by Godrej Pallonji Joshi.

Today, VVF is a global player in following business segment**:**

- Contract Manufacturing.
- Oleo chemicals.
- Consumer Products.

VVF (India) Limited Daman plant is established in 1998.

At present, Company is having two facility, one is under cosmetic license and another building where RB products are being manufactured under drug license no. DD/233. Company mainly engaged with contract manufacturing business and focused on liquid preparation of Antiseptic Liquids, Hand Sanitizers, Face wash, Body wash, and Shampoo and cosmetics oils.

Chorological sequence since establishment as below:

• In 1999 Vita Soaps & Specialities started manufacturing of soap.

• In 2000 Started manufacturing of cosmetics.

• In 2004 Vita Soaps & Specialities renamed as M/s Vita Biopharma Pvt. Ltd.

• In 2013 M/s Vita Biopharma Pvt. Ltd. merge with VVF (India) Ltd.

Started Dettol antiseptic liquid production in 2002 and Started Dettol hand sanitizer production in 2009-10.

Few of business highlights in last 2 years as below:

- Unit is ISO 9001:2008, certified by TUV Nord in 2015 and valid upto 2018.
- Unit is GMP certified by Local FDA.
- OTIF (on time in Full) of unit is 100% with full quality compliances and zero born out complaints.
- Unit has catered 550KL (Approx.) of DAL in a month to support the market requirements. Batch size increased from 10 KL to 15KL for DAL and similarly for DHS from 500 Ltrs. to 1500 Ltrs.

- Quickest response for 5 Ltrs pack of DAL from procurement to dispatch in about 2 weeks' time.
- Unit is the sole manufacture of Dettol Hand Sanitizer for RB.
- Successful commercial production for 3 new variant of DHS, Floral essence, Spring fresh and Natural.

During the follow up audit all the earlier observed observation were verified for their evidence for closure and the open observations are detailed in the current report.
The manufacturing area and Packaging area requires GMP up gradation which is highlighted in detail in the audit report.
Main areas of concern are: Site GMP up gradation, Equipment qualification system, Computer system validation and control, Management of third parties, Self inspection program and departmental procedural compliance with respect to current cGMP procedures and regulatory expectations.
The overall detail is mentioned below:

Manual/Standard	No. of Critical Findings	No. Major Findings	No. Other Findings	Overall Risk
Global Manufacturing Quality Manual (Version-6)	Nil.	05	06	Medium Risk.

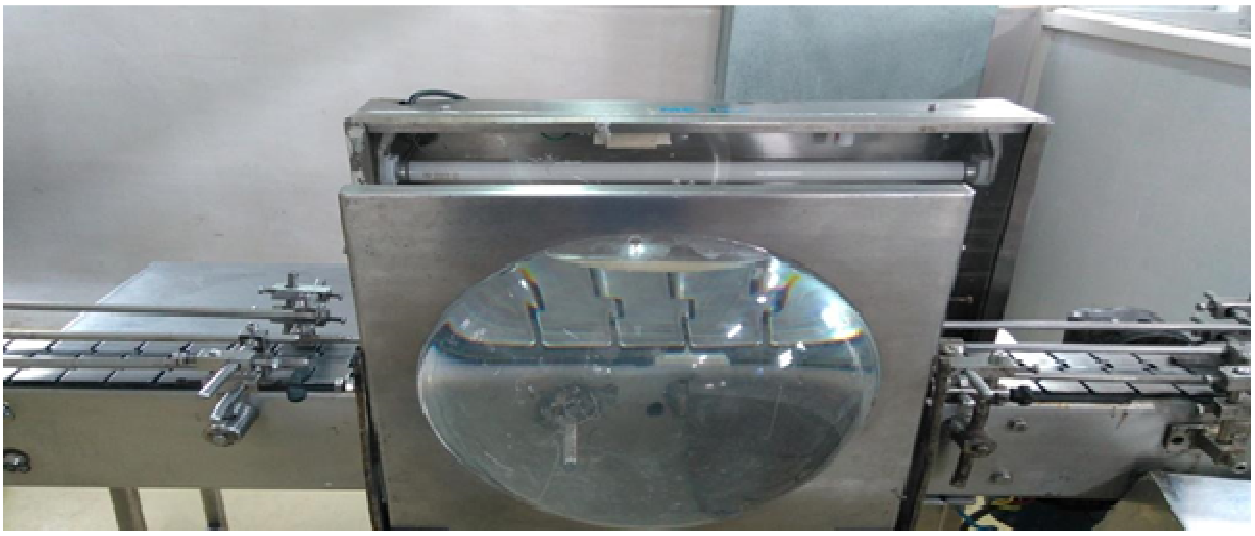
THE FOLLOWING GOOD PRACTICES WERE IDENTIFED:

1. The auditees showed openness and transparency throughout the audit.
2. The Auditees were very keen to make improvements if support is given to understand the requirements and the solution to meet the requirements, through a robust improvement plan.
3. The key initiative in DHS packaging line in recent past taken are summarized below:
   - Monoblock machine installed and commissioned results in auto filling and

   Capping operation. Previously capping operation was Manual. Cap feeding through Vibrator is introduce due to which foreign particles if present are arrested and will fall automatic through chute; hence ensuring foreign particles free capping operation. Bulk from storage tank to hopper of Monoblock machine is by gravity. Auto level sensor

installed to maintain bulk level in hopper. Machine is having CIP system for cleaning.

- Magnifying glass installed for online filled bottle inspection. Visual inspection is strengthen through magnifying glass installed on online packing conveyor and is being inspected through trained person.



- Manual transfer of bottles transferred to Labelling machine removed and now entire packing line is online.

Global Manufacturing Quality Manual v6 & Relevant Regulations

General Requirements

- Manufacturing License No. DD/233 valid till 18-04-2019.
- GMP certificate as per Schedule M is valid up to 30-09-2017.

