



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Authorization for VINCRISTINE 2MG INJECTION

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Vincristine 2mg Injection**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

Section 21 Authorisation re Vincristine 2mg INJ 22062026-1

8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **18 December 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	0
EC-PE	0
FS	1 000
GP	1 860
KZN	1 890
LP	450
MP	210
NC	120
NW	420
SAMHS	54
WC	1 500
Total	7 504

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 26/6/2026

Section 21 Outcome Letter

2026-06-22

Ms Khadija Jamaloodien

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

**REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE
MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):**

Your application dated **2026-06-18** refers

- A. STATUS: Approved**
 - B. APPLICANT: Ms Khadija Jamaloodien**
 - C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
 - D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 50**
 - E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
 - F. TRADE NAME: Vincristine Sulphate for Injection USP 2 mg**
 - G. QUANTITY: 7500 Packs (10)**
-
-

H. LETTER NUMBER: S2100031684

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

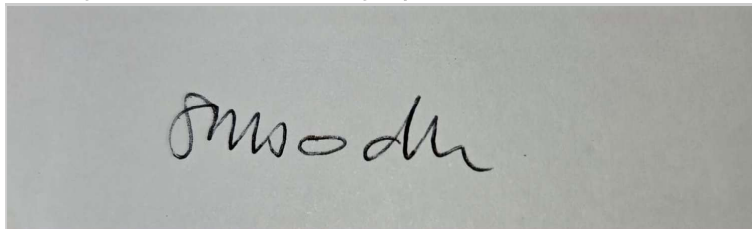
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Shyamli Munbodh' written in a cursive style.

Ms Mahlodi Moropa

Final Approver

S2100031684

A rectangular box containing a handwritten signature in black ink. The signature is stylized and appears to be 'M. P. P.' or similar.



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA,
0187 Tel (012) 395 8000, Fax (012) 395 8918

REQUEST FOR QUOTATION FORM

- Instruction to complete this Request for Quotation (RFQ)**
PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS. IT MAY ALSO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL	SECTION 21	X	S21RFQ172
QUOTE ENQUIRY DATE	09/03/2026	QUOTE CLOSING DATE	18/03/2026	
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)				

REQUESTING INSTITUTION CONTACT DETAILS

NAME OF REQUESTOR	Buhle Mbongo			
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za			
PHONE No.	012 395 9539	FAX No.	N/A	


PRODUCT INFORMATION

DESCRIPTION PER MPC	VINCRISTINE 2MG/2ML INJECTION 2ML			
TRADE DESCRIPTION	Vincristine Sulphate for Injection USP 2mg/vial			
UNIT OF MEASURE	1's	PACK or BOX (SIZE/ QUANTITY)	1's	
QUANTITY REQUIRED	5 100 Vials			

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Equity Pharmaceuticals Pty Ltd			
SUPPLIER NUMBER	MAAA007480			
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	Ehrard van Zyl		
	PHONE	012 345 1747	FAX	012345 1412
	MOBILE	072 040 8511		
	E-MAIL	ehrdard@equitypharma.co.za		
CONTACT PERSON 2	NAME	Hannes Strydom		
	PHONE	012 345 1747		
	MOBILE	082 616 1954		

E-MAIL		hannes@equitypharma.co.za	
<u>QUOTE DETAILS</u>			
PRICE PER VIAL (INCL. VAT)	R 35.42	TOTAL PRICE (INCL. DELIVERY & VAT)	R 180 642.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	36 months		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS	5 100 vials		
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 63DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD	180 days		
NORMAL LEAD/DELIVERY TIME	3 days		
<u>DEVIATION TO SPECIFICATION</u>			
COMMENTS:			
<u>DECLARATION BY SUPPLIER</u>			
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.			
NAME	Ehrard van Zyl		
CAPACITY	Business Unit Manager: Specialist Medicine		
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)			
DATE	18/03/2026		
<u>PROVINCIAL ESTIMATES</u>			
Province	Six Months Estimate		
DCS	0		
EC-MT	0		
EC-PE	0		
FS	0		
GP	1 860		
KZN	1 890		
LP	450		
MP	210		
NC	120		
NW	420		
SAMHS	54		
WC	0		

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- Central Supplier Database Summary Report (CSD), updated for the current month
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)
All the above is required to expedite the process of reviewing the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

NB:

- *The supplier submitting the quotation must be the same entity with which the provinces will place their orders.
- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (only *in cases of a Bivalent Oral Poliomyelitis Vaccine RFQ*).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing required documentation shall not be considered.
- Any submission with blurry required documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION

