RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

DATE OF RISK ANALYSIS	
SUPERSEDE PROTOCOL CUM REPORT No.	**NIL**

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

PROTOCOL CONTENTS

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

1.0 PROTOCOL CUM REPORT APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
OPERATING MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

2.0 OBJECTIVE:

- The objective of this Protocol to reduce the Rinse/Swab testing frequency based on the Risk/Swab testing frequency based on the Risk assessment.
- As per the proposal frequency of Rinse/Swab sampling shall be reduced on the basis of previous Trend. Testing to be done on random basis, as per feasibility, from any area. One year trend shall be prepared & evaluated to verify any non-compliance regarding contamination of the Cleaning agent.

3.0 SCOPE:

- This risk analysis study Protocol cum Report is applicable to reduce the Rinse/Swab testing frequency based on Risk assessment.

4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare &review the Risk analysis Protocol cum Report. • Execution of the Risk analysis Protocol cum Report with Production Quality Control and Engineering. • Shall compile the data &prepare summary report. • Risk analysis Protocol cum Report shall be approved by the QA prior the execution. • Shall review the executed Protocol cum Report to check the compliance and corrective action for any discrepancies found. Also shall prepare the summary and conclusion of the Risk analysis Study.
Production	• Reviewing of Risk analysis Protocol cum Report for correctness, Completeness and technical excellence. • To provide support for execution of Risk analysis Study as per Protocol cum Report. • Post approval of Risk analysis Protocol cum Report after execution.

5.0 REASON FOR RISK ANALYSIS:

- To reduce changeover time.
- To utilize manpower in other work.
- To comply guidelines (APIC).
- To reduce the Rinse/Swab testing.

6.0 SITE OF STUDY:

Granulation, Compression, Coating & Packing.

7.0 RISK COMMUNICATION & TRAINING:

- The Risk analysis team shall be authorized by Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas such as QA and Production.
- Training shall be imparted to the team members before execution of Protocol cum Report for proper understanding of the procedure. Training shall be recorded in Training attendance Record.

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7.1 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Signature of Trainee	Checked by QA (Sign & Date)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Name of the Trainer: _____

Inference:

_____

_____

_____

_____

_____

_____

Reviewed By_____
Manager QA
(Sign & Date)

8.0 RISK IDENTIFICATION, EVALUATION& MITIGATION:

The site is having multi-product facility; more than 315 API's used in different formulations (Annexure I) are being manufactured here. Manufacturing area consist of 10 Granulations, 20 Compressions, 10 Coatings & 30 Packing's respectively. As mentioned above, the areas are not dedicated. All areas in combine consist of more than 550 equipments approximately. As per the cleaning SOP, Type A cleaning of equipment shall be done after batch to batch while type B cleaning of the equipment shall be done after product to product change over. Further for cleaning verification Swab & Rinse samples are taken and tested and based on those result, line clearance is given by QA. UV Spectrophotometer is used for the verification, the rinse & swab samples are scanned at 200-380 nm for any cleaning agent residue (absorbance shall be not more than 0.059 at any wavelength). By rinse & swab analysis report it is assumed that our next upcoming product is free from any residue of cleaning agent, which is already being validated through Cleaning Validation of Cleaning Agent (SLS). While as per PIC/s guideline, no residue of cleaning shall be left after cleaning.

Till now since 2010 after cleaning validation of API &Cleaning agent, no any case of contamination related to API & Detergent had been recorded. This shows the robustness of our cleaning procedure. On the previous trend basis, Rinse & Swab sampling shall be done randomly from any area.

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S.No.	RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
1.	**Cross contamination**	Cross contamination is the major concern in pharma industry, companies did lot of exercise to control it. Rinse/Swab is also a part of it. If verification is removed, it may increase the risk of contamination.	As per the procedure, Cleaning validation is already done for the worst case Alprazolam & also for the Cleaning agent SLS, further Rinse/Swab samples are scanned from 200-380 nm and absorbance shall be NMT 0.023. As this absorbance is for the cleaning agent and it is already validated hence verification not required for the same. Previous trend of more than 3 yrs. does not show any contamination case. **Type A Cleaning:** In batch to batch cleaning, the equipment is rubbed by lint free cloth & gone through visual inspection for final line clearance. **Type B Cleaning:** Three cycles are run in type B cleaning validation, in first cycle equipment is washed by Raw water followed by Cleaning agent & finally by Purified water. **Cleaning SOP's:** A specific validated cleaning procedure is there for each & every equipment. Cleaning procedures are followed as per SOP.
2.	**Visual inspection may fail**	Removal of Rinse/Swab from daily verification may increase the visual inspection failure,	As visual inspection is the part of BMR (line clearance), it is already mentioned that "equipment shall be free from any remains of the previous batch/product material.
3.	**Work overloaded**	Work overload may result into work pendency.	There are more than 250 rinse/swab sampling done on daily basis, there may be the chance of work overload, to mitigate it, one more UV Spectrophotometer is installed.
4.	**Waiting of product change over may increase**	As per Rinse/Swab log book, most of the samples are analysed within 2 minutes, in case of any error, change over time may increase.	To control it, 01 parallel UV Spectrophotometer is installed as used accordingly.