1. Quality System

Observation	Action	Responsible	Status	Comments
1)SMF (02/08-effective date-05/10/15) is deficient: a) The status of release procedure of finished product, management of supplier and contactor, quality risk management and PQR. b) The SMF Numbering system not defined. c) As per page no.26 of 37; AHU-supply with 20micron – 5micron-0.3 micron is mention and class of 1 lakh is mention for building No.2 but actually it is not the case. d)The site master file is deficient in listing the below mention laboratories used for testing & Calibration purpose : I.Precitach Laboratories Pvt. Ltd. II.Autocal. III.Toshwin.	SMF shall be revised to incorporate the deficiency highlighted in the report.	Hitesh/sarong Selote	Closed	The site is recommended to describe the status of the AHU in building -2 in more brief.
2)VMP (VMP/2015/001-Rev-04) is deficient: **a) It is having detailing of AHU and other system which is not applicable to block-2 where DAL& DHS is made but the VMP is not defining any area specific for where it is applicable.** **b) The V model concept is not defined in the SOP.** **c) The Validation master plan does not format as part of tracker for ensuring the completion of annual validation/qualification plan with the status.** **d)As per the clause No.8.2.3.5 below mention deformity is observed:** **I. Water SYSTEM Phase-I and Phase-II qualification frequency is define as 2 weeks instead of 2-4 weeks.** **II. In case of Phase-II requirement of OOS/Deviation is define but for phase-I it is not defined.** **III.VMP detail about usage of Purified water after completion of Phase-I instead of Phase-II.** **e) As per clause No.8.4; the test**	**The VMP shall be revised to incorporate the deficiency highlighted in the report.**	**Hitesh/ Jayesh**	**Open**	**All the observation are closed except for inclusion of annual tracker for monitoring the validation/qualification activity.**

Observation	Action	Responsible	Status	Comments
parameters requirement for compressed air qualification is only Microbial count (Total bacteria/Fungal) and pathogens and are defined as per ISO-8573.				
Quality targets are monitored and reviewed however there is no clear link evidence that they are used to drive the quality improvement program.	The procedure is incorporated and been tracked.	Hitesh/ Jayesh	Closed	The auditor has given feedback to further include more KPI for strengthening the monitoring regime.
1) Raw and packing material Supplier assessment program is not in place. 2) The earlier audit by RB has been performed on 28 SEP 13 and the points pending till date for compliance has not been escalated for closure as on date and no status for delay for closure of the audit observation is available with Audittee. The points pending for closure from the previous audits are: a) Dettol antiseptic Liquid test for efficacy is not done in the Lab. b) Chemical compatibility chart is not available for all the chemicals Store in the laboratory. c) Technical agreement with the laboratory. d) Retention samples for DAL and DHS is not kept for 6 months after expiry date.	1. We have communicated to the suppliers to submit us the TSE & BSE certificates. For some of the materials we have received the certificates. 2. a) We have technical agreement with the contract lab. Where the test is performed. b) To display the charts. c) To prepare technical agreement. d) To revise the SOP.	Jayesh Desai / Hitesh	Closed	NA.

The QMS system was reviewed against the requirements of the Global Manufacturing Quality Manual during the follow up audit. The below observation was noted:

1.1

1) The site master file (SMF-02; rev-09-effective date -10/12/2015) is found deficient for the below mentioned observations;
   a) Konark laboratories, invochem laboratories and analytical solution is present in SMF as external laboratories but the technical agreement with them not found and was informed by the auditee that the labs. are not used for testing purpose any more but the same is not updated in the SMF.
   b) Revision history of the SMF is not maintain.
2) VMP (VMP-03; Rev-05; Effective date- 30/12/2015) is found deficient for the below mentioned discrepancies:
   a) As per VMP (Refer page no. 18 of 21); the first three validation batches to be charged to Stability as per the stability protocol. Also it has a mention of charging one batch per year of every product manufactured. The practice is found to be not in place.
   b) As per the clause no. 8.4 of VMP and procedure for monitoring of compressed air (SOP No.QA-089/D) the compressed air to be monitored for microbial count,

absence of pathogen, solid particle, water content and oil presence in air but it is not in practiced.

2. People

Observation	Action	Responsible	Status	Comments
1) The contractor training record not found. **2) The Training evaluation for the SOP using questionnaire is not practiced and nor the minimum requirement of the persons scoring in the test for the training evaluation is stated.** **3) The visual inspector qualification is not performed. The list of qualified visual inspector is not available.**	**1. To revise an implement SOP HR 002.** **2. To include written evaluation of trainings to contract workers.** **3. To prepare list of person trained for visual inspections.**	**Sweety**	**Open**	**All the actions are closed beside the formalized qualification of visual inspector through the protocol and according maintaining the list of qualified visual inspector.**

The auditors has observed significant improvement in the training approach from his last time audit. The auditors were shown the trial version of the customized electronic system for managing the training. The process of data feeding was going on during the auditor stay there. With the training management system in place the below mentioned activities of the employee shall be tracked:

1) Training Calendar.
2) Need Identification.
3) History Card.
4) Pending Training.
5) Re-Training Record.
6) MIS (Training Hours).

The employee shall be reminded through system based mail for their pending training activities. The approach shall be currently placed for the company's employee and at the later stage it shall be used for managing the casual workmen's too.

The site has incorporated the GMP, personal hygiene and safety training assessment as the part of the induction and later the casual is mapped for his training as per the allocation of work in the respective area.

Observation	Action	Responsible	Status	Comments
1) As per the procedure the safety Shoe should be provided for entry into the Manufacturing area but Audittee and auditor were without safety shoe as the need for it was not highlighted by the Audittee. 2) Apron usage/cleaning frequency not define in the SOP No.PR 208/C (Entry and exit of visitors) and SOP No. PR 208/C (Entry and exit of Workmen). 3) As per the SOP No.PR 208/C (Entry and exit of visitors); list of different PPE's are listed but their	1. SOP PR - 208 to be revised 2. Area wise PPE displays to be increased	J Bhatt	Closed	NA.

Observation	Action	Responsible	Status	Comments
point of usage not define nor the areas are demarked for the usage of the required PPE's. 4) Eatable, water and mobile restriction are not detailed in the SOP though it was told that it is restricted in the area. 5) No medical checkup programme is available for casual workmen.				

During the follow up audit below mentioned discrepancies were observed:

2.3

1) The medical heath check-up for the employees are practiced but the procedure for same is not available.
2) The disinfectant efficacy test for the disinfectant (IPA) used is not performed.