18/03/2026



Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

QUOTATION # 20260318

TO: National Department of Health

TEL : 012 395 9539

FAX :

Email : Section21Quotes@health.gov.za

CONTACT PERSON / PATIENT : Buhle Mbongo

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
	Vincristine Sulphate for Injection USP 2mg/vial	1 x Vial	1	R 30.80	R 35.42
			5 100	R 157 080.00	R 180 642.00
			5 100	R 157 080.00	R 180 642.00

Valid for 180 days

Employee Signature: 

Date: 18/03/2026

Approved by: Ehrard van Zyl



18/03/2026

National Department of Health
Directorate: Affordable Medicines
E-mail: Section21Quotes@health.gov.za
Attention: Ms Buhle Mbongo

Equity Pharmaceuticals (Pty) Ltd.
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

www.clinigengroup.com
www.equitypharma.co.za

Dear Ms Mbongo

Re: Request for quotation – Vincristine Sulphate for injection USP 2mg – Section 21 Supply

Trust you are well. Please find below our quotation for Vincristine Sulphate for injection USP 2mg/vial, supplied under section 21 terms.

- Quantity: **5100 vials**
- Delivery Time (Weeks): **5 weeks**
- Price (Vat Inclusive): **R 35.42 incl. vat per vial**
- Generic Name: **Vincristine Sulphate for injection USP 2mg/vial**
- Trade Name: **Vincristine Sulphate for Injection USP 2mg/vial**
- Packaging: **1 vial**
- Specifications: **2mg / Vial**
- Shelf Life: **36 months**
- Package Insert: **Please find attached**
- Manufacturer: **Kwality Pharmaceuticals Ltd.**
- Country of Origin: **India**

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards

Ehrhard van Zyl

For the use of cancer Hospital, Institution of Cancer Specialist only.

VINCRIStINE

Sulfate for Injection USP

2 mg/ vial

COMPOSITION:

Each vial contains :

Vincristine Sulfate USP 2 mg

Excipients q.s.

DESCRIPTION: Vincristine Sulfate is the salt of a dimeric alkaloid isolated from a common flowering herb, the periwinkle plant (*Vinca rosea* Linn.). Although the mechanism of action has not been definitely established vincristine appears to inhibit microtubule formation in the mitotic spindle, resulting in an arrest of dividing cells at the metaphase stage.

INDICATIONS: Vincristine Sulfate is indicated in the treatment of acute; leukaemia, and as combination therapy with other oncologic agents in the treatment of Hodgkins disease, non-Hodgkins malignant lymphomas (lymphocytic, mixed cell, histiocytic, undifferentiated, nodular and diffuse types), rhabdomyosarcoma, neuroblastoma and Wilms tumour.

PHARMACOKINETICS: Pharmacokinetics studies in patients with cancer have shown a triphasic serum decay pattern following rapid intravenous injection. The initial, middle and terminal half-lives are 5 minute, 2.3 hours, and 85 hours respectively; however, the range of the terminal half-life in humans is from 19 to 155 hours. The liver is the major excretory organ in humans and animals; about 80% of an injected dose of vincristine sulfate appears in the feces and 10% to 20% can be found in the urine. Within 15 to 30 minutes after injection, over 90% of the drug is distributed from the blood into tissue, where it remains tightly, but not irreversibly, bound.

DOStAGE AND ADMINISTRATION:

This preparation is for intravenous use only. Intrathecal use of the drug could be fatal.

Precaution for administration: Extreme care must be taken in calculating and administering the dose of Vincristine, since over dosage may have a very serious or fatal outcome. The solution should be withdrawn into an accurate dry syringe measuring the dose carefully. No extra fluid should be added to the vial in an attempt to empty it completely. The drug may be injected either directly into a vein or into the tubing of a running intravenous infusion. Injection of Vincristine Sulfate should be accomplished within one minute.

It is extremely important the intravenous needle or catheter may be properly positioned before Vincristine Sulfate is injected. Leakage into surrounding tissue during intravenous administration Vincristine Sulfate may cause considerable irritation. If extravasation occurs the injection should be discontinued immediately and the remaining portion of the dose should then be introduced into another vein. Local of hyaluronidase and the application of moderate heat to the area of leakage will help disperse the drug and may minimize discomfort and the possibility of cellulitis.

The drug is to be administered intravenously at weekly intervals, in the presence of leukopenia, or a complicating infection, administration of the next dose of Vincristine Sulfate warrants careful consideration.