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S.No.	RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
5.	**UV breakdown**	In case of UV breakdown, the whole system of Rinse/Swab analysis may collapse.	
6.	**Rinse bottles/Swab sticks unavailability**	In case of Rinse bottles or Swab sticks unavailability, the job pendency may increase resulting into work overload.	Rinse/Swab bottles & sticks are collected in advance and to avoid any pendency.
7.	**BMR will be impacted**	Rinse/Swab analysis is the part of BMR line clearance from Granulation to packing, in case of testing removal, all BMR/BPR will be impacted and that will be a long project.	Hence Rinse/Swab analysis is not being removed completely only frequency is to be increased.
8.	**Casual approach may develop for cleaning**	If Rinse/Swab sampling is removed from the line clearance part, then there may be the possibility that the Operator may take casual approach for cleaning, knowingly that no one will verify his act.	Cleaning verification is not removed completely and also there is a visual inspection part in BMT line clearance.
9.	**Audit points**	As the site is third party manufacturing company, so audits are of main concern. Increasing frequency of Rinse/Swab shall be properly justified.	**Testing is not removed completely and Swab & Rinse analysis to be done in every shift:** To avoid any error, rinse and swab analysis shall be performed in every shift (if batch continued then sampling shall be done after batch completion). **Swab samples:** For verification of contact parts which are hard to clean, swab samples are taken. Only sample testing frequency is being increased although cleaning method will be same. **Rinse samples:** For verification of contact parts which are hard to reach, rinse samples are taken. Only sample testing frequency is being increased although cleaning method will be same
10.	**Low light intensity may create problem in visual inspection**	Low light intensity may result into failure of visual inspection.	Light intensity is being verified as per scheduled frequency during HVAC/Area qualification.

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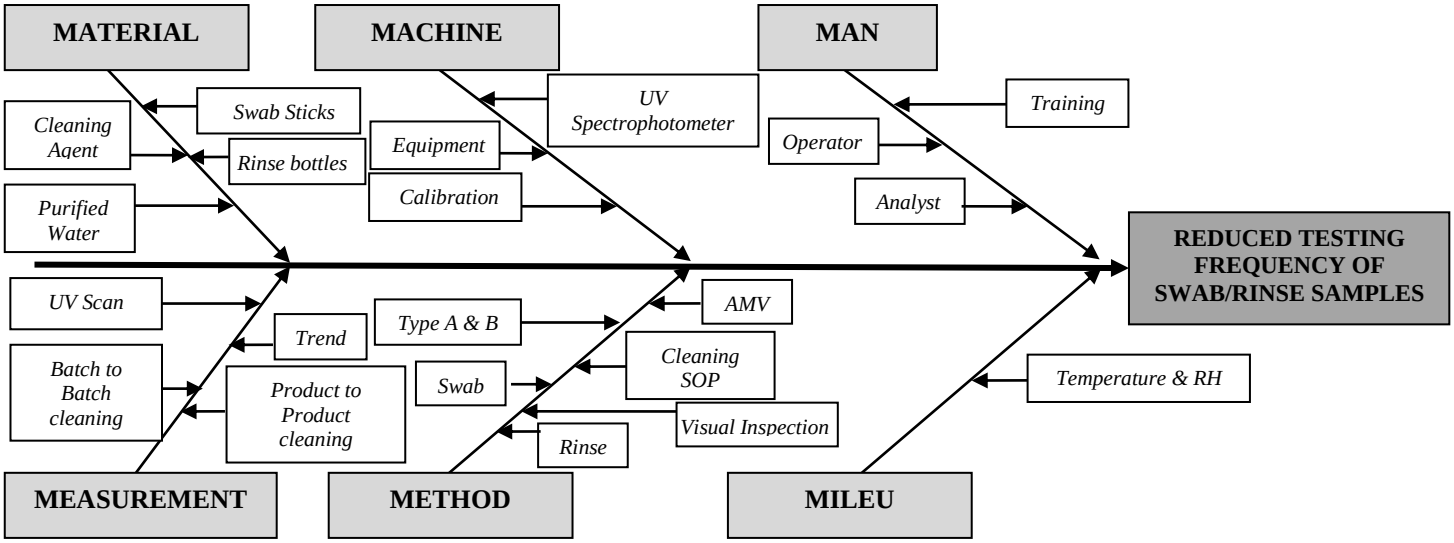
9.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSISCRITERIA:

9.1 Fish bone:



Fish bone tool used for risk assessment, area of concern along with their sub-categories:

1. **Method**
2. **Machine**
3. **Material**
4. **Manpower**
5. **Measurement**
6. **Milieu**

9.2 Failure Mode Effect Analysis:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1:	**Serial number** of Risk Analysis item
Column 2:	**Item/Function:** Identify the process step or component associated with the risk.
Column 3:	**Potential Failure Mode:** Identify the type of risk associated with the process or component.
Column 4:	**Effect of Potential Failure/Cause:** Verify that whether risk have **GMP impact.**
Column 5/6/7/8/9:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 10:	**Risk Mitigation**: Write the risk mitigation strategy as considered in design.
Column 11/12/13/14/15:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated after mitigation by taking Severity, Occurrence & Detection of potential failure into consideration.
Column16:	**Recommended action:** Recommended actions should be given for controlling failure occurrence.