3. Premises

Observation	Action	Responsible	Status	Comments
1) The only light fixture available in the sampling area was found in non Working condition and no maintenance job order for the same found. 2) Wooden pallets are used for storage of material in the facility.	1. To re-check and replace all not working lights. 2. To ensure that pellets used in manufacturing are non-wooden.	Bhavesh / J Bhatt.	Closed	The site has removed the wooden pallets from the manufacturing area & dispensing area and has the plan to remove it in phase wise from the entire site. Currently heat treated wooden pallets are used in warehouse area.
1) Rodabox outside the receiving bay are not found appropriately placed and the location of Rodabox locations requires revisiting and placing at appropriate strategic positions. 2) Two of the Insecticutors were found inside the receiving bay and one of them was found above the balance kept for verification of the incoming material. The locations requires revisiting. 3) The antidotes for pest control chemical are not available. 4) The antidotes for the chemicals used in the laboratory are not available.	1. To relocate rodent trap boxes and insecticutors. 2. To identify the antidotes for the laboratory chemicals and pest control and keep a list of the same.	Mrudang/ Sarang Selote	Closed	NA.

Observation	Action	Responsible	Status	Comments
The rejected bay is getting open while locked.	To repair the latch of the door	Bhavesh	Closed	NA.
1) The cleaning and sanitization of warehouse area (WH009/G) do not have detail procedure for preparation of disinfectant solution of the required concentration and nor have the preparation and usage record for the disinfectant prepared. 2) The cleaning record of warehouse area (RM/PM) on 08 OCT 15 demonstrate that it is performed at 0910 hrs on 08 OCT 15 by housekeeping person (Mr.Mithun) but on enquired it is confirmed by him that he has not performed it at 0910 hrs though instead he has done it at 1300 hrs but for the same record was not found.	1) SOP WH 009/G is revised to include disinfectant preparation & usage record. 2) Re-training is given for daily cleaning & recording.	Bhavesh / Sweety.	Closed	NA.

During the plant round the improvement of the housekeeping at the site is evident though the improvement and sustainability is required.

3.2 The below mention discrepancies with respect to current control for cross contamination at manufacturing and packaging area for Dettol antiseptic liquid (DAL) and Dettol Hand sanitizer (DHS) are observed:

a) During the plant round it is adverdant that the manufacturing area for DAL and DHS is presently having the ventilation & Exhaust system in place whereby the 10 micron fresh air is forced in the area and is exhausted to the environment through 10 micron filter. The area is having no control with respect to the temperature, RH and differential pressure. With the current control in place the possibility of cross contamination cannot be assured.

b) The primary packaging area is currently having the provision for split AC to maintain the temperature of the area within the limit of 24 ± 2 ◦C. The area lacks control for cross contamination with respect to filter air and differential pressure.

c) The DHS packaging area is having the AHU in place wherein the 5 micron filtered air is purge inside the area and exhausted through filtration level of 5 micron.The recirculation system is used in the packing area. The HEPA filters are not installed.

(Note: As per good manufacturing practices for heating, ventilation and air conditioning (HVAC) systems for non-sterile dosage forms (QAS/02.048 /Rev.1) depending on the airborne contaminants in the return air system, it may usually be acceptable to use recirculated air, provided that HEPA filters

are installed in the supply air stream to remove contaminants, and thus prevent cross-contamination.)

Note: During the review process the site has shown the change control (CC.No.19/16 dated 14-09-2016) initiated for the facility up gradation.

The site has also shared their firm plan to make the GMP area as class 1 lakh with all the checks to prevent the cross contamination.

It was also leant from the Team that the Drawing layout has been reviewed by RB team and technical/commercial negotiation for the cause are undergoing for its implementation.

The shared drawing are attached as the reference for information and record.

1) The maintenance of differential pressure in the microbiology area found deficient for the below listed observations:
   a) The limit of differential pressure is mentioned in unit of Pascal but the unit of measurement of magnehelic gauges are in MMwc.
   b) It is observed in the microbiology laboratory that magnehelic gauges are not corrected for zero error as they are displaying almost the same differential Pressure reading while opening and closing the door. No deviation for it was raised nor was the maintenance job order raised for the correction of the Error. The format used for recording the differential pressure required to Include the zero error verification.

3.3

1) The rodent control records are recorded for all the rodent box in totality but individual tracking is not practiced.The trending of the pest control observations are not performed to evaluate the effectiveness of the pest control programs.

4. Equipment

Observation	Action	Responsible	Status	Comments
Equipment qualification for the manufacturing, packing equipment and compressed air system of DAL and DHS not performed.	**The equipment qualification for the manufacturing, packing equipment and compressed air system of DAL and DHS shall be performed.**	**J Bhatt / Cyrus / Sharma.**	**Open**	**The manufacturing tank qualification is executed and filling, labelling line qualification is still to be done. The performance qualification for the Compressed air is to be done.**

Observation	Action	Responsible	Status	Comments
The Purified water system is found to be deficient for the below listed discrepancies: a) The qualification has not considered 3 user point of DAL and DHS area. b) The Phase-I and Phase-II qualification has not considered sampling (Chemical & Microbial) from all the sampling points. c) The phase-III has not considered chemical sampling from all the sampling point apart from one sampling Point (SP-26). d) No conclusion is derived from the qualification about the action and alert limit for microbial load and sanitization frequency to be followed in routine. e) The purified water is stored in the storage tank from where it is again transfer to the manufacturing tank in case of manufacturing of the batch and is not monitor for conductivity/TOC/pH before usage and also is not under control monitoring. f) The sampling point at user point after UV is having dead leg and the MOC is not SS 316. g) The Purified water user points in the manufacturing and washing area of DAL and DHS is not having sampling identification number.	1.To carry our 2 weeks water testing from the point 30 and test the same for chemical as well as microbiological test parameters. 2. To prepare a protocol for the validation including the time period, parameters for monitoring, sampling points to be covered. 3. To revise the water specification for meeting the IP requirements, including microbiological SOP for water testing. Two qualification round of Phase I - 2 weeks & Phase II - 2 weeks shall be done. 4. The action and alert limit is now derived from the historical trend of 1 year. 5. The correction shall be done to put the user point SP 30 in the loop. 6. In order to comply we will put the line in loop at user point. 7. Sampling point S30 will be monitored for chemical & Microbiological testing after qualification. 8. To remove the dead leg at sampling point at user point after UV. 9. To verify the testing pipe MOC and if required the same will be changed. 10. To prepare a P&ID for the area. 11. To revise the SOP for water sampling and to put the ID. No. for the points in the building 2 area.	Bharat/Mahesh/Tejal/Hitesh/Jayesh / Sarang Selote / Dinesh Kabra.	Closed	NA.
The compressed air system is found to be deficient for the below listed discrepancies: **a) The compressed air qualification as per ISO-8573 is not performed and only microbial test is performed as per the qualification.** **b) The compressed air and its distribution system is having pipeline rusted.** **c) The dew point meter is not available for monitoring of dew point of the compressed air passed through distribution system.** **d) The user/sampling point of compressed air system is not having identification number.**	**1) The compressed air monitoring shall be performed as per ISO-8573 and the compressed air monitoring SOP shall be revised.** **2) The pipe line will be re-checked and where ever required the same will be replaced.** **3) We will discuss the installation of the Dew point meter with OEM.** **4. As our compressor is heatless and design is based on - 20 Deg. C we need get confirmation from the OEM regarding the requirement of the dew**	**Tejal / Jayesh Desai / J Bhatt / Mahesh/Cyrus.**	**Open**	**The observations pertaining to qualification of Compressed air as per ISO-8573 and regarding the dew point installation is still open.**

