

Company Name XXX	STANDARD OPERATING PROCEDURE FINISHED GOOD WITHDRAWAL		Page 1 of 3
			No XXX
	Department	Section	Validity date XXX
Prepared by XXX Date XXX	Checked by XXX Date XXX	Approved by XXX Date XXX	Replaced No. XXX Date XXX

1. OBJECTIVE

This procedure used if there is finished good on market makes consumer loss, because of quality defect or inflict a loss reaction on the product.

2. WITHDRAW REASON

1. Quality defect, divided in 2 groups:

- Aesthetics side quality defect is the defect that doesn't directly risk the user, but had to withdraw, such as label/packaging damage, unsuitable cap placing.
- Production technique side quality defect is quality defect that inflict a loss risk to consumer, such as wrong content, wrong value, wrong label.

2. Loss reaction of finish product.

Loss reaction of finish product is reaction that inflicts a serious risk to health or increasing the frequency of side effect that being complain by person or institute.

3. WITHDRAW ESTABLISHMENT

Product withdraw of finish product established by:

- Company or
- Government institute (POM)

4. FINISH GOOD WITHDRAW LEVEL

Finish god withdraw level decided on wide and far parameter area of the product on market.

Level -1

Finish product only reach central distributor.

Level – 2

Finish product already reach sub-distributor or country agent

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Level – 3

Finish product already distribute and reach retailer.

Level – 4

Cosmetics already distributed widely and reach the consumer.

5. SAFETY PRECAUTION

With complain report on product with technical quality defect or inflict a high risk loss reaction to human health, there for marketing dept. have to take necessary action by freezing the product distribution that being complain and informing the action by phone, fax, e-mail and letter depend on withdrawal and risk level.

6. CONSIDERATION FOR WITHDRAW

After evaluation the Quality dept. laboratory results on sample and retained sample of the complained product, inform to all consumer by letter, and so finished product (cosmetics) can be withdraw from market. Product withdraws decision take after a deep investigation by Finished Product withdrawn Committee (PKPJ) affiliate by Marketing dept, Medical affair dept, Quality dept and Directory.

7. WITHDRAW IMPLEMENTATION

1. After finished product withdrawal issued, based to finished product withdrawal level as explained in section 5, Marketing dept. informed distributor by fax, e-mail or letter to freeze product distribution and withdraw back to factory.
2. Directory and pharmacist responsible to inform the withdrawn product to government institute (Badan POM).
3. Main distributor and its branch create withdraw execution and send the product back to factory.
4. Ware house dept. create product receiving report (see annex) and given to Directory, Quality Control Manager, Production Manager, and Marketing Manager.
5. Ware house and Quality control dept. plan and perform the destruction and also create the Destruction Memo.

ANNEX

PRODUCT NAME	:	BATCH No	:
TYPE OF FP	:	BATCH SIZE	:
PRODUCT No.	:	DELIVERY QTY. TO	:
PACKING SIZE	:	WARE HOUSE	:
STARTED	:	DISTRIBUTION QTY	:
FINISHED	:	REMAIN	:

RECEIVED

RECEIVED DATE	DELIVERY No.	RETURN BY	QTY RETURN
			TOTAL QUANTITY:
<div style="text-align: center; margin-bottom: 20px;"> $\text{Returned percentage} = \frac{\text{Delivered Quantity}}{\text{Distributed Quantity}} \times 100 \% = \dots\dots\dots\%$ </div> <p>Date :</p> <p>Reported by</p> <p>.....</p>			