Adult : 1.4 mg/m²

Children : 2.0 mg/m²

For children weighing 10kg or less the starting dose should be 0.05 mg/kg once a week.

Impaired hepatic function: Vincristine Sulfate should not be given to patients while they are receiving radiation therapy through ports that include the liver.

In patients having a direct serum bilirubin value above 3mg/100ml the dose is reduced by 50 percent. Subsequent doses may be increased depending on tolerance to the initial treatment.

Patients Monitoring : Since dose-limiting clinical toxicity is manifested as neurotoxicity, clinical evaluation is necessary to detect the need for dosage modification. Following vincristine therapy some individuals may have a fall in the WBC and platelet count. Therefore a complete blood count should be done before each dose, as well as determine the serum uric acid levels during the first 3-4 weeks of therapy to prevent uric acid nephropathy.

CONTRAINDICATIONS : Demyelinating form of Charcot-Marie Tooth Syndrome.

Warnings and Precautions DRUG INTERACTIONS:

L-asparaginase : Administering L-asparaginase before vincristine may reduce the hepatic clearance of the drug. Therefore when used in combination, vincristine should be given 12-24 hours before L-asparaginase administration to minimize toxicity.

Mitomycin C : Acute pulmonary reactions might occur on concomitant administration of mitomycin C.

Phenytoin : The simultaneous oral or intravenous administration of phenytoin and antineoplastic chemotherapy combinations that included vincristine sulfate has been reported to reduce blood levels of the anticonvulsant and to increase seizure activity. Dosage adjustment should be based on serial blood level monitoring. The contribution of vincristine sulfate to this interaction is not certain. The interaction may result from reduced absorption of phenytoin and an increase in the rate of its metabolism and elimination.

Solvents : Vincristine Sulfate should not be diluted in solutions that raise or lower than pH outside the range of 3.5 to 5.5; it should not be mixed with anything other than normal saline.

PREGNANCY : There are no adequate and well-controlled studies in pregnant women. Vincristine can cause fetal harm when administered to a pregnant woman. If the drug is used during pregnancy or if the patient becomes pregnant receiving it, the patient should be apprised of the potential hazards to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

NURSING MOTHER: It is not known whether the drug is secreted in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made on whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

IN IMPAIRED HEPATIC FUNCTION: See Dosage and Administration.

OTHERS: Acute uric acid nephropathy may occur.

CNS leukaemia has occurred in patients undergoing otherwise successful therapy with vincristine. If CNS leukaemia is diagnosed additional agents may be required since this drug does not adequately cross the blood-brain barrier.

Particular attention should be given to dosage neurological side effects, if administered to patients with pre-existing neuromuscular disease.

Eye contamination should be avoided with concentration used clinically. If accidental contamination occurs severe irritation may result. Eyes should be washed immediately and thoroughly.

SIDE EFFECTS: In general, adverse reactions to vincristine are dose-related and reversible. The most common adverse reaction is hair loss; the most troublesome adverse reactions are neuromuscular in origin.

When single weekly doses of the drug are employed, the adverse reactions of leukopenia, neuritic pain and constipation occurs but are usually of short duration. When the dosage is reduced the reactions may lessen or disappear. The severity of such reactions seems to increase when the calculated amount of drug is given in divided doses. Other adverse reactions, such as hair loss, paraesthesia, difficulty in walking, slapping gait, loss of deep tendon reflexes and muscle wasting may persist for at least as long as therapy is continued. Almost all symptoms usually disappears by about the sixth week after discontinuance of therapy. Some neuromuscular difficulties may persist for prolonged periods in some patients. Regrowth of hair may occur while maintenance therapy continues. The following adverse reactions have been reported.

Hypersensitivity or allergic type reactions: Anaphylaxis, rash.

Gastrointestinal : Constipation, abdominal cramps, nausea, weight loss, vomiting, oral ulceration, diarrhoea, paralytic ileus, intestinal necrosis and /or perforation and anorexia have occurred. All cases have responded to high enemas and lesatives.

Genito urinary : Polyuria, dysuria, urine retention due to bladder atony.

Cardiovascular : Hypertension and hypotension.

Haematologic : Serious bone marrow depression is usually not a major dose limiting event. However anaemia, leukopenia and thrombocytopenia have been reported.

Ophthalmic: Optic atrophy with blindness, transient cortical blindness, diplopia, photophobia.

Endocrine: Rare cases of syndrome attributed to inappropriate antidiuretic hormone secretion have been observed. With fluid deprivation improvement occurs in the hyponatremia and in the renal loss of sodium.