Observation	Action	Responsible	Status	Comments
e) The line filters (0.2µ & 0.3 µ) integrity certificates are not found and also the replacement criteria/frequency is not documented. f)The monitoring (operational log) of the compressed air system is not in place.	**meter. 5. A risk assessment will be carried out to check the need of the dew point. 6. Visible checks of air shall be recorded in the BMR. 7. SOP shall be prepared accordingly to include the replacement of filters or change frequency. 8. Compressed air is being monitoring once in a month & log book is maintained & available.**			
The Computer System Validation is not performed for Quality control laboratory instruments.	**The Computer System Validation for Quality control laboratory instruments to be performed.**	**Sarang Selote**	**Open**	**The site is having IQ, OQ and PQ of the equipment done but the CSV for the equipment is not done.**
The cleaning validation not performed for the equipments pertaining to DAL and DHS.	**The cleaning validation shall be done.**	**J Bhatt / Tejal / Jayesh Desai.**	**Open**	**The dedicated equipment are used for the manufacturing and filling operation but the cleaning validation study is not available.**
The qualification of LAF (QAE-32), RLAF (WME-18,EME-58&LME-125) is having below mentioned discrepancy: a) The area is considered as ISO class-100 and qualification is done yearly but non-viable count is not performed as per the frequency of 6 months defined as per ISO-14644-2. b) The non-viable test performed for LAF (QAE-32), RLAF (WME-18,EME-58&LME-125) is not performed at operation condition along with rest condition in alignment with IS0-14644. c) The other test such as differential pressure test across HEPA, Viable count, air flow pattern etc. in alignment with IS0-14644 is not done.	1. Non-viable is monitoring by external agency once in year, will be done twice in a year from 2016 for LAF & EME-58. 2. The non-viable test for ISO-5; shall be done at rest and operation condition. 3. Other tests shall be done as per the requirements of ISO 14644.	Hitesh / Jayesh Desai	Closed	NA.
The qualification of Autoclave is found to have below mentioned discrepancies: a) The Qualification study has not established the steam pressure during the hold time nor the protocol established acceptance criteria for steam pressure. b) Equilibrium time (Time difference between the first sensor reaches sterilization temperature and sterilization hold start) is not monitored during the empty chamber heat penetration	1) Autoclave is manually operated, temperature & pressure acceptance criteria mentioned in raw data sheet. The acceptance criteria's will be incorporated in the protocol and report. 2) To revise the validation protocol accordingly to carry out the validation required as per IP. 3) The validation cycle is carried out at 20 mines time cycle at temp 122.5 & pressure	Hitesh / Tejal	Closed	NA.

Observation	Action	Responsible	Status	Comments
study. c) For the media load the Max. Fo calculated as 28.14 against the cycle time of 20 Mins.; which has all possibility of denature of the media used in the auto clave cycle as the Biological indicator used Fo value is for 15 Min. only.	18 Lbs. As per the report the minimum F_0 achieved in probe no P8 was 20.98. This value is more than the F_0 value 15 achieved for the biological indicator "Geobacillus stearothermophilus. All the media sterilized is subjected to GPT and this is done for all the loads of sterilization. Each lot of media sterilized in each autoclave cycle is subjected to GPT and as there is no failure for GPT, it is evident that the media is not denatured at this temp and pressure autoclave cycle.			
The platforms balance (LME-62); is found below the stair case in close condition and was away from its fixed position. The balance fixed position is also not marked.	1. Platform balance is placed at its fixed position with marking. 2. Training provided to people involved	Cyrus / J Bhatt.	Closed	NA.
Safe zone of the sampling booth is marked outside the sampling booth and not marked as per air flow pattern.	To paint the marking for safe zone based on the air flow patter study.	J Bhatt.	Closed	NA.
Sampling is done while person standing outside the safe zone of the sampling booth while handling the product inside the sampling booth which is not adequate.	1. To mark the area appropriately defined so that the user is aware of how to work in the safe zone. 2. To provide training to users 3. To display signs on the same	Mahesh	Closed	NA.
The safe zone for dispensing booth not marked.	To paint the marking for safe zone based on the air flow patter study.	J Bhatt.	Closed	NA.
1) The weighing balance kept in the receiving bay has the below mentioned discrepancy with respect to calibration: a) As per the SOP No.WH007/F (Calibration of weighing balance) clause no 4.1; levelling of the balance through spirit label is to be performed but it is found that it is not performed. b) As per clause No.4.3 of the SOP No. WH 007/F (Calibration of weighing balance); place the weight at 5 different place and take the mean of the weight observed but actually it is not performed. c) As per clause No.4.1.5 of the SOP No.WH 007/F (Calibration of weighing balance); repeat the calibration with the standard weight mentioned as per annexure-I and Annexure-II but weights are not detailed in the annexure referred.	1. To revise the SOP to simplify the procedure. 2. To revise the annexures of the reports 3. To provide training on the revised procedure.	Bhavesh / J Bhatt	Closed	NA.