Table 1: Instruction for each column given above

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

Procedure: Risk in reducing Swab & Rinse testing	**Quality Risk Assessment Date:** **QRA No.:**

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
1.	**Cleaning Verification**	Swab/Rinse sampling not done after each product to product change over	May leads to contamination	•Product failure •Product recall •Product quality	•Cleaning process has been validated for practically insoluble API (Alprazolam tablet & Domperidone capsule). • Cleaning validation already done for Tablets & Capsules. •Cleaning method is robust (Previous trend of swab & rinse). •Visual inspection is the part of line clearance.	•SOP No.: "Procedure for Swab/Rinse Sampling". •Cleaning validation protocol of Tablets	4	2	2	16	NA.	NA	NA	NA	NA
		Improper sampling	Inattentiveness or Lack of training	•Procedure failure. •Product failure. •Contamination.	•Cleaning validation already done for Tablets & Capsules. • Cleaning method is robust (Previous trend of swab & rinse). • Training is given as per OJT schedule.	•SOP "Procedure for Swab/Rinse Sampling". •Cleaning validation protocol of Tablets.	4	2	2	16	NA	NA	NA	NA	NA
		Improper Visual inspection	Residue contamination may occur	•Colour contamination may pass on to next batch leading to failure in description. •Cleaning agent residue may leads to toxicity. •Impurity may pass on to next batch leading to batch failure.	•Cleaning validation already done for Tablets & Capsules. • Cleaning method is robust (Previous trend of swab & rinse). • Cleaning validation of cleaning agent (SLS) already validated.	•Cleaning validation protocol of Tablets • Cleaning validation protocol of Cleaning agent	4	2	2	16	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
					•Light intensity of critical areas is verified & recorded during HVAC/Area qualification.							NA	NA	NA	NA
2.	**Cleaning Validation**	Cleaning validation not done	Worst case not selected	May leads to contamination	• Cleaning validation completed for both tablet & Capsules • Rinse & Swab sampling after every change over	•Cleaning validation protocol of Tablets. •Cleaning validation protocol of cleaning agent.	4	1	1	1	Cleaning validation to be evaluated periodically (Yearly). SOP of cleaning validation to be revised. CVMP to be revised.	NA	NA	NA	NA
		Cleaning validation not effective	•Worst case changed •Deviation in Cleaning method •Proper evaluation not done	May leads to contamination	• Evaluation of new API done • SOP of cleaning followed and verified by QA	• "Evaluation of New product for cleaning validation" • SOP's of equipment cleaning	4	1	1	4	NA	NA	NA	NA	NA
3.	**Swab/Rinse Sampling**	Sampling method not adequate	•Untrained person •Sampling method not followed.	• May leads to contamination • False results generated	• SOP of sampling already distributed • Sampling done by trained QA personnel	•SOP "Procedure for Swab/Rinse Sampling".	4	2	2	16	NA	NA	NA	NA	NA
		Untrained person	•New person •Negligence	May leads to contamination	• Training given to every new joinee. • OJT training given to IPQA personnel.	• Employee training card	4	2	3	24	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
		Sampling/location procedure wrongly selected	•Untrained person •New person •Negligence •Sampling procedure not available.	May leads to contamination	• Cleaning validation completed for both tablet & Capsules • SOP of cleaning strictly followed and verified by QA. • OJT training given to IPQA personnel. • SOP of sampling is in place.	•Cleaning validation protocol of Tablets for tablet & Capsule.	4	2	2	16	NA	NA	NA	NA	NA
		Sample hold for long period	•Hold time not defined •Negligence •UV scanner out of service •Workload	False results generated	• Hold time defined in Analytical Method Validation Protocol • Testing done online at shop floor and instrument is dedicated • Optional UV spectrophotometer is available.	• AVP	4	2	3	24	NA	NA	NA	NA	NA
		Rinse sample collected in plain clear bottle	•Negligency	False results generated	Amber coloured bottles used for sampling	SAP System	4	1	1	4	NA	NA	NA	NA	NA
4.	**SOP not validated**	Cleaning method of equipment not validated	• Evaluation of new equipment.	Cross contamination chance	•Procedure for New equipment evaluated after installation is in place. •Change control initiated and shared to QA by Engineering dept.	•Evaluation of New equipment for cleaning validation	4	1	1	4	NA	NA	NA	NA	NA
5.	**Visual Inspection**	Visual inspector not fit for inspection	• Weak eye sight of person. • Untrained person.	Cross contamination chance	Eye sight tested as per schedule	Medical examination certificate.	4	1	1	4	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
6.	**Light Intensity**	Light intensity not suitable	Area not qualified	Cross contamination chance	Procedure for check light intensity during area qualification is in place.	Validation Master Plan	4	2	2	16	NA	NA	NA	NA	NA
7.	**Cleaning Agent**	Cleaning agent not validated	Cleaning agent changed	Cross contamination chance resulting into Product failure.	• Cleaning validation protocol of cleaning agent • Any change initiated as per change control SOP	Reason of re-validation	4	1	1	4	NA	NA	NA	NA	NA
		Wrong dilution used for cleaning	• Untrained person • Negligence	Cross contamination chance	• SOP of preparation of cleaning agent. • Verification of remaining stock.	As per SOP of equipments (specific).	4	1	1	4	NA	NA	NA	NA	NA
8.	**New Formulation**	New API not evaluated	• Worst case might change & SOP's need to be re-validated of API evaluation not performed. • Procedure for evaluation of new API not available.	Cross contamination chance	• Provision for new API evaluation in CVMP. • Batch offer sheet to be verified daily with current list.	Cleaning Validation Master Plan	4	1	1	4	NA	NA	NA	NA	NA
9.	**API sticky in nature**	Sticky API not identified	New API not evaluated	• Cross contamination chance. • Product failure.			4	1	1	4	NA	NA	NA	NA	NA
10.	**Coloring agent**	Coloring agent not identified	New coloring agent not evaluated	• Product will fail in description. • Contamination.	During line clearance visual inspection is done before taking swab or rinse sample. Further sample is verified for any froth or color.	• As per protocol of cleaning validation. • BMR line clearance.	4	2	1	8	NA	NA	NA	NA	NA

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
11.	**Method of analysis**	Analysis method not proper	SOP not followed	Effectiveness of method,	Procedure of AMV SOP is in place.	• Reason of re-validation	4	1	1	4	NA	NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

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***The Risk Priority Number (RPN/Overall Risk) changes based upon the risk. The Risk assessment team shall decide the acceptance criteria. For example the risk priority number is categorized as below:**

Risk Priority Number (RPN)	Risk levels
Upto 25	Low
26-50	Medium
51 to ≤ 125	High

RPN = Severity x Occurrence x Detection

Remark if any:

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Quality Risk Management Team			Reviewed By Head Operations Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		
	PRODUCTION			
	QA			

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility		Oral Dosage Block	
S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	SOP of Cleaning Validation shall be revised and Yearly Cleaning Verification part shall be incorporated.		
2.	CVMP shall be revised & Yearly Cleaning Verification part shall be incorporated.		