Neurologic : Loss of deep tendon reflexes, foot drop ataxia and paralysis have been reported with continued administration. Myalgias have occurred. Severe pain in the jaw, pharynx, parotid gland, bone, back and limb.

OVERDOSE : Side effects are dose related. Therefore following administration of more than the recommended dose, patients can be expected to experience exaggerated side effects. Supportive care should include :

Prevention of side effects that result from the syndrome of inappropriate secretion of antidiuretic hormone

- Administration of anticonvulsants
- Use of enemas or cathartics to prevent paralytic ileus
- Monitoring the patients cardiovascular system and
- Daily blood counts for guidance in transfusion requirements.

DIRECTION FOR USE :

Reconstitute by adding 2ml of sterile Water for Injection

STORAGE : Store at temperature between 2° to 8°C. Protect from light. Do not freeze. Keep out of reach of the children.

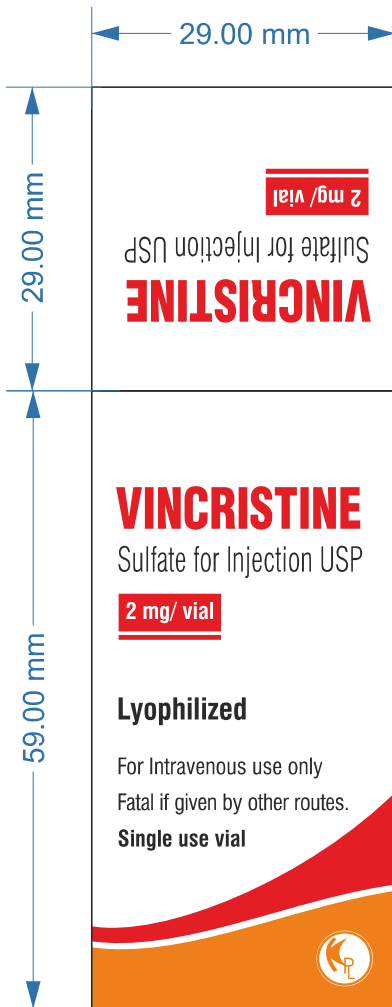
PRESENTATION : Each vial packed in a printed carton

Manufactured by:
Kwality Pharmaceuticals Ltd.

1-A, Industrial Area, Raja Ka Bagh, Tehsil -
Nurpur, Dist. - Kangra, (H.P.) - 176201. INDIA




Component : Carton
Dimension : 29 x 29 x 59 mm
Colour : CMYK
GSM : 320 gsm ITC Cyber XL
Coating: Drip off + Spot U.V.



VINCRIStINE
Sulfate for Injection USP
2 mg/ vial

Lyophilized

For Intravenous use only
Fatal if given by other routes.
Single use vial



Composition:
Each vial contains:
Vincristine Sulfate USP ... 2 mg
Excipients q.s.

Dosage :
As directed by the physician.

Store at temperature between 2° to 8°C. Protect from light. Do not freeze.

Keep out of reach of the children.


Dissolve the contents as per instructions in enclosed insert.

If any foreign particle is visible after dissolving the contents, please do not use the solution.

VINCRIStINE
Sulfate for Injection USP
2 mg/ vial

Lyophilized

For Intravenous use only
Fatal if given by other routes.
Single use vial



Mfg. Lic .No. : BNZ/08/41

Batch :
Mfg :
Exp :

NVZ
20X16

Manufactured by:
Kwality Pharmaceuticals Ltd.
1-A Industrial Area,
Raja ka Bagh, Teh. Nurpur,
District Kangra (H.P), INDIA

Shelf Life : 36 Months	Checked with Dossier (Rohit)	Checked with Q.C. Dept.:
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Check List for Labeling													Formulation No. :	
Work Order No. :	Version	Pharmacop.	Spell.	Compo.	Batch, Mfg. Exp.	Expiry as per Schedule 'P'	M.R.P.	Mfg. Lic.No./ Nutral Code	Packing	Category	Mfg. Name	Reg. No.	Check Order for strength, Volume & Packing	STORAGE
13433/1	English													
Matching all parameters between Box and Label														
Previous specimen artwork : NA				Designed by : SAJAN				Order Quantity		Party Name		Packing		
Checked by :		Approved by :		Authorized by :		Party Approval		2000 VIALS		RAPHAEL				
Production Incharge		QC Incharge		Q.A.		M.D.		Card Board used for carton :						
								<input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl						

Note : Since you have approved the artwork and did not implement our suggestion. Any claim arising out of such contents of artwork shall not be entertained.