Observation	Action	Responsible	Status	Comments
d) Daily and monthly calibration Format does not have any acceptance criteria for pass/fail of the calibration test nor is it detailed in the SOP. e) On verification of daily and monthly calibration record it is found that the calibration is performed with different weight than the previous occasion and sometime daily calibrations are not including the minimum and maximum weight measured using the balance. f) The weighing balance kept in the area is having two decimal digits but the recording format demonstrate that the readings are round off before reporting and it is not reporting what is displaying actually. Note: Other balances in warehouse also have same problem.				
The dispensing area balance calibration is performed through SOP No. PR 222/C (Calibration of weighing balance); which do not have list of weights to be used for daily and monthly calibration and their acceptance criteria.	1. To revise the SOP to simplify the same. 2. To revise the annexures of the reports 2. To provide training	J Bhatt	Closed	NA
The only thermometer (ID.-GTM-12) found in the IPQC area is found to be out of calibration (Calibration done on – 11/11/13 and calibration due on -10/11/14).	Thermometer to be calibrated.	J Bhatt	Closed	NA
pH meter in the IPQC area is found which is not having any procedure available for operation and calibration. No calibration record of pH meter could be traced.	1) SOP to be prepared. 2) To carry out the calibration & to include the instrument in the list of instruments for calibration.	J Bhatt	Closed	NA
The dirty & clean equipment hold time study for manufacturing and packing equipment for DAL and DHS not performed.	To carry out the hold time study.	J Bhatt / Tejal / Jayesh Desai.	Closed	NA
The deduster kept for cleaning the Incoming material has no cleaning log maintain as it is not incorporated as part of the format to the SOP for operation of the deduster (WH-029/A).	SOP WH-029/A to be revise to include cleaning & operation of de duster.	Bhavesh	Closed	NA
The dispensing tools cleaning procedure and records for cleaning are not available.	SOP to be prepare for cleaning of dispensing tools.	Bhavesh / Hitesh	Closed	NA
The Cleaning procedure of manufacturing and Storage tank (PR-218/C); is deficient in providing the step by step procedure for cleaning and end point of cleaning is not clearly identify in the SOP.	SOP PR-218/C to be revised to capture all the cleaning steps thoroughly.	Bhavesh / Hitesh	Closed	NA

Observation	Action	Responsible	Status	Comments
The cleaning procedure for filter pads of sparkler filter machine (PR 221/C) is deficient for the below mention observation: a) As per the clause 4.2; hot purified water is used for cleaning but no procedure is available for generation of hot purified water. b) As per clause No.4.3; allow compressed air for drying but actually it is not practiced. c) Filter pads of 5 micron is used but filter integrity certificate for the same is not available.	1) SOP to be revised to incorporate the procedure actually followed and training to be provided to the concern personnel. 2) Filter integrity certificate to ensure.	J Bhatt.	Closed	NA
RO sanitization frequency in the SOP for Operation of water plant (PR- 061/J) is defined only in case of 6 hours breakage though frequency of sanitization of one month in addition of the defined frequency is practiced.	**SOP to be revised and training to be provided to all the concern personnel.**	**Bhavin / J Bhatt**	**Open**	**SOP revision and training pending.**
After sanitization of RO system; no check of pH and conductivity is defined in the SOP for Operation of water plant (PR 061/J) before releasing it for routine purpose.	The recording of parameters like pH & conductivity will be incorporated.	Sharad	Closed	NA
The sanitization of the purified water line is performed by passing raw steam in purified water line for 10-15 minutes which is not govern through qualification procedure and nor after the sanitization the record of performance of sanitization is maintained. Also the purified water distribution line for user point is not in the continuous loop with the storage system.	1) Hot water sanitization to be performed. 2) The loop will be maintain under continuous loop.	Sarang Selote / Dinesh Kabra.	Closed	NA
Plastic dispensing scoop is found in the dispensing area.	Plastic scoops to be replaced by SS 304 scoops.	J Bhatt	Closed	NA

During the follow up audit the equipment qualification documents along with their operation procedure are reviewed and the discrepancies observed are listed below:

4.1

1) The manufacturing tank qualification is found deficient for below discrepancy:
   a) The calibration equipment used during qualification i.e. tachometer and clampmeter are not verified for their calibration prior to qualification.
   b) The tests specification requiring the numerical values are having the observation as “Complies” instead of numerical observed values.
2) The OLV verification for Dettol antiseptic liquid label for identification and rejection of labelling defect is not in place.

4.4

During the verification of the calibration programme during follow up audit, below mentioned discrepancies observed:

1. The procedure for operation and calibration of weighing balance (SOP No.WH-023/C) is found deficient for the below mentioned observation:
   a) The procedure is deficient for mentioning the cleaning procedure and cleaning frequency of the balance.
   b) Daily calibration record (WH-026/C-AI) has calibration done date as 20/03/2014 and due date as 19/03/2019. The actual calibration is performed on 26/05/2016 and due date is of 25/05/2017.
   c) The daily calibration is performed with weight of 50,100 and 200 kg but the minimum weight used in the balance is of 20 kg and maximum weight used in the balance is of 250 kg. The weight is not calibrated on its minimum and maximum usage range.
2. The DIP rod calibration is to be performed for the qty. to be added as per batch record of Dettol antiseptic liquid.

5.0 Raw and Packaging Materials

Observation	Action	Responsible	Status	Comments
1) Approve vendor list available at site is not the updated list and also do not have the supplier & manufacturing site address along with the packing mode detail in it. 2) TSE/BSE compliance for incoming raw and packing material is not ensured.	1) Updated with approved vendor list with supplier & manufacturing site address. 2) Inform to respective parties to provide TSE/BSE certificates.	Prasanna / Jayesh Desai	Closed.	NA
The material inward registers as per SOP No. WH-020/F (Receipt and storage of raw and packing material) kept at area is having below mention discrepancies: a) It has detail supplier name as “Reckitt benckiser” instead of the actual supplier name of the material. b) Code No. is kept empty instead of mentioning the required detail. c) QA remark column is kept empty. d) On the audit date i.e. on 08 OCT 15; the inward entry register was found deficient for listing the entry of current date for the material (outer) received from “Patel packaging”. No material receipt checklist, inward material checklist report for received packing material was filled. e) As per material inward register on 07 OCT 15 the raw material (Denature alcohol) is received but the received consignment doesn’t have	The training on GDP to be provided to all the concern personnel.	Mahesh / Dipen	Closed.	NA

material receipt checklist, Inward material checklist report.				
As per SOP No.WH020/F (Receipt and storage of raw and packing material); 3 approved labels on the pallet of PCMX is to be present but actually only one label is found.	Labels are pasted as per respective Sop's, But due to jute bags packing labels are getting peeled off, during transits. Retraining is given for Good documentation practices	Jayesh Desai.	Closed.	NA
The PCMX bags in the area were found having sampling performed from the bags without affixation of the sampling label.	Sampled Labels are pasted 100% for PCMX sampling as per respective Sop's, But due to jute begs packing labels are getting peeled off, during transits. Retraining is given for Good documentation practices	Jayesh Desai.	Closed.	NA
The MSDS of the raw and packing materials were not found in the warehouse.	MSDS to be maintain at store.	Jayesh Desai.	Closed.	NA