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*In-case any recommendations Not completed, to be tracked through CAPA System)

Remark if any:

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Verified By
(QA)
Sign & Date……..

Reviewed By:
(Manager QA)
Sign & Date……..

10.0 CONCLUSION:

Risk analysis data shall be written on Risk Analysis Study Protocol cum Report for reducing the testing frequency of Swab & Rinse sample clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the Risk analysis and in case of failure, investigation carried out and their findings.

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11.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report for reducing the testing frequency of Swab & Rinse testing, clearly stating that there is no impact/adverse impact on the product quality & personnel.

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12.0 REFERENCES:

APIC (Page 23 & 24, Point 5.3.2.3): "After Cleaning Validation, the analytical verification may be omitted. However, Visual Inspection should be maintained in the dried equipment and no visible residue should be observed".

13.0 DOCUMENTS TO BE ATTACHED:

Reference SOP's.

14.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations from the pre-defined acceptance criteria observed in accordance with QA SOP **"Handling of Deviations"**, shall be documented in the Risk analysis Protocol cum report.

15.0 CHANGE CONTROL, IF ANY:

Change control observed in accordance with QA SOP **"Change Management"**, **SOP** shall be documented in the Risk analysis Protocol cum report.

16.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis
GMP : Good Manufacturing Practices
RPN : Risk Priority Number

17.0 PROTOCOL CUM REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
OPERATING MANAGER (QUALITY ASSURANCE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

19.0 ANNEXURES:

ANNEXURE I (API LIST)

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
1.	ACEBROPHYLLINE	IH	SLIGHTLY SOLUBLE
2.	ACECLOFENAC	IP/BP	PRACTICALLY INSOLUBLE
3.	ACETAZOLAMIDE	IP/BP	VERY SLIGHTLY SOLUBLE
4.	ACETYL L - CARNITINE HCL	IH	-
5.	ACETYLCYSTEINE	BP	FREELY SOLUBLE
6.	ACTIVATED DIMETHICONE	IH	INSOLUBLE
7.	ADENOSYLCOBALAMIN	IH	SPARINGLY SOLUBLE
8.	ALBENDAZOLE	IP/BP/USP	PRACTICALLY INSOLUBLE
9.	ALFACALCIDOL	IP/BP	PRACTICALLY INSOLUBLE
10.	ALFUZOSIN HCL	IP/BP/USP	FREELY SOLUBLE
11.	ALPHA GLYCERYLPHOSPHORYLCHOLINE	IH	FREELY SOLUBLE
12.	ALPHA LIPOIC ACID	IH	INSOLUBLE
13.	ALPRAZOLAM	IP/BP/USP	PRACTICALLY INSOLUBLE
14.	AMBROXOL HCL	IP/BP	SPARINGLY SOLUBLE
15.	AMISULPRIDE	IP/BP	PRACTICALLY INSOLUBLE
16.	AMITRIPTYLINE HCL	IP/BP/USP	FREELY SOLUBLE
17.	AMLODIPINE BESYLATE	IP/BP/USP	SLIGHTLY SOLUBLE IN WATER
18.	ALPHA AMYLASE/DIASTASE	IP	-
19.	ANASTROZOLE	IP/BP/USP	VERY SLIGHTLY SOLUBLE
20.	ARIPIPRAZOLE	IP/BP	PRACTICALLY INSOLUBLE
21.	ASPIRIN	IP/BP/USP	SLIGHTLY SOLUBLE
22.	ASTAXANTHIN	IH	-
23.	ATENOLOL	IP/BP/USP	SPARINGLY SOLUBLE
24.	ATORVASTATIN CALCIUM	IP/BP	VERY SLIGHTLY SOLUBLE
25.	AZITHROMYCIN	IP/BP/USP	PRACTICALLY INSOLUBLE
26.	BACILLUS CLAUSII	IH	-
27.	BACILLUS MESENTRICUS	IH	-
28.	BACLOFEN	IP/BP/USP	SLIGHTLY SOLUBLE
29.	BENFOTHIAMINE	IH	-
30.	BETACAROTENE	BP/USP	PRACTICALLY INSOLUBLE
31.	BETACYCLODEXTRIN	IH	-
32.	BETAHISTINE HCL	IP/BP/USP	VERY SOLUBLE
33.	BETAMETHASONE	IP/USP	PRACTICALLY INSOLUBLE
34.	BIOTIN	BPIUSP	VERY SLIGHTLY SOLUBLE
35.	BISACODYL	IP/BP/USP	PRACTICALLY INSOLUBLE
36.	BISOPROLOL FUMARATE	BP/USP	VERY SOLUBLE
37.	BROMELAIN	IH	-
38.	BROMHEXINE HCL	IP/BP	VERY SLIGHTLY SOLUBLE
39.	BROMOCRIPTINE MESYLATE	IP/BP/USP	PRACTICALLY INSOLUBLE