During the verification of the warehouse control for the received material during follow up audit, below mentioned discrepancies observed:

5.3 The receipt and storage of raw and packing material (WH-020/G) is found deficient for the below mentioned observation:

a) The material receipt checklist as per Annexure-II of the SOP not maintain.

b) The inward material checking record-RM as per annexure-III and inward material checking record-PM as per annexure-IV is not maintain as per SOP. The SOP is deficient for mentioning the no. of unit of the received RM and PM to be verified for weight of the received consignment.

6. Production

Observation	Action	Responsible	Status	Comments
The line clearance verification by IPQA for dispensing is not part of the Dettol and DHS BMR though it is part of the line clearance procedure.	It is to be made part of the BMR.	Jayesh Desai.	Closed.	NA
1) Dettol batch record for batch No. VR458 is having detail of used purified water AR No. as HPW259 {Result of sampling point (SP-25)} which is not used in manufacturing of the batch. On detail investigation it is revealed that the sampling/user point for the purified water used for manufacturing of the batch is covered as weekly sampling plan for microbial testing only and daily monitoring is not performed. 2) The manufacturing instructions do not include the amount of material to be added and the qty. reconciliation for build-up of the batch size. The dip system is used or measurement of the qty. in the manufacturing tank but the measurement is not recorded in the batch record. 3) The procedure for performing	1) Sampling point S30 will be monitored for chemical & Microbiological testing after qualification. 2) The BMR will be revised, to add the quantities in each stages. 3) The LTP is done at QC laboratory. The log book is updated for the performance of the test.	Jayesh Desai / Dipen / J Bhatt.	Open.	The observation with respect to the usage e of the Dip system for the measurement of the qty. addition in the manufacturing tank and its recording is open. Though the Dip system is used for the measurement after completion of the batch manufacturing.

Observation	Action	Responsible	Status	Comments
UTP, LTP, pH and colour is not defined in the batch record. The facility for performing the test for LTP and lovibond test at IPQC laboratory is not available but the entries were made in the BMR by stating that it is done in the QC laboratory by them but no traceability record in the usage log book could be traced. The instruments used for test is not detailed in the batch record.				

During the follow up audit the below listed observation with respect to the control sample management is observed:

7.1 The procedure for Sample retained programme (QA-011/D) is found deficient for the below discrepancies:

a) As per annexure-2 of the SOP the temperature and RH to be monitored which is found to be not followed in case of the retain sample of DHS and DAL.
b) The SOP is deficient in mentioning the temperature and RH condition to be monitored.
c) The control sample register is deficient in maintaining the qty. of the retention sample removed from the area.
d) The destruction of the control sample is not documented as part of SOP. The SOP requires to be elaborated for defining the destruction procedure.
e) The control sample of Dettol hand sanitizer (Batch no. VR 262) having manufacturing date as 08/14 and expiry date as 07/17 is found in leaked condition.
f) The expired control sample found lying in the area for destruction which was supposed to be destroyed in August-2016.

7. Inspection and Testing

Observation	Action	Responsible	Status	Comments
Water testing Schedule (QA 33/L) is having below mentioned discrepancies: a) Microbial monitoring is done weekly for sampling point SP-1 to SP-13 and no chemical sampling is done. b) Sampling point ID for Liquid oral Manufacturing, Liquid oral washing and Dettol/Germol manufacturing not provided. c) For user point (Liquid oral Manufacturing, Liquid oral washing and Dettol/Germol manufacturing) microbial monitoring is done biweekly but chemical testing is not performed at all.	1) Water sampling SOP revised. 2) Sampling point ID displayed. 3) SP-30 daily monitoring included for chemical and microbiological.	Tejal / Jayesh Desai	Closed.	NA

Observation	Action	Responsible	Status	Comments
Microbiological test for water used in Manufacturing (QA 034/G) is deficient for below mentioned discrepancy : a) As per clause no.4.6.8 Microbial count limit and action limit of 50 cfu/ml for purified water is defined. b) Only pathogens test for pseudomonas aeruginosa and coliform is done and it is not performed for other pathogens i.e. E coli, Salmonella and Staphylococcus aureus. c) The format (QA034/A-II) used for reporting the results for microbial evaluation of Purified water system is not matching with the actual format of SOP. d) The Format (QA034/A-II) used for reporting the results for microbial evaluation of Purified water system is also used for reporting the raw water.	1) Alert, Action & Regulatory Limit is separately defined in the log book. 2) Testing is started for E.coli, Salmonella, & S aurous. 3) Format A-II log book revised to match with the SOP QA-034. 4) Format A-II log book revised to separate raw water & purified water SOP QA-034	Tejal / Jayesh Desai	Closed.	NA
Raw datasheet for chemical and microbial test of water is not present and the results are directly recorded in the certificate of analysis.	Raw data sheet for chemical to be started & for Micro to be maintained in separate log book.	Tejal / Jayesh Desai	Closed.	NA
No incubators log book for inward of the sample is maintained.	**Incubator log book to be introduced.**	**Tejal / Jayesh Desai.**	**Open.**	**Log book implement ation is pending.**
Raw water test for chemical test (TDS, pH & hardness) is to be conducted daily as per the procedure in place but no results/certificate for analysis is found and nor the instrument log book is updated for its usage for the test.	Raw data sheet for chemical to be started & for Micro to be maintained in separate log book.	Tejal / Jayesh Desai	Closed.	NA
The raw water specification and the format (QA034-AII) use for reporting the raw water results are not mentioning the verification of pathogens but “nil” remark is still updated. Not sure whether it is actually done.	The raw water is checked for microbial count, as the count is “Nil” then the pathogen testing and verification is not required and not done. 2. The log book to have remarks as Not required "NR" whenever the tests of verification is not done on account of microbial load being NIL.	Tejal / Jayesh Desai	Closed.	NA