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S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
40.	CAFFEINE	IP/BP/USP	SPARINGLY SOLUBLE
41.	CALCITRIOL	IP/BP/USP	PRACTICALLY INSOLUBLE
42.	CALCIUM ASCORBATE	BP/USP	FREELY SOLUBLE
43.	CALCIUM CARBONATE	IP/BP/USP	PRACTICALLY INSOLUBLE
44.	CALCIUM CITRATE	USP	SLIGHTLY SOLUBLE
45.	CALCIUM DOBESILATE MONOHYDRATE	IP/BP	VERY SOLUBLE
46.	CALCIUM OROTATE	IH	INSOLUBLE
47.	CALCIUM GLUCONATE	IP/BP/USP	SPARINGLY SOLUBLE
48.	CALCIUM PANTOTHENATE	IP/BP/USP	-
49.	CAMPHOR	IP/BP/USP	SLIGHTLY SOLUBLE
50.	CARBONYL IRON	USP	PRACTICALLY INSOLUBLE
51.	CETIRIZINE HCL	IP/BP/USP	FREELY SOLUBLE
52.	CHLORAMPHENICOL	IP/BP	SLIGHTLY SOLUBLE
53.	CHLORDIAZEPOXIDE	IP/BP/USP	PRACTICALLY INSOLUBLE
54.	CHLORTHYMOL	IH	INSOLUBLE
55.	CHLORPHENIRAMINE MALEATE	IP/USP	FREELY SOLUBLE
56.	CHLORTHALIDONE	IP	PRACTICALLY INSOLUBLE
57.	CHLORZOXAZONE	USP	SLIGHTLY SOLUBLE
58.	CHOLESTYRAMINE	USP	INSOLUBLE
59.	CHOLINE BITARTRATE	USP	FREELY SOLUBLE
60.	CHROMIUM PICOLINATE	IH	-
61.	CHYMOTRYPSIN	IP/BP/USP	SPARINGLY SOLUBLE
62.	CILNIDIPINE	IH	PRACTICALLY INSOLUBLE
63.	CINNARIZINE	IP/BP	PRACTICALLY INSOLUBLE
64.	CIPROFLOXACIN HCL	IP/BP	SOLUBLE
65.	CITICOLINE SODIUM	IP	FREELY SOLUBLE
66.	CITRIC ACID	IP/BP	VERY SOLUBLE
67.	CITRUS BIOFLAVONIDS	IH	-
68.	CLIDINIUM BROMIDE	USP	SOLUBLE
69.	CLINDAMYCIN HCL	IP/USP	FREELY SOLUBLE
70.	CLOBAZAM	IP/BP	SLIGHTLY SOLUBLE
71.	CLONAZEPAM	IP/BP/USP	PRACTICALLY INSOLUBLE
72.	CLOPIDOGREL BISULPHATE	IP/BP/USP	FREELY SOLUBLE
73.	CLOSTRIDIUM BUTYRICUM	IH	-
74.	CLOTRIMAZOLE	IP/BP/USP	PRACTICALLY INSOLUBLE
75.	COLISTIN SULPHATE	IP/BP	FREELY SOLUBLE
76.	COLLOIDAL SILICON DIOXIDE	IP	PRACTICALLY INSOLUBLE
77.	COPPER SULPHATE	BP	FREELY SOLUBLE
78.	CUPRIC SULFATE	USP	SOLUBLE
79.	CYCLANDELATE	USP	PRACTICALLY INSOLUBLE
80.	CYPROHEPTADINE HCL	USP/IP	SLIGHTLY SOLUBLE
81.	DEFLAZACORT	IH	PRACTICALLY INSOLUBLE

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
82.	DELPODINE	IH	-
83.	DESLORATADINE	IH	PRACTICALLY INSOLUBLE
84.	DESVENLAFAXINE SUCCINATE	IH	PRACTICALLY INSOLUBLE
85.	DEXRABEPRAZOLE	IH	SOLUBLE
86.	DEXTROMETHORPHAN HBR	IP/BP	SPARINGLY SOLUBLE
87.	DIACEREIN	IP/BP	PRACTICALLY INSOLUBLE
88.	DIBASIC CALCIUM PHOSPHATE	IP	-
89.	DICLOFENAC POTASSIUM	BP/USP	SPARINGLY SOLUBLE
90.	DICLOFENAC SODIUM	IP/BP/USP	SPARINGLY SOLUBLE
91.	DICYCLOMINE HCL	IP/USP	SOLUBLE
92.	DILTIAZEM HCL	IP/BP/USP	VERY SLIGHTLY SOLUBLE
93.	DIMENHYDRINATE	BP/USP	SLIGHTLY SOLUBLE IN WATER
94.	DIMETHICONE/SIMETHICONE	IP/BP/USP	PRACTICALLY INSOLUBLE
95.	DISODIUM TETRABORATE	IH	-
96.	DIVALPROEX SODIUM	IP/USP	INSOLUBLE
97.	DL METHIONINE	IH	SPARINGLY SOLUBLE
98.	DOCOSAHEXAENOIC ACID 40% OIL	IH	-
99.	DOCUSATE SODIUM	IH	-
100	DOMPERIDONE	IP/BP	PRACTICALLY INSOLUBLE
101	DOSULEPIN HCL	BP	FREELY SOLUBLE
102	DOXOFYLLINE	IP	SOLUBLE
103	DOXYLAMINE SUCCINATE	BP	VERY SOLUBLE
104	DRIED ALUMINIUM HYDROXIDE	IH	INSOLUBLE
105	DROTAVERINE	IH	SPARINGLY SOLUBLE
106	DULOXETINE HCL	BP/USP	SPARINGLY SOLUBLE
107	DUTASTERIDE	IP/BP/USP	PRACTICALLY INSOLUBLE
108	ENALAPRIL MALEATE	IP/BP/USP	SPARINGLY SOLUBLE
109	EPHEDRINE HCL	BP/USP	FREELY SOLUBLE
110	EPERISONE HCL	IH	SOLUBLE
111	ESCITALOPRAM OXALATE	IP/USP	SPARINGLY SOLUBLE
112	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	IP/BP/USP	SLIGHTLY SOLUBLE
113	ETAMSYLATE	BP	VERY SOLUBLE
114	ETIZOLAM	IH	PRACTICALLY INSOLUBLE
115	ETODOLAC	IP/BP	PRACTICALLY INSOLUBLE
116	ETORICOXIB	IP	SPARINGLY SOLUBLE IN ETHANOL
117	EUCALYPTOL	USP	PRACTICALLY INSOLUBLE
118	FEBUXOSTAT		INSOLUBLE
119	FENOFIBRATE	IP/BP	PRACTICALLY INSOLUBLE
120	FERROUS ASPARTATE	IH	-
121	FERROUS FUMARATE	IP/BP/USP	SLIGHTLY SOLUBLE
122	FERROUS GLUCONATE	IP/BP/USP	FREELY SOLUBLE

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
123	FEXOFENADINE HCL	IP/BP	SLIGHTLY SOLUBLE
124	FINASTERIDE	IP/BP/USP	PRACTICALLY INSOLUBLE
125	FLUCONAZOLE	IP/BP/USP	SLIGHTLY SOLUBLE
126	FLUNARIZINE DIHYDROCHLORIDE	BP	SLIGHTLY SOLUBLE
127	FLUPENTIXOL DECANOATE	BP	VERY SLIGHTLY SOLUBLE
128	FLUPIRTINE MALEATE	IH	FREELY SOLUBLE IN DILUTE NAOH SOLUTION
129	FLUVOXAMINE MALEATE	IP/BP/USP	SPARINGLY SOLUBLE
130	FOLIC ACID	IP/USP	PRACTICALLY INSOLUBLE
131	FRUCTOSE	IP/BP/USP	VERY SOLUBLE
132	GABAPENTIN	BP/USP	SPARINGLY SOLUBLE
133	GINKGO BILOBA EXTRACT	IH	-
134	GINSENG EXTRACT	IH	-
135	GLIBAMIDE	IH	-
136	GLIBENCLAMIDE/GLYBURIDE	IP/BP	PRACTICALLY INSOLUBLE
137	GLICLAZIDE	IP/BP	PRACTICALLY INSOLUBLE
138	GLIMEPRIDE	IP/BP/USP	PRACTICALLY INSOLUBLE
139	GLUCOSAMINE HCL	IP/BP	FREELY INSOLUBLE
140	GREEN TEA EXTRACT 60%	IH	-
141	GUAIPHENSIN	BP/USP	SPARINGLY SOLUBLE
142	HARPAGOPHYTUM	IH	SOLUBLE
143	HYDROCHLOROTHIAZIDE	IP/BP	VERY SLIGHTLY SOLUBLE
144	IBANDRONATE SODIUM	IH	SOLUBLE
145	IBUPROFEN	BP/USP	PRACTICALLY INSOLUBLE
146	INOSITOL	BP/USP	VERY SOLUBLE
147	ISOSORBIDE MONONITRATE	BP	FREELY SOLUBLE
148	ISOTRETINOIN	BP	PRACTICALLY INSOLUBLE
149	ISOXSUPRINE HCL	BP	SPARINGLY SOLUBLE
150	ISPAGHULA HUSK	IH	SWELLS IN WATER
151	ITOPRIDE HCL	IH	-
152	ITRACONAZOLE	BP/USP	PRACTICALLY INSOLUBLE
153	IVERMECTIN	IP/BP/USP	PRACTICALLY INSOLUBLE
154	LABETALOL HCL	IP/BP/USP	SPARINGLY SOLUBLE
155	LACTIC ACID BACILLUS	IH	INSOLUBLE
156	LACTITOL MONOHYDRATE	BP/USP	VERY SOLUBLE
157	LAFUTIDINE	IH	VERY SLIGHTLY SOLUBLE
158	LAMOTRIZINE	IP/BP/USP	VERY SLIGHTLY SOLUBLE
159	L-ARGININE	IP	FREELY SOLUBLE
160	L-CARNITINE	IH	-
161	LEVETIRACETAM	BP/USP	VERY SOLUBLE
162	LEVOCARNITINE	BP/USP	FREELY SOLUBLE
163	LEVOCETIRIZINE HCL	IP	FREELY SOLUBLE
164	LEVOFLOXACIN HEMIHYDRATE	IP	SOLUBLE IN DILUTE NAOH SOLUTION