During the calibration and laboratory system compliance verification during the follow up audit below mentioned discrepancies observed:

7.1

1) The gas chromatography available is found deficient for the below mentioned observations:
   a) C& D drive is assessable to all. All the raw data is store in D drive which is accessible to all. The possibility of erasing the data can’t be ruled out.
   b) The GC is having only one user point access. The common user name

and password is used by all the analyst.

c) Record log for Data Backup Process to Pre-defined Secondary Drive and from predefined Secondary drive to storage media is not available.

d) Procedure for Data retrieval and restoration not available.

e) List of users for application software's is not available.

f) Requisition for User Account is not part of SOP.

g) Record of user request for unlock / activate user account is not maintain.

h) Audit trail review is not practiced.

i) Antivirus updation/expiration verification is not maintained.

j) The procedure for Creation of Database/Project/Folder is not defined.

Note: It is recommended to escalate the observations to others available system in laboratory.

8. Quality Documentation and Records

Observation	Action	Responsible	Status	Comments
The Verification check for shipper weight is not performed for batch no.VR457 by production and QA personnel on 09/10/15.	Retraining is imparted for Good Documentation practices.	J Bhatt	Closed.	NA
The below mentioned discrepancy observed with respect to the water system (RO plant): a) The conductivity record after EDI (Limit- ‹ 1.3 µS/cm) along with pH after EDI is not filled in the log book for RO plant from 25/09/15 till 09/10/15.Also no limit for pH is define in the log for monitoring. b) ORP meter monitoring is included in the SOP for Operation of water plant (PR 061/J) but not included in the operational log. c) Replaced 5 micron filters; filter integrity certificate not found. d) It was evident from the TOC meter printout that the TOC meter was not operational on 05/10/15 to 06/10/15 but no deviation for the same is taken by the concern personnel.	1. Log Book is updated to include the limits & SOP is revised with defined limit for pH. 2. In log book we will enter by ink & when the book is over we will print the same in new log books. 3. SOP PR-061/J is revised to include operational Log book. 4. Informed to supplier to provide certificate for 5 Micron filters. 5. The plant was under circulation and not in service and as the water was not in use for production deviation was not taken.	Sharad	Closed.	NA
SOP No.QA-001/K is found to be deficient for the below mention observations: a) The SOP is deficient in detailing the format Numbering procedure. b) The SOP is not catering the list of annexure as per the SOP and its current version status. c) Format control procedure is not defined.	1. SOP QA-001/K to be revised. 2. SOP QA-001/K to be revised to include the current version in Annexures. 3. Training to be imparted for SOP QA-001/I for all sections.	Hitesh / Jayesh	Closed.	NA

Observation	Action	Responsible	Status	Comments
d) SOP log for issuance and retrieval is not part of SOP and not found. e) SOP NO.QA-001/K; is made effective on 02/01/2015 after having training of only QA/QC person and not ensuring the training of all cross functional tem. f) The SOP is not having format for ensuring the header and other part of the SOP/Format as per the requirement. g) The procedural for retrieval not defined. It was evident from the record shown to the auditor that there is no documentary evidence that complete retrieval of SOP No.QA-001/J is ensured from all the issued department before issuing them next version i.e. QA/001/K.				
The discrepancy with respect to the Product complaint (QA019/F): a) Classification of complaint is not defined in the SOP. b) The reporting of the adverse event to drug safety officer is not included.	SOP QA 019/F to be revised to incorporate classification of complaints and reporting of adverse event.	Hitesh / Jayesh	Closed.	NA
The documents and record retention is not as per Global document retention and file Maintenance policy.	SOP shall be revised as per the RB global procedure.	Hitesh / Jayesh	Closed.	NA
The below mentioned discrepancy observed with respect to the water system (RO plant): a) The procedure for pH and hardness testing is not described in the SOP for Operation of water plant (PR 061/J). b) TOC action and alert limit not define in the SOP for Operation of water plant (PR 061/J).Also it was evident from the record that on 04/10/15 at 0006 hrs; TOC of 497 ppb against limit of 500 ppb is observed.	Based on the suggestion the alert and action limit for TOC will be defined in the SOP for operation of RO plant.	Hitesh / Jayesh	Closed.	NA
The Dettol batch record is deficient in identification of the below listed information in the batch record: a) The dispensing calculation and assay calculation for the alcohol is performed behind the batch manufacturing record for batch No. VR458 as there is no provision in the batch record for calculation. b) The Batch yield acceptance criteria are not defined in the batch record. c) The speed verification of the filling and packing line is not part of the batch record. d) The shipper weight calculation for determining the minimum weight	1. BMR to be revised to include calculation and speed verification. 2. BMR is revised to elaborate Batch yield along with the acceptance criteria. 3. Shipper weight calculation is maintained through batch record.	Hitesh / J Bhatt	Closed.	NA

Observation	Action	Responsible	Status	Comments
of the filled shipper for verification of the filled weight of the DAL is not part of the batch record.				
The operation log book for manufacturing equipment is not available.	It will be introduced.	Hitesh / J Bhatt	Closed.	NA
The acceptance quality level for the various filling and packing defect is not displayed in the concern area which may cause the defects escaping in the final product shipped to market as the activities are performed by casual personnel.	Display will be assured.	Hitesh / J Bhatt.	Closed.	NA

8.3 The SOP for root cause analysis, change control, deviation management require to be review and revised to incorporate necessary information in the SOP and recording format.

Note: In general it is recommended to review the site SOP for all the function effective and revise the SOP to include the step by step approach which is missing.

9. Storage and Distribution

Observation	Action	Responsible	Status	Comments
The wooden pallets are used for storing the FG and the pallets are not having procedure for cleaning/sanitization or pest control to avoid any contamination during storage.	1. Wooden pallets replaced with environmental friendly and heat treated "Chap" pallets. 2. SS Pallets used in manufacturing	J Bhatt	Closed.	NA

9 1. The procedure for Receiving, storage and distribution of FG (WH-013/I) is found deficient for the below mentioned observation:
As per clause No. 4.5 of the SOP; loading slip needs to be filled and ensured by security check but it is not practiced.