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
165	LEVOSULPIRIDE	IH	-
166	LINEZOLID	IP	SOLUBLE IN CHLOROFORM
167	LIPASE	IH	-
168	LITHIUM CARBONATE	IP/BP	SLIGHTLY SOLUBLE
169	L-METHYLFOLATE CALCIUM	IH	-
170	LOPERAMIDE HCL	IP/BP/USP	SLIGHTLY SOLUBLE
171	LORATADINE	BP/USP	PRACTICALLY INSOLUBLE
172	LORAZEPAM	IP/USP	PRACTICALLY INSOLUBLE
173	L-ORNITHINE L-ASPARTATE	IH	FREELY SOLUBLE
174	LORNOXICAM	IH	SLGHTLY SOLUBLE IN 0.1 N NAOH
175	LOSARTAN POTASSIUM	IP/BP/USP	FREELY SOLUBLE
176	LUTEIN 40% OILY FORM	USP	-
177	LYCOPENE 10% POWDER FORM	IH	INSOLUBLE
178	LYSINE HYDROCHLORIDE	BP/USP	FREELY SOLUBLE
179	MAGNESIUM ALUMINIUM SILICATE	USP/IP	PRACTICALLY INSOLUBLE
180	MAGNESIUM OXIDE	BP/USP	PRACTICALLY INSOLUBLE
181	MANGANESE SULPHATE	IP/BP/USP	FREELY SOLUBLE
182	MEFENAMIC ACID	IP/BP/USP	PRACTICALLY INSOLUBLE
183	MELITRACEN	IH	SOLUBLE
184	MELOXICAM	IP/BP/USP	PRACTICALLY INSOLUBLE
185	MENADIONE SODIUM BISULPHITE/VIT. K	IH	SOLUBLE
186	MENAQUINONE-7	IH	-
187	MENTHOL	USP/IP	SLIGHTLY SOLUBLE
188	METFORMIN HCL	IP/BP/USP	FREELY SOLUBLE
189	METHYL ERGOMETRINE MALEATE	IH	SOLUBLE
190	METHYL SULPHATE	IH	-
191	METHYLCOBALAMIN	IH	SPARINGLY SOLUBLE
192	METHYLPREDNISOLONE	IP/BP/USP	PRACTICALLY INSOLUBLE
193	METOPROLOL TARTRATE	IP/BP/USP	VERY SOLUBLE
194	MONTELUKAST SODIUM	IP/BP/USP	FREELY SOLUBLE
195	MOSAPRIDE CITRATE DIHYDRATE	IP	PRACTICALLY INSOLUBLE
196	ACETYLCYSTEINE	BP/USP	FREELY SOLUBLE
197	NAPROXEN SODIUM	BP/USP	FREELY SOLUBLE
198	NATURAL MIXED CAROTENOIDS	IH	-
199	NEMODIPINE	IH	-
200	NEOMYCIN SULPHATE	IP/BP	VERY SOLUBLE
201	NIACINAMIDE	IP/USP	FREELY SOLUBLE
202	NICKEL SULFATE	IH	SOLUBLE
203	NIMESULIDE	BP	PRACTICALLY INSOLUBLE
204	NITAZOXANIDE	IH	-
205	NITRAZEPAM	BP	PRACTICALLY INSOLUBLE
206	NITROFURANTOIN	IP/BP	VERY SLIGHTLY SOLUBLE

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
207	NORFLOXACIN	IP/BP/USP	VERY SLIGHTLY SOLUBLE
208	NORTRIPTYLLINE HCL	IP/BP/USP	SPARINGLY SOLUBLE
209	OFLOXACIN	IP/BP/USP	SLIGHTLY SOLUBLE
210	OLANZAPINE	IP/BP/USP	PRACTICALLY INSOLUBLE
211	OLMESARTAN MEDOXOMIL	BP/USP	PRACTICALLY INSOLUBLE
212	OMEGA-3-MARINE TRIGLYCEIDE	BP	PRACTICALLY INSOLUBLE
213	OMEPRAZOLE MAGNESIUM	IP/BP/USP	VERY SLIGHTLY SOLUBLE
214	ONDANSETRON HCL	IP/BP/USP	SPARINGLY SOLUBLE
215	OPIPRAMOL DIHYDROCHLORIDE		-
216	ORNIDAZOLE	IP	SOLUBLE IN CHLOROFORM
217	OXACEPROL	IH	-
218	OXCARBAZEPINE	IP/BP/USP	PRACTICALLY INSOLUBLE
219	PAMABROM	USP	-
220	PANCREATIN	IP/USP	-
221	PANTOPRAZOLE SODIUM	IP/BP	FREELY SOLUBLE
222	PAPAIN	IP	SPARINGLY SOLUBLE
223	PARA AMINO BENZOIC ACID	IH	-
224	PARACETAMOL	IP/BP	SPARINGLY SOLUBLE
225	PAROXETINE HCL	IP/BP	SLIGHTLY SOLUBLE
226	PENTOSAN POLYSULFATE SODIUM	IH	-
227	PHENOBARBITONE SODIUM	IP/BP/USP	FREELY SOLUBLE
228	PHENYLEPHRNE HCL	IP/BP/USP	FREELY SOLUBLE
229	PHENYTOIN SODIUM	IP/BP/USP	SOLUBLE
230	PIOGLITAZONE HCL	IP/BP/USP	PRACTICALLY INSOLUBLE
231	PIPERINE	IH	-
232	PIRACETAM	IP/BP	FREELY SOLUBLE
233	PIROXICAM	IP/BP/USP	PRACTICALLY INSOLUBLE
234	POTASSIUM IODIDE	IP/USP	VERY SOLUBLE
235	PRAMIPEXOLE DIHYDROCHLORIDE	BP/USP	FREELY SOLUBLE
236	PRAZIQUANTEL	IP/BP/USP	VERY SLIGHTLY SOLUBLE
237	PREGABALIN	IP	SPARINGLY SOLUBLE
238	PRIMROSE OIL	IH	-
239	PROCHLORPERAZINE MALEATE	IP/BP/USP	VERY SLIGHTLY SOLUBLE
240	PROPRANOLOL HCL	IP/BP/USP	SOLUBLE
241	PSEUDOEPHEDRINE HCL	BP	FREELY SOLUBLE
242	PYRIDOXAL -5 PHOSPHATE	IH	SPARINGLY SOLUBLE
243	QUETIAPINE FUMARATE	IP/BP	SLIGHTLY SOLUBLE
244	RABEPRAZOLE SODIUM	IP	SOLUBLE
245	RACECADOTRIL	IP/BP	PRACTICALLY INSOLUBLE
246	RAMIPRIL	IP/BP/USP	SPARINGLY SOLUBLE
247	RANITIDINE HCL	IP/BP/USP	FREELY SOLUBLE
248	REFINED WHEAT GERM OIL	BP	PRACTICALLY INSOLUBLE
249	RISPERIDONE	BP/USP	PRACTICALLY INSOLUBLE

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
250	ROSUVASTATIN CALCIUM	IP	FREELY SOLUBLE IN ACETONITRILE
251	ROXITHROMYCIN	IP/BP	VERY SLIGHTLY SOLUBLE
252	RUTOSIDE TRIHYDRATE	BP	PRACTICALLY INSOLUBLE
253	SACCHAROMYCES BOULARDII	IH	-
254	SECNIDAZOLE	IP	SOLUBLE
255	SELENIOUS ACID	USP	SOLUBLE
256	SELENIUM DIOXIDE	IH	SOLUBLE
257	SELENOMETHIONINE	IH	-
258	SERRATIOPEPTIDASE	IP	-
259	SEVELAMER CARBONATE	IH	INSOLUBLE
260	SILDENAFIL CITRATE	IP/BP/USP	SLIGHTLY SOLUBLE
261	SIMVASTATIN	IP/BP	PRACTICALLY INSOLUBLE
262	SODIUM BORATE	USP	SOLUBLE
263	SODIUM FEREDATE	BP	-
264	SODIUM METAVANADATE	IH	-
265	SODIUM MOLYBDATE DIHYDRATE	BP	FREELY SOLUBLE
266	SODIUM SELENITE PENTAHYDRATE	BP	FREELY SOLUBLE
267	SOYA ISO LECITHIN	IH	PRACTICALLY INSOLUBLE
268	SOYA ISOFLAVONES 40%	IH	-
269	SPARFLOXACIN	IH	SOLUBLE IN 1N NAOH
270	SPIRULINA	IH	-
271	STANNOUS CHLORIDE DIHYDRATE	BP/USP	FREELY SOLUBLE
272	STREPTOCOCCUS FAECALIS	IH	-
273	SYLIMARIN	IH	-
274	SYNARIN	IH	-
275	TADALAFIL	BP	PRACTICALLY INSOLUBLE
276	TAMSULOSIN HCL	IP/BP/USP	SLIGHTLY SOLUBLE
277	TAPENTADOL HCL	IP	-
278	TAURINE	USP	SOLUBLE
279	TELMISARTAN	IP/BP	PRACTICALLY INSOLUBLE
280	TERBINAFINE HCL	BP/USP	SLIGHTLY SOLUBLE
281	TERBUTALINE SULPHATE	IP/BP/USP	FREELY SOLUBLE
282	TERPINEOL	BP	VERY SLIGHTLY SOLUBLE
283	THIOCOLCHICOSIDE	IP	SOLUBLE
284	TINIDAZOLE	IP/BP/USP	PRACTICALLY INSOLUBLE
285	TIZANIDINE HCL	IP/USP	SLIGHTLY SOLUBLE
286	TOLPERISONE HCL	JP	FREELY SOLUBLE
287	TOPIRAMATE	IP	-
288	TORSEMIDE	BP/USP	PRACTICALLY INSOLUBLE
289	TRAMADOL HCL	IP/BP/USP	FREELY SOLUBLE
290	TRANEXAMIC ACID	IP/BP/USP	FREELY SOLUBLE
291	TRIAMCINOLONE	IP/BP/USP	PRACTICALLY INSOLUBLE

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING FREQUENCY OF RINSE & SWAB SAMPLING

S.No.	ACTIVE	PHARMACOPOEIA	SOLUBILITY IN WATER
292	TRIHEXYPHENIDYL	USP	SLIGHTLY SOLUBLE
293	TRIMETAZIDINE HCL	IP/BP	FREELY SOLUBLE
294	TRYPSIN	BP	SPARINGLY SOLUBLE
295	UBIDECARENONE/COENZYME Q 10	BP/USP	PRACTICALLY INSOLUBLE
296	UNIMYCIN	IH	-
297	URSODEOXYCHOLIC ACID	IP	INSOLUBLE
298	VALPROIC ACID	BP/USP	VERY SLIGHTLY SOLUBLE
299	VITAMIN B1	IP/BP/USP	FREELY SOLUBLE
300	VITAMIN B2/RIBOFLAVIN	IP/BP/USP	VERY SLIGHTLY SOLUBLE
301	VITAMIN B6	IP/BP	FREELY SOLUBLE
302	VITAMIN B12	IP/BP/USP	SPARINGLY SOLUBLE
303	VITAMIN C/ASCORBIC ACID	BP/USP/IP	FREELY SOLUBLE
304	VITAMIN D3	IP	PRACTICALLY INSOLUBLE
305	VITAMIN E ACETATE	IH	-
306	VOGLIBOSE	IP/JP	VERY SLIGHTLY SOLUBLE
307	ZINC	IH	-
308	ZINC CARNOSINE	IH	-
309	ZINC GLUCONATE	BP/USP	SOLUBLE
310	ZINC LACTATE	IH	FREELY SOLUBLE IN HOT WATER
311	ZINC OXIDE	IP/BP	PRACTICALLY INSOLUBLE
312	ZINC SULPHATE	IP/USP	VERY SOLUBLE
313	ZOLPIDEM TARTRATE	IP/BP/USP	SLIGHTLY SOLUBLE
314	SPIRONOLACTONE	IP	PRACTICALLY INSOLUBLE