10. Control of Non-Conforming Material:

Observation	Action	Responsible	Status	Comments
The rejected bay control is found deficient for the below listed observation: a) The rejected bay is getting open while lock in place. b) No list was found available in the area for the rejected material kept in the area. c) The 50ml Dettol DHS (B.No.-DPIC140750DA) of qty.9408 bottles are having status as “Under Hold” though it is rejected and kept in the area.	1) Rejected Bay is maintained under lock & Key. 2) Lists prepared for the Items kept under rejection bay. 3) It was Under hold bottles, due to on Line quality problem and kept there in rejected area. Training to be provided to all concern personnel. 4) Labels are pasted as per respective Sop's, But due to jute begs packing labels are getting peeled off, during transits Retraining is given for Good documentation practices.	Mahesh / Jayesh	Closed.	NA

Observation	Action	Responsible	Status	Comments
d) The 06 bags of PCMX (Qty.-50 kg each) were found in the area without any status label.				
1) The authorization format for rejection of the packing and raw material is not available. 2) The SOP for destruction of rejected packing material (WH 011/B) doesn't have the detail procedure for destruction. 3) The procedure for handling of rejected raw material is not available.	1. Procedure for authorization introduce. 2. SOP WH 011/B is to be revised to include detailed destruction procedure. 3. The SOP QA103/A covers the handling of rejected materials and is being followed accordingly.	Bhavesh / Hitesh	Closed.	NA

11. Change Control

Observation	Action	Responsible	Status	Comments
The change control No.36/10 is closed in the log on 06/10/15 but the activity is not closed and completed in the change control form. Also it is evident from the change control form that the impact assessment due to the change proposed is not done effectively.	Change control 36/15 is detailed & closed.	Bhavesh / Hitesh	Closed.	NA
The change control format is not adequate as it is not having the field for reporting the completion of approved activity by the user and afterwards verification of same by QA personnel before closure of the change control.	Document revision to be done.	Jayesh Desai / Sarang Selote	Closed.	NA

12. Management of 3rd Parties

Observation	Action	Responsible	Status	Comments
There is no Technical Agreement with the lab testing service and validation services providers for the site.	The TA will the external laboratory will be prepared.	Bhavin Malaviya/Sarang Selote.	Open.	The technical agreement with the QC testing lab maintained but other external service provider it is pending.

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1) Testing lab. agreement is present but the testing laboratory is not audited.
2) Technical agreement with Waters, toshwin, Kevin scientific Instruments, Autocal solution Pvt. Ltd., savrashtra marketing cooperation and A one pest Control services not present.

13. Quality Audits

Observation	Action	Responsible	Status	Comments
The self inspection of complete site is done by one time though the frequency in once in six month and it is observed that department wise checklist is also not available to ensure that all strategic check points are included.	The frequency of the internal audit is once every 6 months. As the external audit of the facility had been carried out in April 2015 it was decided to postpone the internal audit accordingly Internal Audit check list is available in QA-016/E the same will be improved to department wise.	Sarang Selote	Closed.	The department wise checklist is very brief and required more checks.
Response to action request not found for the self inspection conducted on 19-20 FEB 15.Nor the other required format for closure of the action items are filled.	The last audit report mainly had suggestions for improvements and therefore no action report was prepared and no closure was reported.	Sarang Selote	Closed.	NA

The self inspection program is found to be deficient for the below mentioned observations:

a) The self inspection is performed on March -2016 but the response to action request (Annexure-V) and quality system audit summary report as per annexure-VI of the SOP no. is not followed.
b) The SOP is deficient for defining the procedure for tracking the CAPA of the self inspection for closure.
c) The Self inspection is not performed as per the checklist mention in the SOP.
d) The self inspection checklist for the department requires to be maintain and executed.
e) The procedure for the selection of the auditor and maintaining the record is not define in the SOP.

Note: The self inspection program needs to be strengthen.

LEAD AUDITOR SIGNATURE

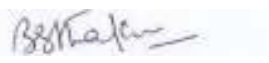
Lead Auditor	Designation	Signature	Date
Baldev Singh Thakur	**CMO-Quality Coordinator-India.**		**10-10-2016.**

Exhibit Collected:

Exhibit 1: Proposed Dettol GMP Drawing for Ground Floor.

Exhibit 2: Proposed Dettol GMP Drawing for First Floor.

Exhibit 3: Proposed Dettol GMP Drawing for Second Floor.

APPENDIX 1 – Audit Classifications

Critical EU Classification Health Canada Classification RB Global Classification	The observed item is considered extremely serious and immediate corrective action is required. A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal. A situation which may result in an immediate or latent heath risk and any observations that involves fraud, misrepresentation or falsification of products or data (Risk 1). Is applied when non-compliance is exposing the business to a serious risk in the short-term. A Critical high risk overall rating will trigger the Critical Events Procedure D8068970 and will be managed in the same way as a potential product recall. This overall rating can be applied for systematic failure, indicated by multiple high risk findings leading to the conclusion that overall control is not in place, or for a single high risk finding which places RB at serious short term risk.
Major EU Classification Health Canada Classification RB Global Classification	The observed item is serious, or a significant number of Other observations have occurred in the same area or system. Prompt corrective action by Auditee is required. A non-critical deficiency: which has produced or may produce a product, which does not comply with its marketing authorisation; *or* which indicates a major deviation from EU Good Manufacturing Practice; *or* (within EU) which indicates a major deviation from the terms of the manufacturing authorisation; *or* which indicates a failure to carry out satisfactory procedures for release of batches or (within EU) a failure of the Qualified Person to fulfil his legal duties; *or* a combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such. A situation which may result in the production of a product no consistently meeting its marketing authorization (Risk 2). Relevant requirement not met leading to significant risk to product quality which includes: ▪ Product cannot be proved to be safe. ▪ Potential risk of Recall, Major ▪ Quality Issue, or serious / major increase in complaints ▪ Failure to resolve actions from previous audits.
Other (Minor) MHRA Classification Health Canada Classification RB Global Classification	Observed item is not yet serious but could become a problem if not corrected in a timely manner. Auditee Management follow-up is required to assure that a systematic problem does not exist. A deficiency, which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. (A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as a major or critical). A situation that is neither critical nor major but is a departure from GMP (Risk 3). Not a high risk finding, but relevant requirement is not in place or effective.